

Evaluation support study on Horizon Europe's contribution to a Resilient Europe

Final Report Phase 2 - Annexes





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Evaluation support study on Horizon Europe's contribution to a Resilient Europe – Final Report Phase 2 – Annexes

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Evaluation support study on Horizon Europe's contribution to a Resilient Europe

Final Report Phase 2 - Annexes

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Key definitions, acronyms and glossary

AAL	Active and Assisted Living Programme
AAL2	Active and Assisted Living Research and Development Programme 2
AGA	Annotated Grant Agreement
AI	Artificial Intelligence
AIDS	Acquired Immune Deficiency Syndrome
AMR	Anti-microbial resistance
Applicant	Legal entity submitting an application for a call for proposals.
Application	The act of involvement of a legal entity in a Proposal. A single Applicant can
	apply for different proposals.
ASR	Annual Summary Report
Associated	Third Countries that are party to an association agreement with the European
Country	Union
AU-EU	The Africa-EU Partnership
AWP	Annual Work Plan
BM	Border Management
BMR 2022	Biennial Monitoring Report 2022 on Partnerships in Horizon Europe
BRG	Better Regulation Guidelines
CEPI	Epidemics Preparedness Initiative
СН	Coherence
CS	Case Study
CSA	Coordination and Support Action
CVD	Cardiovascular diseases
DEC	Dissemination, Exploitation and Communication
DG	Directorate-General
DG Connect	Directorate-General for Communications Networks, Content and Technology
DG Grow	Directorate-General for Health and Food Safety
DG RTD	Directorate-General for Research and Innovation
DG Sante	Directorate-General for Health and Food Safety
DRS	Disaster-Resilient Society
EA	Executive Agencies
EAV	EU added value
EC	European Commission
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EDAP	European Democracy Action Plan
EDCTP	European and Developing Countries Clinical Trials Partnership
EDCTP2	European and Developing Countries Clinical Trials Partnership 2
EDCTP3	European and Developing Countries Clinical Trials Partnership 3
EFC	Effectiveness
EFF	Efficiency
EFSA	European Food Safety Authority
EHEN	European Human Exposome Network
EIP on AHA	European Innovation Partnership on Active and Healthy Ageing

EIT	European Institute for Innovation and Technology
EMA	The European Medicines Agency
ENI	European Neighbourhood Instrument
ENP	European Neighbourhood Policy
EPRS	European Parliament's Research Service
ERA	European Research Area
ERA4Health	Fostering a European Research Area for Health Research Partnership
ERAB	Ethics and RRI Advisory Board
ERA-CVD	Network on Cardiovascular Diseases
ESF+	European Social Fund Plus
ESIR	Expert group on the economic and societal impact of research and innovation
EU	European Union
EWS	Early Warning System
FAIR	Findable, Accessible, Interoperable, and Reusable
FAIR data	Data that meet principles of Findability, Accessibility, Interoperability, and
	Reusability
FCT	Fighting Crime and Terrorism
FET	Future and Emerging Technologies
FP	Framework Programme
FWCI	Normalised Citation Index
GA signature	Signing the grant agreement
GACD	The Global Alliance for Chronic Diseases
GDP	Gross domestic product
GEP	Gender Equality Plan
GH EDCTP3	Global Health EDCTP3 Joint Undertaking
JU	
GIOPID-R	The Global Research Collaboration for Infectious Diseases
	European Health and Digital Executive Agency
	European numan Biomonitoring initiative
	Higher Education Institutions
HES	Higher or Secondary Education institutions
High-Quality	A proposal that scores above a set evaluation threshold making it eligible for
Proposal	funding
IA	Innovation Action
ICPC	International Partner Cooperation Countries
IHI	Innovative Health Initiative
IICS	Investigator-Initiated Clinical Studies
IMI	Innovative Medicines Initiative
IMI2	Innovative Medicines Initiative 2
INFRA	Resilient Infrastructure
IPA III	Instrument for Pre-accession Assistance
IRDIRC	The International Rare Disease Research Consortium
JCS	Joint Call Secretariat
JPI	Joint Programming Initiative
JPI HDHL	Joint Programming Initiatives: a Healthy Diet for a Healthy Life

JPI MYBL	Joint Programming Initiative More Years Better Lives
JRC	Joint Research Centre
JTC	Joint Transnational Call
JU	Joint Undertaking
KIC	Knowledge and Innovation Community
KIP	Key Impact Pathways (KIPs)
KIPs	Key Performance Indicators
KSOs	Key Strategic Orientations
LEA	Law Enforcement Agency
LEIT	Leadership in Enabling and Industrial Technologies
MENA	The Middle East and North Africa
MSCA	Marie Skłodowska-Curie Actions
NAM	New Approach Methodologies
NCPs	National Contact Points
NDICI	Neighbourhood, Development and International Cooperation Instrument
Newcomer	A Horizon 2020 participant who was not involved in an FP7 project (not an FP7 participant)
NGO	Non-governmental organisation
NGO	Non-Governmental Organisation
NGRA	Next-generation risk assessment
NIH	National Institute of Health
OECD	Organisation for Economic Cooperation and Development
OPC	Open public consultation
OTH	Other entities
P2P	Public-to-Public Partnership
PARC	European Partnership for the Assessment of Risks from Chemicals
Participant	Any legal entity carrying out an action or part of an action under Horizon 2020
Participation	The act of involvement of a legal entity in a Project. A single Participant can
	be involved in multiple Projects
PCP	Pre-Commercial Procurement
PPI	Public Procurement of Innovative Solutions
PPP	Public-Private Partnerships
PRC	Private for-profit institutions
Project	Successful proposals for which a Grant Agreement is 'signed'.
PSC	Partnership-Specific Criteria
PSIA	Participating States Initiated Activity
PSIPs	Partnership-Specific Impact Pathways
PUB	Public bodies
R&D	Research and development
R&I	Research and Innovation
RA	Risk Assessment
REA	Research Executive Agency
	Research Organisations
RIA	Deserve and Inneviation Actions
DM	Research and Innovation Actions
RM	Research and Innovation Actions Risk Management
RM RRI	Research and Innovation Actions Risk Management Responsible Research and Innovation

SC1	Horizon 2020, Pillar 2, Societal Challenge 1: Health, demographic change and well-being
SC6	Horizon 2020, Pillar 2, Societal Challenge 6: Europe in a changing world - inclusive, innovative and reflective societies
SC7	Horizon 2020, Pillar 2, Societal Challenge 7: Secure societies protecting freedom and security of Europe and its citizens
SDG	Sustainable Development Goals
SME	Small or Medium-Sized Enterprise
SRIA	Strategic Research Innovation Agenda
SSH	Social Sciences and Humanities
STAB	Strategic Advisory Board
Success rate	The share of proposals that are retained for funding out of the total number
	of eligible proposals
SWG	Synergies Working Group
ТВ	Tuberculosis
TFEU	Treaty for the Functioning of the European Union
THCS	Transforming Health and Care Systems
Third Country	A state that is not a Member State of the EU. The 'Third Countries' list does
	not include Associated Countries
TO-REACH	Transfer of Organisational innovations for Resilient, Effective, Equitable,
	Accessible, sustainable and Comprehensive Health Services and Systems
TRL	Technology Readiness Levels are indicators of the maturity level of particular
	technologies. This measurement system provides a common understanding
	of technology status and addresses the entire innovation chain: TRL 1 – basic
	principles observed; TRL 2 - technology concept formulate; TRL 3 -
	experimental proof of concept; IRL 4 – technology validated in lab; IRL 5 –
	technology validated in relevant environment; IRL 6 – technology
	demonstrated in relevant environment; IRL / – system prototype
	demonstration in operational environment; IRL 8 – system complete and
TTO	qualified; IRL 9 – actual system proven in operational environment
IIG	nime-ro-Grant (The elapsed time between the call closing date and the
TTI	Time To Inform (The time from cell closure until the potification of evaluation
	nine-no-inform (the time from call closure until the notification of evaluation
ттр	Time-To-Pay (The time from invoice issuance to invoice navment date)
TTS	Time-To-Sign (Time from the evaluation outcome to Grant Agreement (GA)
	signature)
VFT	Vocational Education and Training
WHO	World Health Organisation
Widening	Countries that are low performing in the area of research and innovation (70%)
countries	of the EU average)
WP	Work Programme
WT	The Wellcome Trust

Introduction to the Annexes

This document is a complementary file to the Final Report submitted as part of the *Evaluation* study of the European Framework Programmes for Research and Innovation for a Resilient Europe (further referred to as the Resilient Europe study).

The present document contains the following Annexes:

- Annex 1: Complementary analysis to Clusters 1, 2 and 3 and overall efficiency analysis (the complementary sections are included selectively, specifically for those rubrics where additional data (e.g., in-depth analysis, tables, figures) were available to further complement the study findings);
- Annex 2: Intervention logic for the analysed programme parts;
- Annex 3: Additional methods (incl. Network analysis, bibliometric analysis, analysis of synergies with programmes outside of Horizon Europe, unstructured data analysis: FET scores, SDG analysis);
- Annex 4: Case studies;
- Annex 5: Benchmark reports;
- Annex 6: Co-funded partnership reports (6-pagers);
- Annex 7: Analysis of the Online Public Consultation Results;
- Annex 8: Surveys (synopsis);

Annex 1: Complementary analysis to Clusters 1, 2 and 3 and overall efficiency analysis

This Annex is an addition to the primary report, offering further insights into Clusters 1, 2, and 3 and overall efficiency analysis. Providing supplementary data, graphs, and tables for relevance, coherence, effectiveness and efficiency evaluation criteria, Annex 1 delves deeper and complements the key findings of each cluster where needed.

1.1. Relevance

1.1.1. Addressing stakeholder and target group needs (Cluster 1, 2, and 3)

The Figure below presents the SME's involvement in Cluster 1, 2, and 3 activities while comparing micro, small, and medium-sized SMEs across the three clusters regarding their overall participation in Horizon Europe. Across all clusters, small SMEs (10 to <50) show the highest representation within the clusters, while medium-sized SMEs (50 to <250) have the lowest.

Overall, the finding presents that SME involvement within the clusters is very similar to overall SME involvement in Horizon Europe, indicating that various-sized SMEs are included in the Cluster 1, 2 and 3 actions.





Source: EC administrative and monitoring data.



Figure 2. Research-intensive SMEs attracted in Cluster 2

Cluster 2 Horizon Europe

Source: EC administrative and monitoring data.

Figure 3. Research-intensive SMEs attracted in Cluster 3



Source: EC administrative and monitoring data.

1.1.2. Flexibility to respond to emerging and changing circumstances

Cluster 1

The assessment of the programme's flexibility to cope with changing circumstances indicates that Horizon Europe's Cluster 1, as its predecessor SC1, continues to produce research that corresponds to the changing circumstances. Our analysis shows that this is particularly evident from the research activities on infectious diseases, poverty-related neglected diseases and cancer-related research.

The Figure below presents the share of cancer-related publications, considering the total publications produced by each funder (for the context of the FPs, we have results only for FP7 and Horizon 2020), as publication data is not yet available for Horizon Europe. We observe that, over time, EU FPs keep up with the NIH, having a similar share of cancer-related publications in terms of the top 5 neoplasm types.



Figure 4. Share of cancer-related publications by neoplasms histologic type

Source: Cancer Mission case study.

When we looked at the share of cancer-related projects, we **observed a gradual increase** in the share of cancer-related projects from FP7 up until the mid-term results of Horizon Europe, as well as the increase in the share of EC contributions to cancerrelated projects (from 5.3% in FP7 to 5.7% up until now in Horizon Europe). This result is not surprising, as Horizon Europe puts a lot of effort into ensuring maximum synergies with other EU initiatives tackling the growing cancer burden. Europe's Beating Cancer Plan is just one example of that. Moreover, as discussed in earlier sections, Cancer Mission is a novelty under Horizon Europe – this could explain the increased share of projects on cancer.

Figure 5. Overview of cancer-related projects and EU contributions in FP7, Horizon 2020, and Horizon Europe

Programme	Total number of projects	Number of cancer- related projects	Share of cancer- related projects (%)	Share of EC contribution to cancer-related projects (EUR, million)	EC contribution (total) (EUR, million)
FP7	25 790	1 574	6.1	5.3	46.0
Horizon 2020	35 856	2 254	6.29	4.8	68.3
Horizon Europe (mid-term results)	9 459	641	6.78	5.7	24.6

Source: Cancer Mission case study.

Cluster 1 Work Programmes are largely responsive to evolving health challenges. The adaptability and alignment with global health priorities demonstrated by Cluster 1 Work Programmes are crucial for promoting health, well-being, and preparedness in Europe.

The Cluster 1 Work Programmes are directed towards two Key Strategic Orientations (KSOs) for research and innovation set by Horizon Europe's strategic plan 2021 – 2024. With the goal of creating a more resilient, inclusive and democratic European society and promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains, Cluster 1 contributes to the six destinations (also see intervention logic presented in Annex 2) of the Work Programme:

- Staying healthy in a rapidly growing society;
- Living and working in a health-promoting environment;
- Tackling diseases and reducing disease burden;
- Ensuring access to innovative, sustainable and high-quality healthcare;
- Unlocking the full potential of new tools, technologies and digital solutions for a healthy society;
- Maintaining an innovative, sustainable and globally competitive health industry.

As part of the analysis of this study question, the team assessed the Cluster 1 – health Work Programmes (2021-2022 and 2023-2024). The study team observed a notable evolution in the Work Programmes' calls, yet a sustained relevance to the programme's original objectives.

Work Programme 2021-2022¹

The WP 2021-2022 was designed during the midst of the coronavirus pandemic, which, at the time, was a key (still) newly emerged health threat. The examples of dedicated calls linked to the pandemic included the following:

- Building a European partnership for pandemic preparedness;
- Pandemic preparedness.

¹ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-4-health_horizon-2021-2022_en.pdf

In addition to the translational research-related calls, the study team observed calls targeting new-emerging threats such as **risks to mental health associated with a transforming Europe** (e.g., the socio-economic consequences of the COVID-19 pandemic, climate change, environmental degradation, energy transition, demographic and migration factors, digitalisation, and exponential technological advancements). The calls for **boosting mental health in Europe in times of change** and **molecular and neurobiological understanding of mental health and mental illness for the benefit of citizens and patients** correspond to the Cluster 1 destination of **staying healthy in a rapidly growing society.**

Work Programme 2023-2024²

The latest WP 2023-2024 is reflecting further emerging circumstances in Europe and the world. The present Cluster 1 WP is aimed at supporting the Health Environment Research Agenda for Europe (HERA) and Europe's pandemic preparedness by investing in research into **better management of epidemics**, **adaptable clinical networks** for drugs and vaccines and **better comprehension of the emergence of cross-border health threats**.

In addition to the particular attention being paid to translational research, facilitating the development and implementation of new ways to prevent, diagnose, and treat infectious diseases, we now observe a focus on the wider societal impacts of health crises, e.g., on peoples' mental health and well-being and healthcare system resilience. The latter comes of particular importance due to the ongoing **war in Ukraine, which has greatly impacted health and care systems** and the resulting migration to bordering countries. Some of the calls addressing the wider societal impacts of health crises include the following:

- Resilience and mental well-being of the health and care workforce;
- Planetary health: understanding the links between environmental degradation and health impacts;
- Comparative effectiveness research for healthcare interventions in areas of high public health need.

Benchmark study 1 (B1) on NIH's **response to COVID-19** found that Horizon Europe for **2021 – 2027 continues to invest in research and innovation to tackle infectious diseases, including poverty-related and neglected diseases**³. The European Commission is mobilising EUR 123 million from Horizon Europe to research **COVID-19 variants**⁴. This funding contributes to the EC's action to prevent, mitigate and respond to the impact of COVID-19 variants together with the new European bio-defence preparedness plan and the Health Emergency Preparedness and Response Authority (HERA) Incubator to prepare Europe for an increased threat of coronavirus variants⁵.

Our findings are further confirmed through the interview programme. For example, according to the interview representatives from HaDEA, the Framework Programme has shown its agility in responding to crises and adapting to new policy initiatives. It has showcased its ability to reallocate resources and redirect focus towards pressing research areas such as

² https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-4-health_horizon-2023-2024 en.pdf

³ https://research-and-innovation.ec.europa.eu/research-area/health/coronavirus_en

⁴https://research-and-innovation.ec.europa.eu/research-area/health/coronavirus/coronavirus-projects_en

⁵ https://ec.europa.eu/commission/presscorner/detail/fr/ac_21_666

COVID-19. By staying responsive to evolving needs and challenges, the Programme maintains its relevance and ensures that its efforts align with the most pressing societal and political priorities.

Cluster 1 has the necessary tools to adapt to emerging socio-economic problems and scientific and technological developments. This finding was further confirmed through the interview programme with the EC officials. For instance, HaDEA representatives confirmed that the Agency maintains contact with all the parent Directorates to match the policy needs with the supported research projects.

Maintaining the relevance of the present policy needs is achieved through structured and adhoc feedback on policy, evaluation reports, and participation in the Missions Secretariat meetings, European Partnerships meetings, various networks, and working groups.

1.1.3. Timeliness of the performed research and innovation activities

Cluster 1

The assessment of the timelines of the performed research and innovation activities suggests that Cluster 1's **actions address new or fast-growing R&I topics to a large extent** and outperform the average Pillar 2 score and the average Horizon Europe programme score. As can be seen from the table below, the top 5 corresponding FET topics in Cluster 1 are: 1) Open science (269), 2) Middle-income country (108), 3) Translational research (99), 4) Open data (95) and 5) Electronic health record (79).

Programme part	Average FET Score	Top 5 corresponding FET topics (and number of corresponding projects)
Cluster 1	13.71	Open science (269) Middle income country (108) Translational research (99) Open data (95) Electronic health record (79)
Pillar 2	12.22	Open science (2039) Open data (942) Findability (805) Deep learning (582) Climate change mitigation (517)
Horizon Europe	8.59	Open science (5 877) Open data (1 795) Deep learning (1 440) Findability (1 403) Open peer review (1 097)

Table 1. Average FET Score Cluster 1

Source: HE administrative data, MAG/OpenAlex database.

This finding corresponds to the 2023 European Innovation Scoreboard⁶, which found that, as measured by the Summary Innovation Index, **the EU has increased its innovation performance by 8.5%** since 2016. While the scope is not directly linked to Cluster 1 actions, it is important to consider that Horizon Europe, in general, is designed to promote excellence-

 $^{6\} https://research-and-innovation.ec.europa.eu/statistics/performance-indicators/european-innovation-scoreboard_en-inn$

based Research and Innovation and support top-quality researchers and innovators to realise the EU's objectives, cross-border cooperation on technology development in European Partnerships (esp. Innovative Health Initiative).

Additionally, we looked at examples of contributions to innovative solutions from the European Partnership for EIT Health and Cancer Mission. According to the study report (submitted as a separate deliverable), EIT Health makes a significant contribution to the digital transition. EIT Health's non-degree education programmes (addressing the digital dimension of the healthcare industry) feature in EIT Health's education activities. More specifically, Science4Pandemics, a citizens' engagement digital platform for collective intelligence in pandemics, had around 5,000 participants in 2022. This programme targeted European adolescents using gamification and Artificial Intelligence to enhance public understanding of preventing and managing pandemics further (for further details, please see the individual partnership report on EIT Health). Other similar non-degree education programmes that contribute to citizen engagement are AIProHealth, HelloAI (Artificial Intelligence) or Basics of Digital Health⁷.

The partnership report on EIT Health further found that EIT Health is also highly relevant in supporting small and medium-sized enterprises (SMEs), contributing to technological innovation and digital transition. For instance, around 900 companies (which make up 69% of the total supported companies) produced some technology contributing to the digital transition, whereas around 600 companies (48%) produced deep tech innovations⁸.

Similarly to EIT Health, the Cancer Mission has developed various digital tools to meet its objectives, which also underlines the emergence of innovation under Horizon Europe. Tools have been developed for specific objectives, such as understanding cancer, prevention and early detection, diagnosis and treatment and quality of life for the patients and their families. For example, eSMART gives patients and professionals virtual means to assess and manage symptoms during chemotherapy in home care settings (for further details, see case study 6 on Mission on Cancer, Annex 4.

1.1.4. Relevance and flexibility of partnerships

Analysis of partnerships demonstrated **flexibility in updating the Strategic Research Innovation Agendas**. The partnership report on EIT Health (submitted as a separate deliverable) discovered that one of the ways EIT Health has proven its flexibility is by establishing **four Flagship programmes**. The Flagship defines topics yearly and focuses on addressing the relevant challenges (e.g., to an ageing population, delivering new healthcare models, facilitating the uptake of digital medical services). Similarly, the partnership report on PARC (European Partnership for the Assessment of Risks from Chemicals) **demonstrates its flexibility by establishing a research and innovation agenda for chemicals**, fostering multidisciplinary research and digital innovations for innovation (e.g., advanced tools, methods, models). Furthermore, the partnership report on THCS (European Partnership for Transforming Health and Care Systems) **acknowledges its SRIA's different reports** of the EU on health and care that further illustrate THCS's alignment with the EU-level objectives.

⁷ Analysis of EIT Health Grant Assessment data 2021-2022

⁸ EIT Health Startup Database. https://startups.eithealth.eu/dashboard. The following keywords were used to classify companies based on technologies produced: artificial intelligence, mobile app, big data, deep tech, machine learning, iot internetofthings, virtual reality

1.2. Coherence

1.2.1. Coherence of Cluster 1, 2 and 3 between Framework Programme parts covered by this study

To assess the coherence of clusters 1, 2 and 3, we looked at the results of the open public consultation.

The online public consultation launched by the EC in 2023 asked respondents, compared to the Strategic Plan 2021-2024, if they saw any unexploited potential for complementarities between different clusters. As a result, some respondents saw unexploited potential for complementarities between the different clusters. The results for Clusters 1, 2 and 3 are illustrated below.

Figure 6. Compared to the Strategic Plan 2021-2024, do you see any unexploited potential for complementarities between different clusters? Cluster 1 - Health



Source: Open public consultation.

Figure 7. Compared to the Strategic Plan 2021-2024, do you see any unexploited potential for complementarities between different clusters? Cluster 2 - Culture, Creativity and Inclusive Society



Source: Open Public Consultation.



Figure 8. Compared to the Strategic Plan 2021-2024, do you see any unexploited potential for complementarities between different clusters? Cluster 3 - Civil security for society

Source: Open public consultation.

1.2.2. The internal coherence of Cluster 1 instruments and partnerships

In the assessment of the internal coherence of Cluster 1 instruments, we found that **Cluster 1 funded 315 projects** amounting to EUR 2.3 billion in EU contributions **in 2021 and 2022**. The State of Play section has already presented the dynamics of projects funded under the Health Cluster in recent years.

Table 2. Distribution of projects and EU contribution by call deadline year (in EUR million) $_{9}$

Year	Cluster 1 - Health	
	Number of Projects	EU contribution (EUR)
2021	114 (36.2%)	989.9 million (41.7%)
2022	201 (63.8%)	1.3 billion (58.2%)
Total for 2021 and 2022	315 (100%)	2.3 billion (100%)
Total HE budget	20 962 ¹⁰	
Total HE projects	7 998 ¹¹	

Source: Compiled by the study team with eCORDA data.

The study team looked at the participant data to assess whether there were any crossovers in terms of the participants attracted by each Cluster 1 action type. We found that **HEIs received the majority of funding (35%),** followed by RECs, who received 34.4% of funding. Notably, PRCs received 17.2% of EU contributions, although most participants represented the PRCs. This suggests that, like with the predecessor SC1, Cluster 1 continues to cater for a specific type of participant group through different actions. A detailed overview of the distribution of beneficiaries and EU contributions by organisation type is presented in the State of Play chapter.

⁹ The data excludes all the Rejected, Suspended and Terminated projects

¹⁰ The data excludes the Rejected projects

¹¹ The data excludes EIT and EIC Accelerators

The study team also looked at the different action types used by Cluster 1 and their distribution according to the number of projects covered and the amount of EU contributions received.

Table 3. Distribution of beneficiaries

Type of Action ¹²	Definition
RIA (Research and Innovation Actions)	Establishes new knowledge and explores new technology, products, services, or solutions.
CSA (Coordination and Support Actions)	Improves cooperation among EU and Associated Countries strengthens the ERA (e.g., standardisation, dissemination, policy dialogues).
IA (Innovation Actions)	Designs plans for improved products, processes or services (e.g., prototyping, testing, piloting).
Joint Undertakings CSA	Efficiently executes EU research, technological development, and demonstration programmes.
Joint Undertakings RIA	Efficiently executes EU research, technological development, and demonstration programmes.
Pre-Commercial Procurement	Stimulates innovation and enables the public sector to steer the development of innovative solutions (e.g., approach to public procurement of R&D services)
COFUND	Provides multi-annual co-funding for European partnerships (e.g., bringing together public and private partners).

Source: Compiled by the study team.

Participant type	RIA	CSA	IA	Join Undertaking s CSA	Join Undertakin gs RIA	PCP	COF UND
Higher or Secondary Education (HES)	464 (24.8%)	41 (16.3%)	6 (17.6%)	9 (17.3%)	77 (33.0%)	1 (12.5%)	91 (34.0 %)
Other (OTH)	229 (12.2%)	48 (19.0%)	3 (8.8%)	3 (5.8%)	26 (11.2%)	2 (25.0%)	8 (3.0%)
Private for- profit entities (PRC)	630 (33.6%)	28 (11.1%)	15 (44.1%)	6 (11.5%)	54 (23.2%)	1 (12.5%)	1 (0.4%)

Table 4. Breakdown of participants by action type in Cluster 1

¹² https://rea.ec.europa.eu/horizon-europe-how-

 $apply_en \#: \sim: text = Coordination \% 20 and \% 20 support \% 20 action \% 20 (CSA, dialogues \% 2C\% 20 mutual \% 20 learning \% 20 or \% 20 studies \% 20 mutual \% 20 learning \% 20 or \% 20 studies \% 20 mutual \% 20 mut$

Public bodies (PUB)	117 (6.2%)	54 (21.4%)	5 (14.7%)	20 (38.5%)	16 (6.9%)	3 (37.5%)	76 (28.4 %)
Research organisatio ns (REC)	435 (23.2%)	81 (32.1%)	5 (14.7%)	14 (26.9%)	60 (25.8%)	1 (12.5%)	92 (34.3 %)

Source: Compiled by the study team with CORDA dataset.

To assess the adequacy of the instruments under Cluster 1, the study team has also looked into the thematic relationship. The thematic relationships between projects were calculated using the keywords extracted from project reports, monitoring data and publications using a specialised ontology. The study team assigned up to 50 of the most frequent keywords from the ontology to each project. If two projects share five keywords or more, we consider them related.

The study team has also looked at how the similarity relationships between project pairs were distributed between the different action types. This was calculated "by dividing the number of pairs linking action type 'X' with action type 'Y' by the number of distinct similar project pairs", but by dividing the number of similar pairs, linking action type 'X' with action type 'Y' by the number of total number of pairs linking action type 'X' with action type 'Y'.

As can be seen from the chord graph below, there are few to no thematical overlaps between different Cluster 1 funding instruments, suggesting that so far, the Health Cluster instruments mostly cover different research grounds. Our findings are very similar to that of the predecessor SC1 - there is a greater thematic cohesion within the different action types than between them.





Source: Compiled by the study team.

1.2.3. Coherence among assessed partnerships

Coherence among partnerships covered under this study (i.e., GH EDCTP3 JU, IHI, EIT Health, THCS, PARC, ERA4Health) was assessed with regard to the extent to which different partnerships foster collaboration and avoid overlapping or duplication between their activities. The evidence gathered from individual partnership reports features the following:

Example of Transforming Health and Care Systems Partnership (THCS) co-funded partnership

The CS13 on the new Transforming Health and Care Systems partnership (THCS) concluded that THCS demonstrates high coherence with other partnerships and initiatives in the healthcare sector. It builds on the experiences of previous partnerships/initiatives. Emphasises synergies with other European initiatives to avoid duplication and ensure coherence. The partnerships' SRIA (several initiatives have been developed that are now ready to be consolidated under a single synergistic approach to build upon them and increase their impact)¹³ underlines that **synergies are sought with other European initiatives**, and this way, **THCS aims to avoid duplication and ensures coherence between the partnerships** and other initiatives of Horizon Europe or other relevant EU programmes.

¹³ THCS, Strategic Research and Innovation Agenda, 2022

Example of the ERA4Health co-funded partnership

Even though **ERA4Health** has only recently started its activities and there are no significant complementarities achieved yet between the partnerships under Horizon Europe, **ERA4Health is actively working towards looking for and establishing coherences and synergies** with other partnerships as well as modalities under Horizon Europe. For instance, the 6-pager on ERA4Health notes that ERA4Health has several **work packages** dedicated to promoting synergies and actively engaging with relevant stakeholders and initiatives at the EU and international level within the area of ERA4health to increase mutual awareness and establish an effective and efficient collaboration to avoid duplication of investments, work, and related activities¹⁴. In addition to the work packages, ERA4Health established a **Synergies Working Group (SWG)**, and its main role is to help define the synergies among the identified European/international initiatives and to organise and participate in the Annual Workshops where the initiatives for synergies are presented¹⁵. ERA4Health has already successfully organised its 1st International Annual Workshop for the search of Synergies of the Partnership ERA4Health in June 2023¹⁶.

Example of the European Partnership for the Assessment of Risks from Chemicals (PARC) co-funded partnership

According to the 6-pager on the European Partnership for the Assessment of Risks from Chemicals (PARC), PARC avoids overlapping activities and **ensures synergy with existing programmes, mainly through coordination with regulatory bodies**, such as the European Food Safety Authority (EFSA) and European Chemicals Agency (ECHA), as noticed by the beneficiaries. The PARC prevents overlapping activities with other funding programmes by establishing a governing board with representatives from national ministries, Directorates-General (DGs) of the EC and funding agencies.

Example of GH EDCTP3 JU

It is too early to assess the level of coherence and synergies between the GH EDCTP3 JU and other partnerships under Horizon Europe, mainly because the JU is still in the early stage of implementation; however, the partnership report European Partnership for the Global Health EDCTP3 Joint Undertaking reveals that the **GH EDCTP3 JU aims to achieve a high level of internal coherence**, by reviewing the conditions of calls for proposals, aiming to establish or restrict their potential achievements, and adapting to other ongoing developments through collaboration to avoid duplications.

Example of EIT Health

EIT Health demonstrates clear efforts to **integrate with the other EU funding programmes**. According to the partnership report on the European Partnership for EIT Health, EIT Health is synergic with other EU funding programmes, particularly with the European Innovation Council (EIC) and the European Investment Fund (EIF). EIT Health is also involved in the Partnership for Personalised Medicine and seeks to create partnerships with cancer-specific initiatives.

¹⁴ ERA4Health Partnerships. D18.5 Working Group RRI Established WP18. Page 16

¹⁵ ERA4Health Partnership. D8.1-D1.3.2 Synergies Working Group Establishment WP8. Page 9

¹⁶ ERA4Health (2023). 1st International Annual Workshop for the search of Synergies of the Partnership ERA4Health.

https://era4health.eu/event/1st-international-annual-workshop-for-the-search-of-synergies-of-the-partnership-era4health/

EIT Health and the Innovative Health Initiative (IHI) united to drive healthcare innovation by contributing to EU priorities by creating collaborative innovation ecosystems (not previously existent) that promote entrepreneurship and innovation in healthcare¹⁷. For instance, EIT Health has a pan-EU representation via seven Co-Location Centres (CLCs) in Austria, Belgium-Netherlands, France, Germany, Scandinavia (Denmark, Estonia, Finland, Norway, Sweden), Spain, Ireland-UK; the InnoStars CLC covers Hungary, Italy, Poland and Portugal. EIT Health also operates a Regional Innovation Scheme (RIS), which covers 14 regions in 13 European countries (for example, Croatia, Czechia, Greece, Latvia, Lithuania, Slovakia, Slovenia, and Romania). EIT Health has also set up a Global outreach hub in Israel to create synergies between EIT Health and the Israeli innovation ecosystem.

In addition to assessing coherence among the partnerships covered in the study, the team looked at whether partnerships might be more effective in achieving synergies compared to other programme modalities.

According to the Biennial Monitoring Report¹⁸, "<...this new impact-oriented approach expects European Partnerships to take a **more systemic approach** to achieving the objectives. In particular, Partnerships should not act in isolation but in the broader landscape of R&I and sectoral policies by seeking and exploiting synergies with related Horizon Europe and other initiatives at the EU or national level, including with the EU Missions" (p.83).

This implies that **partnerships are now more goal-oriented and collaborative**, aiming to prevent duplication or working in isolation. Our interviews with EC officials support this notion. They agree that this shift towards a more systemic approach has made partnerships more visible, with well-defined objectives and a narrow focus on specific targets. This clarity in **purpose also facilitates outreach efforts as the identity of each partner is clearer**. For instance, when two organisations collaborate, having distinct identities simplifies the process of identifying an additional identity for their cooperation.

Due to their directional nature, partnerships and missions serve as tools for fostering future synergies. They are instrumental in guiding the direction of Horizon Europe, ensuring a more focused and purposeful approach to collaborative initiatives.

Furthermore, the study team examined the outcomes of the public consultation conducted by the EC in April 2023. The findings reveal that approximately a quarter of the respondents (23%) acknowledged that the streamlining of European Partnerships has facilitated the attraction of extra public and private investments for R&I. Similarly, roughly another quarter of respondents (22%) expressed agreement that the simplification of European Partnerships has led to a greater number of solutions benefiting society, the environment, and the economy.

Considering the synergies between partnerships and the national governments, Member States significantly influence the setup of partnerships, engaging closely with the Commission through pre-consultations. Each partnership inherently embeds synergies and coherence, with Member States well-represented in governance structures, allowing them ample freedom to shape partnership selection and implementation. However, according to the EC, recent changes aiming for enhanced synergy and systemic

¹⁷ EIT Health and IHI unite to drive healthcare innovation https://eithealth.eu/news-article/eit-health-and-ihi-unite-to-drive-healthcareinnovation/

¹⁸ Performance of European Partnerships, Biennial Monitoring Report 2022,

https://era.gv.at/public/documents/4676/Biennial_Monitoring_Report_2022.pdf

approaches have resulted in some negative reactions, particularly from the Member States, encountering difficulties in implementing these modifications, while the private sector remains relatively unaffected by these adjustments. Our discussions with the EC indicate that, as is common with any transformative change, initial negative reactions to restructuring and repurposing are not uncommon. However, these reactions tend to shift over time toward a more positive direction.

1.2.4. Positioning of Cluster 1, 2 and 3 within the overall European R&I landscape

Cluster 1

Cluster 1 plays a pivotal role in shaping the EU's stance and competitiveness in R&I. Specifically, CL1 focuses on strengthening the EU's capabilities and leadership in fundamental areas such as health, life sciences, and biotechnologies. According to the Horizon Europe Strategic Plan 2021-24, by prioritising R&I in health-related fields, **CL1 aims to enhance the EU's global position in addressing societal challenges, promoting health equity, and fostering economic growth through cutting-edge advancements in health technologies, treatments, and methodologies. Additionally, CL1's emphasis on addressing pressing health concerns helps solidify the EU's reputation as a frontrunner in R&I, driving scientific excellence and societal impact on a global scale.**

The Cancer Mission within Horizon Europe's CL1 showcases the EU's strategic positioning in the research and innovation landscape, notably through its collaborative synergy with Europe's Beating Cancer Plan (EBCP). As highlighted in the CS6: Cancer Mission, this alignment is particularly evident in their shared objectives, which address the entire cancer pathway. While the Cancer Mission primarily focuses on research-related tasks, the EBCP operates at the policy level, fostering a division of labour that enhances their collective impact.

The successful coordination between these initiatives is pivotal for their effectiveness. They collaborate closely, manifesting their alignment through various activities and networks, such as the Comprehensive Cancer Infrastructures network and the Cancer Patient Digital Centre. The Cancer Mission significantly supports the implementation of the EBCP by accelerating novel research approaches and policymaking strategies. Through joint projects and preparatory actions, funded research endeavours by the Cancer Mission contribute directly to the EBCP's policy implementations, ensuring thematic coherence, avoiding duplication of efforts, and amplifying their overall visibility.

The coherent partnership between the Cancer Mission and the EBCP is notable in terms of their joint actions and mutual support. For instance, a substantial proportion of EBCP's actions are aligned with calls from the Cancer Mission, emphasising their coordination and complementarity. Moreover, the Cancer Mission actively facilitates the implementation process of flagship initiatives within the EBCP, further underscoring their symbiotic relationship and thematic synergy.

Insights from interviews with EC officers and National Contact Points reinforce the collaborative synergy between the Cancer Mission and the EBCP. The establishment of joint groups, such as the Commission Services Group and the Cancer Subgroup, indicates a concerted effort between DG SANTE and DG RTD, fostering collaborative meetings and shared participation, ensuring streamlined coordination, and engaging stakeholders in aligning their strategies for enhanced effectiveness.

This close collaboration and shared thematic focus between the Cancer Mission and the EBCP exemplify CL1's significant role in positioning the EU as a leader in addressing complex health challenges through research, innovation, and policy integration.

1.2.5. Horizon Europe's approach to fostering synergies and coherence with other initiatives, including at the regional and national level

Cluster 1

Respondents were asked whether their Horizon Europe project is a continuation of research activities carried out under previous Framework programmes/other funding schemes. This question has a total of 449 responses, out of which 61.5% said that the project is not a follow-up or continuation of previous projects. However, 11.9% claimed that their project is a continuation of a project funded under Horizon 2020, 6.1% claimed that their project is a continuation of a project funded under national/regional public funding programmes, and 3.5% claimed that their project is a continuation of a project is a continuation of a project search under national/regional public funding programmes, and 3.5% claimed that their project is a continuation of a project funded under Review Programmes/Other funding schemes.





Source: Compiled by the study team based on the survey programme, n=449.

Respondents were asked whether any activities planned for their project would be implemented in collaboration with projects funded under the Horizon Europe programmes or clusters. This question received a total of **476 responses**, out of which 35.7% claimed that their projects do not have any joint activities with the Horizon Europe programmes, and

36.2% do not hold any particular opinion. Notably, 23.5% claimed collaborative activities with Cluster 1.

Do not know/Not Applicable		36,29	%		
No, my project does not have joint activities with projects funded under other Horizon Europe		35,7%	6		
Pillar II - Cluster 1 - Health		23,5%			
Widening participation & spreading excellence	2,6%				
Pillar I - Marie Składowska-Curie Actions	2,6%				
Pillar II - Cluster 4 - Digital, Industry & Space	2,3%				
Pillar II - Cluster 6 - Food, Bioeconomy, Natural Resources, Agriculture & Environment	1,4%				
Pillar II - Cluster 5 - Climate, Energy & Mobility	1,4%				
Pillar I - Research Infrastructures	1,4%				
Pillar I - European Research Council	1,2%				
Pillar III - European Innovation Ecosystems	0,9%				
Pillar II - Cluster 2 - Culture, Creativity & Inclusive Society	0,9%				
Pillar III - European Institute of Innovation and Technology	0,5%				
Pillar III - European Innovation Council	0,5%				
Pillar II - Cluster 3 - Civil Security for Society	0,5%				
Reforming & enhancing the European R&I system	0,2%				
	0% 20%	% 40%	60%	80%	100%

Figure 11. Activities implemented in collaboration

Source: Compiled by the study team based on the survey programme, n=476.

Below, we present the cross-tabulation of Annex IV of Horizon Europe regulation programmes, including indications of synergies between the Annex IV programmes and Clusters 1, 2 and 3. The study team analysed all the programmes stated in Annex IV of Horizon Europe regulation. These programmes were analysed qualitatively, and analysis can be found in Annex 3.

Table 5. Synergies with Annex IV (HE) programmes with Cluster 1, 2 and 3

Programme	Cluster 1	Cluster 2	Cluster 3
The European Agricultural Guarantee Fund (EAGF) and the European Agricultural Fund for Rural Development (EAFRD)	-	-	-
The European Maritime, Fisheries and Aquaculture Fund (EMFAF)	-	-	yes (source: internal mapping of DG RTD)
The European Regional Development Fund (ERDF)	-	-	yes (source: Cluster 3 WP 2021-2022 & 2023-2024)
The European Social Fund Plus (ESF+)	-	-	-
The EU4Health Programme	yes (sources: synergies analysis)	-	-
The Connecting Europe Facility (CEF)	-	-	-
The Digital Europe Programme (DEP)	-	-	yes (sources: synergies analysis; Cluster 3 WP 2021- 2022 & 2023-2024)
The Single Market Programme	-	-	-
The LIFE - Programme for Environment and Climate Action (LIFE)	-	-	
Erasmus+	-	-	-
The Union Space Programme	-	-	-
The Neighbourhood, Development and International Cooperation Instrument (NDICI) and the Instrument for Pre- accession Assistance (IPA III)	-	yes (source: synergies analysis, Cluster 2 WP 2021-2022 & 2023- 2024)	-

Programme	Cluster 1	Cluster 2	Cluster 3
The Internal Security Fund (ISF) and the instrument for border management as part of the Integrated Border Management Fund (IBMF)	-	-	yes (sources: synergies analysis; Cluster 3 WP 2021- 2022 & 2023-2024)
The InvestEU Programme	-	-	-
The Innovation Fund under the Emission Trading Scheme (the 'Innovation Fund')	-	-	-
The Just Transition Mechanism	-	-	-
The Euratom Research and Training Programme	-		-
The European Defence Fund	-	-	yes (sources: internal mapping of DG RTD; Cluster 3 WP 2021-2022 & 2023-2024)
The Creative Europe Programme	-	yes (source: synergies analysis, Cluster 2 WP 2021-2022 & 2023- 2024)	-
The Recovery and Resilience Facility	-	-	-

Source: Compiled by the study team.

1.3. Efficiency analysis of Clusters 1, 2 and 3

1.3.1. Reporting on eligibility rates, success rates and time-based performance indicators

The following section focuses on budgetary resources and the efficiency of their use, programme attractiveness, and the efficiency of the application selection and project implementation processes for the three clusters analysed. The report presents quantitative monitoring data for the following key indicators:

- Share of ineligible proposals, success rate, and success rate of high-quality proposals;
- Time-to-Inform (TTI). Measured by the time from the call closure to the notification of evaluation outcome;
- *Time-to-Sign* (TTS). Measured by the time from the notification of evaluation outcome to a grant signature;

- Time-to-Grant (TTG). Measured by the time from call closure to grant signature;
- Time-to-Pay (TTP). Measured by the time from invoice issuance to invoice payment date.

The study team derived indicators, listed above, based on the administrative CORDA data. In addition, data from executive agencies such as the Research Executive Agency (REA), which manages Clusters 2 and 3, and the European Health and Digital Executive Agency (HaDEA), which manages Cluster 1, were used to complement the findings.

The indicators are assessed against the overall Horizon Europe performance and the legal targets (where relevant). Also, they are compared against the H2020 performance of the relevant benchmark years to determine whether the efficiency level was maintained since the previous framework programme. The assessment of the programme-level analysis of TT targets can be found in a parallel study, "Evaluation study on Excellent Science in the European Framework Programmes for Research and Innovation".

Cluster 1: Health

Cluster 1, titled Health, funded 315 projects, amounting to EUR 2 372.1 million in EU contributions (28.8% of the budget) in 2021 and 2022. As of the time of this analysis, there was no data available yet in the dataset for 2023. There were 288 signed projects and 27 projects under preparation. There were also no closed projects in Cluster 1.

	Indicators	2021	2022	Total for 2021 and 2022	Total HE allocated contributions (in EUR million)	Total H2020 allocated contributions in 2014 and 2015 (in EUR million)	
Cluster 1	Number of funded projects	114	201	315	8 246	757.4	
	EU contribution (in EUR million)	989.9	1 382.2	2 372.1			
	Avg. project size (in EUR million)	8.7	6.7	7.5			
Cluster 2	Number of funded projects	59	92	151	2 280	108.4	
	EU contribution (in EUR million)	166.8	270.0	436.7			
	Avg. project size (in EUR million)	2.8	2.9	2.9			
Cluster 3	Number of funded projects	54	43	97	1 596	172.7	
	EU contribution (in EUR million)	229.2	188.7	417.9			
	Avg. project size in (EUR million)	4.2	4.5	4.4			

Table 6. Projects selected for funding and EU c	ontribution 2021-2022 by call deadline year
19	

Source: Compiled by the study team with eCORDA data. June 2023 data release²⁰.

¹⁹ The data exclude all of the Rejected, Suspended and Terminated projects

²⁰ The latest call closure date available in the dataset; CL 1 – 19/10/2022; CL2 – 21/09/2022; CL3 – 23/11/2022. Applies to the rest of the report

The average size of a Cluster 1 project was about EUR 8.7 million in 2021 and EUR 6.8 million in 2022. Compared to H2020, the average project for SC1 was 3.3 million in 2014 and 3.4 million in 2015. Overall, the average project size was EUR 7.5 million for the two years, with the majority (74.6%) funded via Research and Innovation Actions (RIA). The second largest type of action was COFUND, making up 15.2% of the EU contribution for this cluster. Lastly, all of the projects were funded via Action Grants. As a result, Cluster 1 had already spent 28.8% of its total allocated budget by the end of 2022. The study team did not have any data for 2023 at the time of this analysis.

Success Rates - **The success rate for Cluster 1** in 2021 was 17.4%, and in 2022, it was 13.9%, **averaging 15% in total**. This is substantially higher than in the initial years of Horizon 2020 for Societal Challenge 1 (5% in 2014 and 8% in 2015) and is twice as high as the Horizon 2020 average of 7.5%. The success rate is calculated by looking at the share of funded proposals out of all eligible ones. Comparing the initial years of H2020 and HE can offer insights, shedding light on the early uptake, response, and adaptation challenges.

Figure 12. Application success rate by programme and call deadline year; a comparison between Horizon 2020 Societal Challenges and Horizon Europe Clusters. Number of total eligible proposals and the share of successful proposals.



Source: Compiled by the study team using eCORDA data * June 2023 data release.

The success rate of high-quality proposals for Cluster 1 was 31.5%), which is slightly higher than that of high-quality proposals for Societal Challenge 1 - 29.3%, and is in line with the Pillar 2 average of 31.3%. According to our estimation, an additional EUR 3.9 billion contributions would have been needed to fund the remaining 630 high-quality proposals submitted.

Eligibility Rates - The ineligible proposals in the initial years of HE comprise 6.1% of all applications submitted to Cluster 1. This is substantially higher than Societal Challenge 1, which had a total rate of 1% in Horizon 2020 and the overall Horizon Europe average so far of 4.0%. 2021 and 2022 had roughly similar rates of ineligible proposals, standing at 6.4% in 2021 and 6.0% in 2022 (0.8% in 2014 and 0.6% in 2015). **In general, we found that Cluster 1 had high rates of ineligible proposals in those two years,** especially compared to the rate of the initial years of Horizon 2020 (1.1%).

Table 7. Overv	view of the leve	el of competition	by programme
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HEU Thematic Priority	Total number of proposals evaluated	Share of ineligible proposals ²¹	Average success rate (all proposals)	Average success rate (only quality proposals)
Cluster 1: Health	2 056 (17.1%)	6.1%	15.0%	31.5%
Cluster 2: Culture, Creativity & Inclusive Society	1 157 (9.6%)	3.2%	12.9%	22.1%
Cluster 3: Civil Security for Society	706 (5.9%)	7.94% ²²	10.0%	24.3%
Pillar 2	12 044 (100%)	11.3%	19.0%	31.3%
Horizon Europe ²³	51 503 (100%)	4.0%	16.0%	29.8%

Source: Compiled by the study team using eCORDA data. June 2023 data release.

Time-based performance indicators until grant agreement (TTI TTS TTG) - **The analysis of the administrative part of the project selection process showed that, on average, the process was smooth, and most of the targets were met except the time it took from the evaluation outcome decision to the Grant Agreement signature (TTS). The average TTS for the evaluated period was approximately 123 days, 33 days over the target of 91 days (3 months) and 16 days over the Horizon Europe total. Nevertheless, the average TTG took 232.3 days and fell within the maximum target of 243 days (8 months). TTI was also within the target of 152 days (5 months), averaging 112.2 days. The administrative part of project selection demonstrated more efficiency than the overall processes for Horizon Europe (273 days TTG and 154.9 days TTI).**



Figure 13. Time-based performance indicators - a share of projects/payments that met the target

Source: Compiled by the study team using eCORDA data. June 2023 data release

²¹ Ineligible proposals do not include proposals that were categorised as duplicate, inadmissible and withdrawn applications (applies to the table below as well).

²² At the time of this analysis, 218 proposals did not have a stage exit status, for the purpose of the presentation of more precise results, we considered these 2018 proposals as "eligible".

²³ Excludes calculations for EIE and EIC Accelerator.

HEU Themati c Priority	Total number of proposals evaluated 24	HE avg. TTI (number of days and the difference between the target of 152 days)	H2020 avg. TTI in 2014 and 2015 (number of days and the difference between the target of 152 days)	HE avg. TTS (number of days and the difference between the target of 91 days)	H2020 avg. TTS in 2014 and 2015 (number of days and the difference between the target of 91 days)	HE avg. TTG (number of days and the difference between the target of 243 days)	H2020 avg. TTG in 2014 and 2015 (number of days and the difference between the target of 243 days)
Cluster 1: Health (SC1)	2 036	112.2 (- 39.8)	92.9 (- 59.1)	122.9 (+31.9)	77.9 (- 13.1)	232.3 (- 10.7)	167.7 (- 75.3)
Cluster 2: Culture, Creativit y & Inclusive Society (SC6)	1 157	109.9 (- 42.1)	112.7 (- 39.3)	129.9 (+38.9)	89.6 (- 1.4)	239.8 (- 3.2)	211.7 (- 31.3)
Cluster 3: Civil Security for Society (SC7)	461	128.3 (- 23.7)	120.1 (- 31.9)	126.9 (+35.9)	107.7 (+16.7)	262.2 (+19.2)	225.9 (- 17.1)
Pillar 2/Pillar 3	11 219	111.6 (- 40.4)	97.4 (- 54.6)	128.5 (+37.5)	85.2 (- 6.2)	237.5 (- 5.5)	183.9 (- 59.1)
Horizon Europe ²⁵	50 432	154.9 (+2.9)	111.7 (- 40.3)	106.9 (+15.9)	98.8 (+7.8)	273.0 (+30)	231.0 (-12)

Table 8. Time-based performance indicators until grant agreement

Source: Compiled by the study team using eCORDA data. June 2023 data release. Negative values (in green) represent indicators that were reached below the legal target (indicating the difference in days). Positive values (in red) indicate the indicators above the legal targets.

In comparison to Horizon 2020, processes linked to grant preparation took slightly longer in the first two years of the new Framework Programme. Under H2020, the average Time-To-Grant for Societal Challenge 1 was 186 days, the average TTI was 82.9 days, and the average TTS was 97.4 days.

Time-based performance indicator linked to payment (TTP) - In terms of the efficiency of the payment process, Cluster 1 performed well. Out of a total of 371 payments, over 86% were made on time. All but two were pre-financing payments, with a TTP of 13.4 days (target 31 days; Pillar 2 avg. 19.3 days; H2020 SC1 avg. 8.8 days) and + 17.6 days on target. One

25 Excludes calculations for EIE and EIC Accelerator.

²⁴ The total number of applications (n) is based on the data availability for TTI, i.e. if there is no data available for the date of Proposal Information Letter then the proposal is not included in this table.

of the two regular payments was well within the 90-day target, and the other was 87 days over it.

HEU	Total number of projects analysed	Total number of payments made ²⁷	Average TTP: pre- financing (number of days and the difference between the target of 31 days)	H2020 Average TTP in 2014 and 2015: pre- financing (number of days and difference between the target of 31 days)	Average TTP: total (number of days and the difference between the target of 91 days)	H2020 Average TTP: total in 2014 and 2015 (number of days and the difference between the target of 91 days
Cluster 1: Health	191	371	13.4 (-17.6)	7.1 (-23.9)	14.0 (-77)	48 (-43)
Cluster 2: Culture, Creativity & Inclusive Society	133	144	42.8 (+11.8)	6.7 (-24.3)	42.6 (-48.4)	53.8 (- 37.2)
Cluster 3: Civil Security for Society	54	59	8.8 (-22.2)	8.0 (-23)	8.8 (-82.2)	44.6 (- 46.4)
Pillar 2	1 652	2 533	19.3 (-11.7)	6.5 (-24.5)	19.4 (-71.6)	49.3 (- 41.7)
Horizon Europe ²⁸	4 564	5 610	17.0 (- 14)	6.7 (-24.3)	17.1 (-73.9)	27.9 (- 63.1)

Table 9. Time-based performance indicators linked to payments (TTP) for Cluster 1 - 3²⁶

Source: Compiled by the study team using eCORDA data. June 2023 data release. Negative values (in green) represent indicators that were reached below the legal target (indicating the difference in days). Positive values (in red) indicate the indicators above the legal targets.

Cluster 2: Culture, Creativity & Inclusive Society

The EC contribution allocated to implementing the Cluster 2 calls in 2021 and 2022 has been EU 436.7 million (19.2% of the budget), funding 151 projects. This resulted in an average EU contribution of EUR 2.8 million per project in 2021 and 2.9 million in 2022. Compared to H2020, the average project for SC6 was 2.5 million in 2014 and 1.4 million in 2015. In 2022, Cluster 2 funded 61.8% more projects (92) than in 2021 (59) (see Table 6). There was one closed project in 2021 and 144 signed projects in total. In 2022, there were no closed projects. The majority (92%) of the projects were implemented via Research and Innovation Actions (RIAs), and the remaining 8% via Coordination and Support Actions (CSAs). The majority (97.7%) of proposals had Action Grants as their type of funding, and a relatively small fraction (2.3%, 26 proposals) used Lump Sums.

²⁶ Refers to only projects with a status "Closed" and "Signed"

²⁷ Negative payments and regularization are excluded

²⁸ Excludes calculations for EIE and EIC Accelerator
Success Rates - The first two years of Cluster 1 and Cluster 2 show a slight relaxation of the still tense competition relative to their predecessor, Societal Challenge 6 (SC6). In 2021, the success rate was 15.1%, followed by a drop to 11.8% in 2022 (see Figure 12). In comparison, the success rate of Societal Challenge 6 in its initial years was 9% in 2014 and 4% in 2015, with a larger volume of applications than HE. The SC6 average was 6.2%, thus lower than that of the initial years of Cluster 2. It is still early into the FP to draw meaningful conclusions.

The success rate of high-quality proposals was the lowest among all of the Pillar 2 clusters – 22.1% (see Table 7). Nevertheless, it was still higher by six percentage points than its predecessor, Societal Challenge 6. It would have required an additional 1.6 billion to fund the remaining 507 eligible high-quality proposals.

Eligibility Rates - Cluster 2 had the lowest share of ineligible proposals in Pillar 2, averaging 3.2%. The HE Pillar 2 average was 9.6%, the HE total average was 4.0%, and the H2020 SC6 average was 1%. The ineligible proposals were slightly more in 2021 (3.9%) than in 2022 (2.9%). Compared to SC6, the ineligibility rate was 3.1% in 2014 and 1.3% in 2015.

Time-based performance indicators until grant agreement (TTI TTS TTG) - Throughout 2021 and 2022, the average time-to-inform (TTI) period was 106.9 days (target 152 days; SC6 for 2014 and 2015 112.7days), whereas time-to-sign (TTS) took 129.9 days (target 91 days; SC6 for 2014 and 2015; 89.6 days) and time-to-grant (TTG) 239.8 days (target 243 days; SC6 for 2014 and 2015; 225.9days) (see Table 8). While the TTI performance met expectations in terms of time taken for application screening and decision notification, the targets for TTS were, on average, not met. They were only met for 1.3% of the proposals. **The time-based performance indicators TTI and TTG fell within the legal timeframes, whereas the time-to-sign (TTS) performance did not meet its target.** TTS overshot on average by about 39 days per proposal, leading to a total of 5 494 days of delay. The performance on all three indicators to date is worse than the average under Horizon Europe and Horizon 2020 Societal Challenge 6 in its initial years (see Table 10).

Time-based performance indicator linked to payment (TTP) - There were 144 payments made to 133 projects for Cluster 2, of which all but two were pre-financing payments (see Table 9). 46.5% of the pre-financing payments exceeded the legal maximum target of 31 days, on average, by 11.8 days (Pillar 2: 19.3 days, HE: 17 days, SC6 in 2014 and 2015: 6.7 days). Both regular payments were on target (91 days). The data relating to payments reveals that the disbursement of payments led to a total of 1 821 days delay above the target.

Cluster 3: Civil Security for Society

A total of 97 projects were funded under Cluster 3 – Civil Security for Society, amounting to an EU contribution of EUR 417.9 million in 2021 and 2022 (26.2% of the budget). Projects funded in 2021 had an average of EUR 4.2 million, and projects funded in 2022 had an average of EUR 4.4 million (2.6 million in 2014 and 3.3 million in 2015). In 2022, Cluster 3 funded 21.5% more projects (see Table 6). There were no closed projects at the time of the analysis, and only 54 were signed projects, with 43 under preparation for a grant agreement. A little under half of these projects (47.4%) were funded via Innovation Actions (IA), followed by RIAs (43.3%). Most proposals used Action Grants (94.5%; 614 proposals), with a small fraction utilising the novel Lum Sum funding (5.5%; 36).

Success Rates - Cluster 3's success rate (15%) shows a slight positive change compared to Horizon 2020 Societal Challenge 7 (10%). However, it dropped from 16.3% in 2021 to 11.8%

in 2022 (12% in 2014 and 8.0% in 2015) (see Figure 12). The success rate of high-quality proposals under Cluster 3 (24.3%) scored relatively to what could have been expected (Pillar 2: 31.3%; HE: 29.8%; H2020 SC7: 20.3%). As a result, it would take an additional EUR 978 million to fund the 202 remaining high-quality non-funded Cluster 3 proposals so far.

Eligibility Rates – The ineligibility rate was 6.8% in 2021 and 8.92% in 2022 (as compared to 2.5% in 2014 and 0.8% in 2015). The overall ineligibility rate for Cluster 3 was 7,94% (Pillar 2: 11.3%, HE: 4.0%, SC7: 3.5). This is the highest rate of ineligible proposals among the programme parts analysed in this evaluation study.

Time-based performance indicators until grant agreement (TTI TTS TTG) - Cluster 3's average time-to-inform (TTI) periods was 128.3 days (target 152 days; SC7 for 2014 and 2015: 120.1 days), time-to-sign (TTS) was 126.9 days (target 91 days; SC7 for 2014 and 2015: 107.7 days) and time-to-grant (TTG) was 262.2 days (target 243 days; SC7 for 2014 and 2015: 225.9 days) (see Table 8). **TTS and TTG exceed the maximum target by 35.9 and 19.2 days, respectively.** This resulted in 1 937 days of delays to the signature agreement. These targets are higher than the Pillar 2 averages but do not exceed the Horizon Europe average, except for TTS.

Time-based performance indicator linked to payment (TTP) – In terms of the efficiency of the payment process, Cluster 3 performed well. Out of 59 payments, 96.6% were made on time. All of the payments made in 2021 and 2022 (59) were pre-financing with an average of 8.8 days (target: 31 days, Pillar 2 avg.: 19.3 days, SC7 for 2014 and 2015 avg.: 6.5 days) (see Table 9).

1.3.2. Proposal preparation costs and administrative costs of participation

The proposal preparation costs were calculated based on the following survey question: "In your estimation, how many person-days did your organisation spend in preparing your Horizon Europe proposal?" Respondents were asked to choose one of the following options: Less than 5 person-days; 6 to 15 person-days; 16 to 25 person-days; 26 to 35 person-days; 36 to 45 person-days; 46 to 55 person-days; 56 to 65 person-days; More than 65 person-days.

We complement the quantitative evidence on time cost with qualitative information from the survey and Public Consultation (PC) results.

1.3.2.1. Proposal preparation effort for consortium-based projects

The evidence of the effort to prepare a HE proposal was collected by surveying the beneficiaries and unsuccessful applicants. Given that all consortium-based project proposals generally follow the same process, their effort (measured in person-days spent to prepare the proposal) was assessed together. Such an approach allows us to have a maximum possible sample of responses to derive the best estimate of the proposal preparation cost.

Naturally, the lion's share of the proposal preparation effort falls on the coordinating organisation, especially regarding the proposal's administrative aspects. The partner organisations play more of a supportive role in the process. Therefore, this analysis separately presents the costs incurred by the coordinators and partner organisations.

The Table and Figure below present the distribution of survey responses based on the answer option. The median value for the coordinators suggests that, on average, consortium coordinators spend anywhere between 36 to 45 person-days to prepare a Horizon Europe proposal. For partner organisations, such effort is smaller. Partners contribute to coordinators' efforts and, on average, spend between 16 to 25 person-days to prepare a Horizon Europe proposal.

	Coordinator		Partner	
	Count of survey response s	Cumulati ve percenta ge	Count of survey responses	Cumulative percentage
Less than 5 person-days	102	5%	929	12%
6 to 15 person-days	121	12%	2 476	43%
16 to 25 person-days	200	22%	1 936 (median and mode value)	67%
26 to 35 person-days	322	39%	1 205	82%
36 to 45 person-days	310 (median)	55%	714	91%
46 to 55 person-days	203	66%	295	95%
56 to 65 person-days	215	77%	162	97%
More than 65 person-days	443 (mode value)	100%	248	100%
Total number of responses	1 916		7 965	

Table 10. Successful and unsuccessful applicants: Number of person-days spent preparingHorizon Europe proposal

Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "In your estimation, how many person-days did your organisation spend in preparing your Horizon Europe proposal?" The combined number of responses: 9 881.

Figure 14. Share of responses on person-days spent preparing Horizon Europe proposal, as reported by successful and unsuccessful applicants (all consortium-based programme parts in HE)



Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "In your estimation, how many person-days did your organisation spend in preparing your Horizon Europe proposal?" The combined number of responses: 9 881. Median value highlighted.

1.3.2.2. Time effort spent on HE proposal preparation by coordinators

Efforts spent by coordinators differed along a few axes. First, we examine the project's expense level. The funding instruments were categorised into three groups: **High expense level (RIA, IA, PCP and COFUND)**, Medium expense level (CSA, MSCA Cofund/DN, SE) and a separate group for EIC (also called medium expense level)²⁹. The cross-tabulation of survey responses by the project expense level shows that projects funded under RIA, IA, PCP and COFUND actions require more effort than medium-expense level projects. A median respondent spent between 46 and 55 person-days preparing and submitting a high-expense level proposal. A median value for the CSA and MSCA (COFUND/DN/SE) proposals was 36-45 days and even lower for EIC applicants at 26-35 days.

²⁹ The funding instruments were categorised following the example of proposal writing cost analysis in *European Commission,* Directorate-General for Research and Innovation, Interim evaluation of Horizon 2020 – Commission staff working document, Publications Office, 2017, https://data.europa.eu/doi/10.2777/220768 Annex 1, p. 71

Figure 15. Number of person-days spent preparing Horizon Europe proposal, as reported by the coordinators of successful and unsuccessful applications, by project expense level. The number of responses reported³⁰



Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "In your estimation, how many person-days did your organisation spend in preparing your Horizon Europe proposal?" The combined number of responses: 1 916.

The survey results also show that longer projects take more effort to apply for. The Table below illustrates that the median coordinator of a short project (up to 2 years) takes 26 to 35 person-days to prepare the application. Projects planned to take between two and four years take 36-45 days for a median coordinator to apply for. Projects that are four years or longer are estimated to take between 46 and 55 person-days to prepare. In addition, it is worth mentioning that around a third (n=49) of respondent coordinators of projects that lasted four years or longer reported that they spent more than 65 person-days preparing a proposal.

³⁰ Here we refer to EIC Pathfinder and EIC Transitions





Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "In your estimation, how many person-days did your organisation spend in preparing your Horizon Europe proposal?" The combined number of responses: 1 916.

Successful proposals take longer to prepare than unsuccessful proposals. This is especially true for successful proposals that foresee a project length of at least three years or longer. Such an observation potentially hints that the effort coordinators put into preparing the proposal matters and suggests that the proposal selection process is equipped to reward the proposals based on their merit and excellence.

Evidently, **larger consortia require more time from coordinators to prepare proposals**. Further analysis of the comparison between the consortium size and the person-days required to submit a proposal indicated that the effort needed increases by **about ten person-days for every additional 15 partners**. Proposals that included only one partner (i.e., only the coordinator)³¹ required somewhat less time than proposals with larger consortia. This further illustrates that the proposal preparation burden is very much related to the size of the consortium.

³¹ Please note that the HE programme parts to which they applied to are not nonbeneficiary by design





Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "In your estimation, how many person-days did your organisation spend in preparing your Horizon Europe proposal?" The combined number of responses: 1 916.

The consortium size proved to correlate the strongest with the number of days required to prepare the Horizon Europe application. When looking into a combination of aspects discussed above, e.g., project expense level and the size of the consortium or duration of the project and the consortium size, the only significant variation in the effort required to prepare the application was visible at the different consortium sizes in the proposal. Therefore, we conclude that to consider the costs incurred by the proposal coordinators, the breakdown by the size of the consortium should be considered.

Time effort spent by proposal partners

Not all partner organisations are involved in the proposal preparation effort, but those that do, according to our survey results and our survey results' median response, spend between 16 and 25 person-days. Nevertheless, some variation between the types of proposals was observed. Partners in very large consortia also report spending less time than the median for all proposal partners. While the median partner spends between 16 and 25 days, partners involved in proposals with more than 31 participants report spending less (median of 6 and 15 days). Such a pattern suggests that proposal writing does not require the full involvement of all partners.

Figure 18. Successful and unsuccessful applicants' proposal preparation effort by consortium size: The number of person-days spent preparing Horizon Europe proposal, as reported by the consortium partners.



Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "In your estimation, how many person-days did your organisation spend in preparing your Horizon Europe proposal?" The combined number of responses: 7 965.

Finally, an overview Table of all the findings discussed so far is presented below, with the number of responses and percentage of total responses in each category reported.

Table 11. Number of person-days spent preparing Horizon Europe proposal, as reported by the coordinators and partners (successful and unsuccessful applications). The number of responses reported (all consortium-based programme parts in HE)

	Coordi	nator	Partner	
Person-days	Successful (% from total)	Unsuccessfu I (% from total)	Successful (% from total)	Unsuccessful (% from total)
Less than 5 person-days	24 (3%)	78 (6%)	358 (11%)	571 (13%)
6 to 15 person-days	34 (5%)	87 (7%)	991 (29%)	1 485 (33%)
16 to 25 person-days	50 (7%)	150 (12%)	Median response: 847 (25%)	Median response: 1 089 (24%)
26 to 35 person-days	117 (17%)	205 (17%)	572 (17%)	633 (14%)
36 to 45 person-days	115 (16%)	Median response: 195 (16%)	328 (10%)	386 (8%)
46 to 55 person-days	Median response: 90 (13%)	113 (9%)	138 (4%)	157 (3%)
56 to 65 person-days	76 (11%)	139 (11%)	71 (2%)	91 (2%)
More than 65 person-days	197 (28%)	246 (20%)	100 (3%)	148 (3%)
Total number of responses	703 (100%)	1 213 (100%)	3 405 (100%)	4 560 (100)

Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "In your estimation, how many person-days did your organisation spend in preparing your Horizon Europe proposal?" The combined number of responses: 9 881.

To summarise all the findings above, please refer to the Table below. The analysis shows that proposal coordinators take the lion's share of the preparation effort. The time needed to prepare the proposal increases with the size of the consortium. The proposal preparation effort required from the partners does not seem to vary due to the characteristics of the project/proposal.

Table 12.	Summary of	of survey	findings	regarding	costs of	the application

Group of proposals	Median person-days
Consortium-based programme parts: MSCA (DN, SE, Cofund), EIE, EIC (Pathfinder and Transitions)	INFRA, WIDERA, all Pillar 2,
One beneficiary	16 to 25 person-days
Small consortium coordinators (2-14 partners)	36 to 45 person-days
Large consortium coordinators (15-30 partners)	46 to 55 person-days
Very large consortium coordinators (31+ partners)	56 to 65 person-days
Partners in small and large consortiums (2-30 partners), incl. EIC	16 to 25 person-days
Partners in very large consortiums (31+ partners)	6 to 15 person-days
EIC proposal coordinators	26 to 35 person-days

Source: Compiled by the study team.

The survey respondents also tend to agree with the statement that "The application costs (total time and resources needed) are proportionate to the volume of funding requested in the proposal". Such a finding is consistent across the programme parts related to the Resilient Europe evaluation study.

Figure 19. "The application costs (total time and resources needed) are proportionate to the volume of funding requested in the proposal: To what extent do you agree with the following statements about the effort needed to prepare and submit your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July 2023. The combined number of responses: 16 397.

In addition, the survey respondents were asked to compare the effort needed to prepare and submit the proposal between HE and H2020. The results show that there was no significant difference between the two FPs reported by the survey respondents. Suggesting that the simplification efforts introduced in Horizon Europe have a limited impact on reducing the application burden for applicants.

Figure 20. "Proposal preparation and submission in Horizon Europe is simpler than those in Horizon 2020: Based on your overall FP experience, would you agree or disagree with the following statements on the project's lifecycle processes in Horizon Europe, compared to Horizon 2020?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. The combined number of responses: 8 661.

1.3.2.3. Simplification effects of the lump sum model

One of the most prominent simplifications introduced in the HE was the lump sum-based project funding. While it is too early to assess the effect of such simplification on the whole project life cycle (from application to audit), some first insights could already be drawn.

The survey provided some evidence that the proposal preparation effort (measured in person-days) was lower for applicants involved in a lump sum project application and found that **the lump sum proposal preparation process can be shorter by ten or more days**. In addition, we also asked the respondents to reflect on the perceived burden of lump-sum proposal writing. Overall, around half of the respondents suggested that lump sums do not increase the time needed to prepare a proposal. Such a share was lower for Cluster 2 applicants³². It is important to note that the sample size for the Cluster 2 beneficiaries who answered lump sum-related questions is extremely small (8-11 responses depending on a question); hence, Cluster 2-related findings should be taken cautiously.

On the other hand, another half of the respondents claimed that such an arrangement increased the time needed for an application. The open-ended responses from the public consultations conducted by the European Commission earlier this year explained that the workload was shifted from financial reporting during the implementation phase to detailed budget calculations in the proposal phase. This added another layer of complexity and additional workload to the pre-award proposal submission process. On the other hand, the lump-sum model is not designed to reduce the application burden but rather simplify project implementation.

³² So far only cluster 2 applicant were eligible for lump sum funding (as of June 2023)

Figure 21. "Lump-sum increases the time needed for proposal writing compared to a standard proposal: To what extent do you agree with the following statements on lump-sum funding in your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023. The number of responses: 80³³.

The HE beneficiary survey respondents tend to agree that the lump sum scheme facilitates consortium building. One of the respondents from public consultations explained that lump sum funding simplifies the process, enabling researchers to focus more on project execution and outcomes, thereby facilitating improved task distribution. On the other hand, there were claims that such a cost calculation setup leads to more complicated and longer Grant Agreement (GA) negotiations because the GAs need to include the clauses regarding the financial implications of non-completion of Work Packages.





Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023. The number of responses: 5³⁴.

A very clear simplification related to the lump sum funding is related to the development of the project work plan and division into work packages – the absolute majority of our survey respondents (93%) agree with that (see Figure below).

³³ Responses related to the perceptions on the lump-sums were only collected from those beneficiaries that actually received lump sum funding

³⁴ Responses related to the perceptions on the lump-sums were only collected from those beneficiaries that actually received lump sum funding

Figure 23. "Lump-sum simplifies the development of the project work plan and division into work packages: To what extent do you agree with the following statements on lump-sum funding in your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023. The number of responses: 95³⁵.

Lump sums are likely to simplify the reporting at the implementation stage. This finding is consistent with the survey and public consultation responses. Only two survey respondents out of 80 (3%) disagreed with the statement that "Lump-sum simplifies the reporting and limits the risks of errors" (see Figure below). A similar sentiment was among HE beneficiary survey respondents from Cluster 2.

One respondent from the public consultations explained that lump sums simplify the programme by removing the need to report actual costs, meaning easier access to the programme, especially for small organisations and newcomers. In fact, the public consultations showed a lot of support for further applying the lump sum funding mechanism to small-scale projects. Projects funded under the CSA instrument (small consortium) and projects with higher TRL were also mentioned as good candidates to be funded under a lump sum mechanism.

³⁵ Responses related to the perceptions on the lump-sums were only collected from those beneficiaries that actually received lump sum funding

Figure 24. "Lump-sum simplifies the reporting and limits the risks of errors: To what extent do you agree with the following statements on lump-sum funding in your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July. The number of responses: 80³⁶.

On the other hand, some public consultation responses question the usefulness of a simplified reporting process as some consortia still have to collect all financial information due to internal organisational regulations or to be able to prepare for an audit. In addition, given that project partners have to report the proof of the project results, the financial simplification is eliminated by an additional effort to collect the lump sums.

Half (50%) of beneficiary survey respondents believe that simplified funding comes with some financial risks (see Figure below). The perceived risks may arise because the lump-sum scheme is rather new to the Framework programmes, and project partners do not have much experience with it. This can be supported by the fact that the study team could not find any correlation between perceived risk and the characteristics of the respondents. There was no difference in the trend of responses from SMEs vs non-SME participants, and also no difference between newcomers and repeated FP participants.

Respondents to a public consultation mentioned a few risks related to the lump-sum model. However, it is important to keep in mind that these are opinions of very few organisations that may or may not be recipients of the lump-sum grants. The risks mentioned are high dependency on consortium partners for the implementation of work packages and eligibility of costs. To avoid such a risk, partners might start constructing their Work Packages to include fewer and smaller tasks, which can lead to less risky and less collaborative projects. One public consultation respondent noted that linking funding to delivered activities results in the artificial construction of work packages solely to facilitate funding flow rather than aligning with the logical progression of the research itself.

Another risk repeatedly mentioned in the EC's public consultation was the adequacy of the lump sum dashboard. There are concerns that the lump sum amounts presented there are too low and do not account for inflation. Nevertheless, since then, the EC has already adjusted the rates. Finally, public consultation respondents mention the need for more guidance and clarity. For example, the Model Grant Agreement (MGA) is not well-adjusted to the lump sum financing model. Hence, risks concerning financial liability, reporting, and audits are there. According to the public consultation, more guidance on these aspects would be welcome.

³⁶ Responses related to the perceptions on the lump-sums were only collected from those beneficiaries that actually received lump sum funding

Figure 25. "Lump-sum increases the financial risks for project participants: To what extent do you agree with the following statements on lump-sum funding in your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023. The number of responses: 81³⁷.

Overall, it is too early to make any definitive conclusions; however, HE beneficiary survey results show that the lump sum funding mechanism is generally perceived positively. Nevertheless, it is important to note that it is not without flaws. As discussed above, EC's public consultation respondents suggested a few areas for further improvement, the most important of which seem to be more guidance and fair rates for calculating the lump sums.

1.3.2.4. Administrative costs of participation

The beneficiaries' survey suggests that a median consortium-run project allocates around **6% - 10% of the project budget to implement administrative tasks** (such as project reporting, project financial management, and similar). The reported share differs between coordinators and partners. Coordinators' median value falls between 11% - 15%; nevertheless, mode value (the most frequently chosen value) is at 6% - 10%, which gives us ground to assume the 6% - 10% for a total population of projects. The responses are given visually in Figure 26Error! Reference source not found., followed by a numerical breakdown of responses in the Table below. Both median and mode survey responses suggest the same finding. In addition, no variation was observed in terms of different sizes of project teams, different lengths of the projects, or programme parts.

³⁷ Responses related to the perceptions on the lump-sums were only collected from those beneficiaries that actually received lump sum funding



Figure 26. Distribution of responses to the survey question asking what percentage of the budget was spent on administrative tasks

Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023. Question: "In your estimation, what is the percentage share of your Horizon Europe project budget that is spent on administrative tasks (e.g., project reporting, project financial management, and similar)". Number of responses: 4 380. Median value highlighted.

Table 13.	A share of t	he Horizon	Europe project	t budget s	spent on	administrative	tasks, as
reported l	by consortiu	m projects'	beneficiaries.	The numb	per of res	ponses reporte	d.

	Coordinators	Partners	Total of beneficiaries
Less than 1%	2	49	51
1-3%	25	243	268
4-5%	107	633	740
6-10%	181	1 044	1 225
11-15%	175	745	920
16-20%	114	599	713
More than 20%	88	375	463
Total number of responses	692	3 688	4 380

Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023. Question: "In your estimation, what is the percentage share of your Horizon Europe project budget that is spent on administrative tasks (e.g., project reporting, project financial management, and similar)". Number of responses: 4 380.

Survey respondents consider these costs mostly to be proportionate to the project funding. For example, half of the respondents agree that the burden of the administrative and legal requirements for granting procedures was proportionate. However, there are some caveats to this. Around a fifth of the respondents (and that varies by the programme part) disagree with this statement, suggesting that this is one of the areas where the improvements could be welcomed. In addition, as discussed in the drivers and barriers section under

Effectiveness, the burden of the reporting requirements was indicated as one of the barriers to beneficiaries as around a fifth of our survey respondents disagreed that the reporting requirements required a reasonable effort and cost.

Figure 27. "The burden of the administrative and legal requirements for granting procedures were proportional; Would you agree or disagree with the following statements about the administrative and management processes in your Horizon Europe project:"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023. Number of responses: 5 945.

In the beneficiary survey, we also asked respondents to compare the administrative effort now and during their H2020 projects (if they had any). Respondents were asked to compare the grant preparation, project management, implementation, and financial management efforts. When comparing the share of respondents who agree that grant preparation effort in HE is simpler than H2020 with the share of respondents who disagree with that, we see that a more positive sentiment dominates. Nevertheless, it is important to note that those who answered this question participated in EU framework programmes for at least a second time; hence, at least a part of the positive perception comes from their already having experience in Horizon projects. Similar trends were observed regarding project management and implementation as well as financial management efforts. Figure 28. "Grant preparation in Horizon Europe is simpler than in Horizon 2020: Based on your overall FP experience, would you agree or disagree with the following statements on the project's lifecycle processes in Horizon Europe, compared to Horizon 2020?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023. Number of responses: 2 806.

Figure 29. "Project management and implementation (amendments, reporting etc.) is simpler in Horizon Europe than in H2020: Based on your overall FP experience, would you agree or disagree with the following statements on the project's lifecycle processes in Horizon Europe, compared to Horizon 2020?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023. Number of responses: 2 576

Figure 30. "Financial management (financial rules and reporting) is simpler in Horizon Europe than in Horizon 2020: Based on your overall FP experience, would you agree or disagree with the following statements on the project's lifecycle processes in Horizon Europe, compared to Horizon 2020?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023. Number of responses: 2 582.

1.3.3. Costs of applicants: Application support received from internal and external sources and costs of consultancies.

The following analysis provides evidence on different sources of support Horizon Europe applicants accessed when preparing their applications. It also reports on the correlation between proposal success and support received from National Contact Points and consultancies, on comparative time-to-grant values of respondents that used consultancies, and on consultancy fees reported by applicants.

The main source of evidence is the survey of cluster 1, 2, and 3 beneficiaries and unsuccessful applicants.

The information from the survey leads to the following Indicators:

- Application support received from a dedicated internal department in its own organisation, National Contact Points, consultancy internal or external to the consortium (support may extend to proposal preparation, project implementation, dissemination);
- Comparison of success rates between respondents drawing on support from National Contact Points and consultancies, compared to complementing non-user groups;
- Comparison of proposal quality between respondents drawing on support from consultancies, compared to complementing non-user group;
- Comparison of proposal quality between respondents drawing on support from consultancies, compared to complementing non-user group;
- Monetary values of fees paid to external consultancies, reported by respondents.

The responses from the Horizon Europe Beneficiaries and Unsuccessful Applicant Surveys were combined with Commission eCORDA data on the survey respondents).

Applicants' use of support for proposal preparation

The following shares of responding Horizon Europe applicants received support to prepare their proposals (possibly also with project implementation and dissemination) from a range of sources:

- **50.5%** (3688) indicated they received **help from a dedicated department in their** organisation;
- 29.2% (2141) indicated that they had not received any support;
- **19.1%** (1397) of responding **applicants** received support from a **National Contact Point**, and
- **17.2%** (1252) drew upon the support of a **consultancy firm/expert** (inside or outside the consortium.

Each of the three analysed Clusters had its own profile of seeking help with applications:

- 36.5% of Cluster 1 respondents received support from a dedicated department. This is a lower share than the average under Pillar 2 (37.9%) and Horizon Europe (50.5%). 29.7% received no support (Pillar 2: 28.7%), and 23.3% used the help offered by National Contact Points (Pillar 2: 25.1%). It is noteworthy is that Cluster 1 features a comparatively high share of respondents that used external consultants (28.3%), slightly above the average of Pillar 2 (24.2%) and well above the average of Horizon Europe (19.1%).
- 2. 42.5% of Cluster 2 respondents received application help from an internal department in their organisation. This is a higher share than the average under Pillar 2 (37.9%) but still lower than the Horizon Europe average (50.5%). 27.4% received no support (Pillar 2: 28.7%), and equally 27.4% used the help offered by National Contact Points (Pillar 2: 25.1%). A comparatively low share (19.6%) of Cluster 2 respondents, relative to 24.2% under Pillar 2 (received help from external consultants; however, this is still above that of Horizon Europe respondents (17.2%).
- 3. Cluster 3 stands out, as a comparatively high share of respondents (45.9%) did not use any sources of support to prepare their application. This is higher than under Pillar 2 (28.7%) and Horizon Europe overall (29.3%). A possible explanation for this could lie in the sensitivity of the data contained in applications of this cluster 31.2% of Cluster 3 respondents reported they received application help from a dedicated department in their organisation, lower than under Pillar 2 (37.9%) and Horizon Europe (50.5%). A comparatively very low share (13.1%) of Cluster 3 respondents indicated they used an external consultancy to prepare their applications, presumably again due to restrictions to share sensitive information on the proposed projects. This share is well below the 24.2% under Pillar 2, and even lower than the low share under Horizon Europe overall (17.2%). Taken together, a picture emerges of a comparatively self-contained proposal writing process, reflecting the sensitivity of the subject areas. These results are, however, based on the responses of only 85 Cluster 3 applicants, which means they could substantially change if the survey was repeated.



Figure 31. "Did you receive any support for your Horizon Europe project application/preparation?"

Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023.

Overlap between applicants' use of consultancies and National Contact Points

We looked at the overlap between survey respondents who used National Contact Points and those who used or acted as consultants. The survey suggests that, overall, **about a third** (27%) of all responding Horizon Europe applicants who used consultancies or were consultancies themselves <u>also</u> made use of the help offered by NCPs, compared to 19% of all responding Horizon Europe applicants.

Similarly, 26% of NCP users among the responding Horizon Europe applicants <u>also</u> used external consultancies or were consultancies, compared to 17.2% of all Horizon Europe applicants. This suggests that there is some overlap between the users of NCPs and consultancy services. Nevertheless, the share of those who use both sources of support is not significantly larger than the average rates in the total respondent population. This implies that consultancies and users of consultancies are likely not overrepresented among NCP users compared to the overall Horizon Europe applicant.

When looking at the pillar level, Pillars 1 and 2 follow a similar pattern as responding Horizon Europe applicants overall. Pillar 3, on the other hand, stands out, with a high share of 45% of NCP users (21% of all applicants) also using consultancies (or are consultancies themselves). This could be influenced by the fact that Pillar 3, with 51%, is the pillar with the highest share of applicants that involved external consultancies to start with.

HE / Pillar	Total number of respondents (successful and unsuccessful applicants)	Share of total respondents that use external consultancies (or are consultancies themselves) ³⁸	Share of total respondents that use NCPs	Overlap: Share of total respondents that use <u>both</u> external consultancies (or are consultancies themselves) <u>and</u> NCPs	Share of users of external consultancies (or that are consultancies) that also use NCPs	Share of users of NCPs that also use external consultancies (or are consultancies themselves)
HE overall	7 300	19%	19%	5%	27%	26%
Pillar 1	5 059	10%	17%	3%	32%	20%
Pillar 2	1 119	32%	25%	8%	36%	33%
Pillar 3	901	47%	21%	10%	20%	45%
WIDERA	221	24%	29%	7%	28%	23%

Table 14. Overlap between applicants' use of consultancies and National Contact Points

Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "Did you receive any support for your Horizon Europe project application/preparation?" The combined number of responses: 7 300.

Correlation between applicants' use of support for application and success of application

Overall, 27.4% of Horizon Europe's responding applicants successfully secured a grant (see Table 16,17). Among respondents who used **National Contact Points**, success was more prevalent (34.5%; Table 17). The same is true, and even to a slightly greater extent, for respondents who drew on the help of external **consultancies** (36.2%, **Error! Reference s ource not found.**).

Inversely, comparing successful applicants who reported using consultancies (26.5%; 198 of 746 responses) with unsuccessful applicants who used consultancies (20.7%; 290 of 1398 responses) reveals that both percentages are of similar orders of magnitude, with the former somewhat higher than the latter. (Table 15)

It is important to keep in mind that the above **relationships only represent correlations**. While eight survey responses to open an question suggest that at least some applicants believe that hiring external **consultancies** increases their chances of success³⁹, the study did not attempt to isolate the effect of receiving support (e.g. from consultancies) on the likelihood of success. Several factors determine success (for instance, the availability of financial resources overall). Some of them could have made it more likely that the applicant received support from a specific source (e.g. consultancy) and simultaneously affected the proposal's quality (e.g. financial resources afford applicants more time to come up with a quality proposal).

³⁸ The figures in this column combine responses to the question "Did you receive any support for your Horizon Europe project application/preparation?" answer option "Yes, our organisation received support from a consultancy firm/expert (inside and outside the consortium) as well as the respondents who identified their organisation type as "External expert/consultancy firm"

^{39 8} free responses mentioned external consultancies

	Total number of respondents	Number of respondents who used external consultancies	Share of respondents who used external consultancies	Median fee paid to external consultancies (EUR)
Unsuccessful applicants	1 398	290	20.7%	6 500
Succesful applicants (beneficiaries)	746	198	26.5%	10 000

Table 15. Respondents use of consultancies and associated median cost

Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "Did you receive any support for your Horizon Europe project application/preparation?" Answer: "Yes, our organisation received support from a consultancy firm/expert (inside or outside the consortium)." And question: "What was the total amount that your organisation paid to the consultancy firm/expert for the above services in project application/proposal writing?". The combined number of responses received to both of these questions: 2 144.

When looking at the share of successful respondents among users of consultancies by cluster (Table 16), **Cluster 1's share (40.3%)** is similar to the average of Pillar 2 (43%), with a **pronounced 22 percentage point difference to successful respondents not using consultancies (18.3%).** In Cluster 2, this disparity was smaller by around 10 percentage points, where 30% indicated a success rate with an expert instead of a 20% without one. Cluster 3 shows a similar, approximate 10 percentage point difference *in* the share of successful respondents among users and non-users of consultancies.

Table 16. Share of successful respondents –support from consultancy/expert (inside or outside the consortium)

	Share of successful respondents among users of external consultancies	Share of successful respondents among those who did not use external consultancies	Share of successful respondents: All respondents
Cluster 1	40.3%	18.3%	29.7%
Cluster 2	30.2%	20.6%	26.5%
Cluster 3	37.5%	27.9%	32.8%
Pillar 2	43.5%	28.5%	39.1%
Horizon Europe overall	36.2%	22.2%	27.4%

Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "Did you receive any support for your Horizon Europe project application/preparation?" Answer: "Yes, our organisation received support from a consultancy firm/expert (inside or outside the consortium)." The number of responses received to this question: 2 637.

	Share of successful respondents among users of NCP	Share of successful respondents among those who did not use NCPs	Share of successful respondents: All respondents
Horizon Europe overall	34.5%	20.8%	27.4%
Pillar 1	30.4%	19.8%	24.9%
Pillar 2	43.4%	28.2%	39.1%
Pillar 3	36.5%	17.3%	25.1%
WIDERA	45.3%	19.9%	33.0%

Table 17. Share of successful respondents –National Contact Point support for application

Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "Did you receive any support for your Horizon Europe project application/preparation?" Answer: "Yes, we received support from the National Contact Point (NCP)". The number of responses received to this question: 7 300.

Correlation between applicants' use of support for applications and the quality of the project proposal

By combining CORDA data with the survey responses, we calculated the percentage of survey respondents who used consultancies when preparing a proposal that was later evaluated to have a high-quality score⁴⁰. Based on the number of respondents who answered the question, "Did you receive any support for your Horizon Europe project application/preparation?" we found that the overwhelming majority (74-80%) quality (over the threshold) proposals were written without the involvement of external experts. Overall, quality proposals were more frequently prepared with the involvement of consultancies compared to proposals below the quality threshold, but not by a wide margin. Across Horizon Europe respondents, 27% of quality proposals and 25% of proposals below the quality threshold were written with the help of consultancies.

Among the clusters analysed, according to the survey respondents, Cluster 1 had the highest share of proposals above the threshold that used the help of consultancies $(34.7\% \text{ as compared to } 26\% \text{ in total HE})^{41}$.

The share of proposals above the threshold that used consultancies in Cluster 2 was 22%, according to the survey respondents, and the share of proposals below the threshold was 14.5%.

In Cluster 3, respondents suggest that only 10.5% of proposals evaluated above the threshold relied on the help of consultancies, demonstrating the least reliance on such support. This is significantly lower than the Pilar 2, and overall HE averages are consistent with the Cluster's overall profile regarding the use of application support reported above.

⁴⁰ i.e. proposals, whose score exceeded the quality threshold and that may or may not have been funded afterwards.

⁴¹ Cluster 1 also had a relatively high prevalence of success among quality proposals, standing at 53.7%, according to the survey.

	Number of HQ proposals	Share of HQ proposals that used external consultancies	Share of non- HQ proposals that used external consultancies	Success rate of HQ proposals
Cluster 1	121	34.7%	20.4%	53.7%
Cluster 2	150	22.0%	14.5%	38.7%
Cluster 3	38	10.5%	17.4%	52.6%
Pillar 2	773	26.0%	20.2%	56.5%
HE overall	1570	27.2%	25.2%	51.5%

Table 18. Survey respondents' external consultancies use among high-quality proposals

Source: CORDA data (June 2023 data release) and Survey of Horizon Europe beneficiaries, conducted in May-July 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July 2023. Question: "Did you receive any support for your Horizon Europe project application/preparation?" Answer: "Yes, our organisation received support from a consultancy firm/expert (inside or outside the consortium)." The combined number of responses: 2 327.

Correlation between successful applicants' use of support for applications and the time-togrant period

We calculated the average Time-To-Grant period for the sample of successful survey respondents who answered, "Did you receive any support for your Horizon Europe project application/preparation?" We found that the average TTG period in HE was longer among those who used consultancies than those who did not. However, in Pillar 2 specifically, TTGs did not differ significantly. While no causal link has been identified, the use of consultancies may increase the coordination costs: The interaction between consortia, the Executive Agency, and the external experts of the supporting consultancy may have prolonged the process as more stakeholders could consult with and communicate with.

Looking specifically at the three Clusters, Clusters 1 and 2 had slightly longer TTG periods, and Cluster 3 had shorter TTGs for those successful proposals that did not draw on the support of consultancies.

Cluster/ Pillar/ HE	Average TTG [days]	Average TTG with external consultancies [days]	Average TTG without experts [days]
Cluster 1	228.1	226.7	229.0
Cluster 2	237.8	237.0	238.0
Cluster 3	257.5	260.7	256.8
Pillar 2	234.8	234.0	235.1
HE overall	232.0	238.3	228.9

Table 19. Average Time-To-Grant periods of proposals prepared with and without external consultancies

Source: CORDA data and Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "Did you receive any support for your Horizon Europe project application/preparation?" Answer: "Yes, our organisation received support from a consultancy firm/expert (inside or outside the consortium)." The combined number of responses: 2 637.

Applicant costs: time cost and fees linked to the use of external consultancies

We also examined the time that those who use or are consultants need to prepare a proposal. We found that those who used consultancies required more time to prepare a proposal

than the general population did. The median length of time needed for a coordinator who used a consultant was 46-55 person-days, compared with 36-45 person-days among the entire survey population. Among those coordinators who themselves were consultants, the median length of time needed was the same as in the general population: 36-45 person-days for coordinators. The consortia partners, who were themselves consultants, were the only group to indicate less time spent on proposals: 6-15 person-days as opposed to 16-25 needed for the general population. More information on the costs of preparing a Horizon Europe proposal can be found in 1.3.2.1 Proposal preparation effort for consortium-based projects.

Successful applicants reported on average higher consultancy fees (holds both for median and mean) for the support service. Survey respondents mentioned that consultancies may charge an additional fee on the condition that the proposal was successful, which could contribute to the difference in average fee values. As shown in Table 15, the median amount paid by unsuccessful applicants was around EUR 6 500, and the median paid by successful applicants was around EUR 10 000.

External consultancy fee estimation

To estimate the total fees paid to external consultancies so far under Horizon Europe, we used survey responses (matched to CORDA information) on the **rate of consultancy use split by funding instrument** and the **median costs reported** for **three applicant groups: consortia, mono-beneficiary, and EIC Accelerator**. We based the calculation of the expected value of fees for the whole of the CORDA population on observed patterns in the data, in particular two relationships.

- 1. The share of proposals involving an external consultancy differs between funding instruments.
- 2. The value of the fee paid to the consultancy differs between applicant types, namely between consortium, single applicant, or EIC Accelerator applicant.

The above relationships are derived from a close and sustained observation of the data but ultimately enter the analysis as assumptions. The significance of the associations was not statistically tested, which would have increased the robustness of the analysis. The likelihood of the choice of involving an external consultancy depending on the funding instrument was not estimated using a confidence interval formula. To keep the exercise manageable and to remain proportionate, it is assumed that the above are the significant relationships and heterogeneities in the population.

A step-by-step methodology follows.

Step 1 Shares of consultancy involvement by funding instrument - We extrapolated the survey results on the shares of consultancy involvement to the overall CORDA proposal population split by targeted funding instruments. Based on the assumption of relationship number 1 and the survey data, we calculated for each funding instrument a separate confidence interval that provides a **range of upper and lower bounds for the percentage share of proposals involving consultancies**.

The confidence intervals⁴² are given by the formula:

$$CI = p \pm 1.96^* \sqrt{(1/n)^* p^* (1-p)^* (N-n/N-1)}$$

where

p = share of applicants who used external consultancies for a given funding instrument

n = survey sample size

N = population size, given by the number of entities in CORDA data.

The calculated intervals for each funding instrument are reported in the Table below. **We found that, on average, between 21% and 25% of applicants are hiring external consultancies for the application process**⁴³. Those applying for Innovation Actions funding were most likely to use external consultancies, with a range of shares between 24% and 36%. Most Cluster 1 and Cluster 2 applications were submitted to RIA (74.6% and 94.2%, respectively). It appears that CSA applicants were the least likely to use external consultancies (likelihood between 17%-25%). Lastly, most of the Cluster 3 applications (53%) were submitted for Innovation Actions (IAs) funding instruments. We estimated a rate of consultancy involvement ranging between 24% and 36%.

In Horizon 2020 evaluation (phase 1 of this study), the study team used the European Court of Auditors survey (ECA)⁴⁴ data to look at the share of proposals prepared by external consultancies. In comparison to Horizon 2020, the Horizon Europe estimates do not differ greatly. This suggests that, on average, both RIA and IA proposals have a consistently higher rate of involvement of consultancies in the application process than actions funded by CSAs.

⁴² Confidence interval in this case shows that, assuming the pupulation is homogenious, it is 95% probablity that the true share of applicants using consultancies within the calculated interval.

⁴³ The proportion of survey respondents who used consultancy services was used as an estimate of the proportion in the entire population. To express the uncertainty, we calculated the confidence interval for the population proportion (95%). Given, that the sample of projects is sufficiently large (nearly 50 thousand eligble proposals in the whole HE) we used normal approximation (based on z-value). Hence, assuming that the population is homogenous, we can concider the provided intervals as likelyhood estimations

⁴⁴ Special Report: The majority of simplification measures brought into Horizon 2020 have made life easier for beneficiaries, but opportunities to improve still exist. European Court of Auditors, 2018

Table 20. Estimated rates of consultancy use by funding instrument, expressed as a range (based on 95% confidence interval) with lower and upper bound

Funding instrument	Range of the share of proposals involving consultancies (95% confidence interval)
CSA	17% - 25%
IA	24% - 36%
RIA	20% - 26%
Other (Cofund, PCP, FPA, and other) $^{\rm 45}$	21% - 25%
Overall	21% - 25%

Source: Extrapolation from Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "Did you receive any support for your Horizon Europe project application/preparation?" Answer: "Yes, our organisation received support from a consultancy firm/expert (inside or outside the consortium)." The combined number of responses: 6 807.

Step 2 Median value of consultancy fees by type of applicants - The median value of fees reported by 658⁴⁶ survey respondents to the question, "What was the total amount that your organisation paid to the consultancy firm/expert for the above services in project application/proposal writing?", was EUR 7 500 for proposals by consortia and EUR 2 000 for single beneficiaries and EUR 12 000 for EIC Accelerator.

Step 3 Total consultancy fees paid for proposals submitted under Horizon Europe until June 2023. To estimate the total consultancy fees paid within each programme part, we multiplied, for each proposal ("proposal x"), the proportion of proposals involving consultancies of its funding instrument (from step 1) with the median fee value of its applicant type (step 2). This was then summed up in terms of all the proposals that have been submitted. A separate sum was calculated using the upper and lower bound value of the ranges (95% Confidence Interval) from step 1 to generate a range of the total fees paid.

For example, the formula to calculate the upper estimate of fees paid to external consultancies across all of Cluster 1 would be:

[E] = Sum (Upper bound value of the share of proposals involving consultancies corresponding to proposal x's funding instrument * median fee corresponding to proposal x's applicant type)

for all proposals submitted under Cluster 1

We estimate that applicants have spent between EUR 39 and 55 million on consultancy fees across HE until June 2023. In terms of order of magnitude, this is equivalent to around 0.2% of the total HE budget⁴⁷.

⁴⁵ The category "Other" includes Cofund, PCP, FPA, and all other instruments not listed. Only one valid response from this group was given in the survey, therefore the estimates are an average of all instruments

⁴⁶ Invalid responses were not included.

⁴⁷ According to the DG RTD website, the total HE budget is EUR 95.5 billion, refer here for more information: https://research-andinnovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en. Given that the

In all analysed clusters, the estimated consultancy fees were less than 1% of the total EC contribution. Cluster 1 had the highest total estimated fees paid to external consultancies within Pillar 2 – estimated between 2.9 million and 3.8 EUR million. Considering that it also had a relatively large number of proposals, these costs only correspond to 0.1 - 0.2% of the EC contribution for Cluster 1. Cluster 2 had lower estimated fees paid to the external consultancies, with the total ranging from 1.7 to 2.2 EUR million. This corresponds to between 0.4 and 0.5% of the EC contribution for the Cluster. Cluster 3 has the lowest estimates for fees used for external consultancies, ranging from 1.1 EUR million to 1.5 EUR million, reflecting its rarer use of consultancies.

Programme part	Lower estimate of total external consultancy costs (EUR mil)	Upper estimate of total external consultancy costs (EUR mil)	As a % of EC contribution (lower)	As a % of EC contribution (upper)	Number of proposals ⁴⁸
Cluster 1	2.9	3.8	0.12%	0.16%	1930
Cluster 2	1.7	2.2	0.38%	0.50%	1120
Cluster 3	1.1	1.5	0.25%	0.36%	650
HE overall	39.4	55.1	0.16%	0.22%	53 445

Table 21. Summary of total consultancy fee estimates for Cluster 1, 2 and 3

Source: CORDA (June 2023 data release) and survey data extrapolations by the study team. June 2023 data release.

Survey responses to open questions shed light on the nuances of hiring external consultancies. **Some respondents noted that the external consultancies only reviewed and improved proposals rather than writing them**. The consultancy fees were, in some cases, paid via a regional grant or by the national ministry (5 respondents mentioned this), and costs were, in some cases, split between the consortia partners. As noted earlier, many respondents stated that they paid a flat fee upfront with an agreement that another fee would be paid upon the condition of a successful proposal. This additional fee ranged from 3 to 7% of the project budget to a set fee of EUR 2 000 - 5 000⁴⁹.

1.4. Effectiveness

1.4.1. Key barriers and drivers experienced by the applicants

The following section provides qualitative evidence on the efficiency of the application selection, project implementation processes, and the programme's attractiveness. The emphasis is on the perceptions of the applicants and beneficiaries.

application/preparation?" Answer: "Yes, our organisation received support from a consultancy firm/expert (inside or outside the consortium)." And question: "What was the total amount that your organisation paid to the consultancy firm/expert for the above services in project application/proposal writing?". In total we received 50 answers specifying information about the success fees as well as clarifying comments on the role and payment to the consultancies

estimated costs and the overall figures of HE budget are recent (HE was launched in 2021 and the estimations consider 2021, 2022 and 2023 (until June), the figures in the analysis were not adjusted for inflation

⁴⁸ As of June 2023

⁴⁹ Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023 and Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023. Question: "Did you receive any support for your Horizon Europe project

The main source of evidence is the **Survey of Horizon Europe beneficiaries, conducted in May-July, 2023, which shows that** of Clusters 1, 2, and 3 with the following questions.

- Survey question Nr 5: "To what extent are you satisfied with the following aspects related to your Horizon Europe project application process? (ease and clarity, transparency, feasibility, level of feedback, adequacy and feasibility of application process)." Response options: To a very large extent; To a large extent; To a moderate extent; To a small extent; Not at all; Do not know/not applicable⁵⁰.

- Survey question Nr 7: "Would you agree or disagree with the following statements about the administrative and management processes in your Horizon Europe project?" Response options: Strongly Agree; Rather Agree; Neither agree nor disagree; Rather disagree; Strongly Disagree; Do not know/not applicable.

Additionally, the analysis of EFF3 is informed by the following question from the **Survey of Horizon Europe unsuccessful applicants conducted on May-July 2023**.

- Survey question Nr 6; "To what extent do you agree with the following statements about the effort needed to prepare and submit your Horizon Europe proposal?" Response options: To a very large extent; To a large extent; To a moderate extent; To a small extent; Not at all; Do not know/not applicable.

Additional information is also be used from desk research, Public Consultations (PCs) and two case studies, "Case Study 9: Well-being and Inequalities" and "Case Study 8: CCISs for Innovation and Competitiveness".

Cluster 1

In Cluster 1, the feedback from applicants and beneficiaries was overall positive. While the general sentiment is encouraging, we examined each response in depth to discern both the primary drivers aiding success in the Horizon Europe application process and any potential barriers. Key drivers toward progress include easy access to funding opportunities, a transparent application process, timely feedback, and appreciable flexibility from the EC. On a more detailed note, while the overarching feedback is positive, 64 beneficiaries have also pointed out areas to fine-tune. Beneficiaries mention a relatively high application burden, insufficient guidance for unsuccessful applicants, and difficulties with the online platform. This feedback highlights areas of strength and potential improvement in the Horizon Europe framework.

Key Drivers of Application Selection Process: Cluster 1

In Cluster 1, searching for funding opportunities and consortium partners was straightforward. Specifically, a survey of Horizon Europe beneficiaries conducted in May-July 2023 (short: HE beneficiary survey) shows that 98.6% of beneficiaries agreed, to varying extents, that it was easy to identify funding opportunities. Finding relevant partners was also a straightforward task, as more than 97% of respondents, to varying degrees, agreed with this statementBreaking it down by beneficiary type, there was not much difference between the opinions of coordinators and partners, agreeing that the processes were relatively easy.

Compared to Horizon 2020, the ease of finding information did not change significantly, indicating that both the ability to identify relevant funding opportunities across the various

⁵⁰ All the response options with a response 'Do not know/not applicable" have been excluded from the calculations

parts of the Horizon Europe programme and identifying suitable consortium partners have remained consistent and manageable throughout the transition.





Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023.

When it comes to the clarity of the application process, similar to Horizon 2020, most beneficiaries found it reasonably straightforward to comprehend. 99.8% of beneficiaries are satisfied with the "Clarity of the aims and objectives of the calls." Similarly, over 99% of beneficiaries are satisfied with the "Clarity of "General Conditions" and eligibility and funding rules provided in the Funding & Tenders Portal.".

When looking at the overall transparency of the evaluation process, Cluster 1 also performs relatively well and is in line with Horizon 2020. The overall satisfaction with "The transparency of the evaluation process" reached 97.6%. While both partners and coordinators may share similar views on general transparency, partners are twice as likely to be satisfied to a very large extent with the transparency of the evaluation process.

Figure 33. (CL 1 beneficiaries) "To what extent are you satisfied with the following aspects related to your Horizon Europe project application process?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023.

Most beneficiaries also were satisfied with "The level of detail of the feedback provided in the evaluation report". For example, four responses to the EC's public consultation (April 2023) suggested that feedback could be more detailed and tailored to specific topics, avoiding generalisations.

When looking at the extent of satisfaction with the "Timelines of funding decisions," the overwhelming majority (98.4%) agreed that they were rather satisfactory. In fact, 21.5% of the respondents expressed high satisfaction with the funding timelines, which marked this aspect of the application selection process as the one receiving the most positive responses. This is also evident from the Time to Inform (TTI) indicator, which fell well within the legally prescribed timeframe.

When looking at the administrative and management processes, most beneficiaries agree (18.2% strongly agree, 46.5% rather agree) that "The EC is sufficiently flexible with respect to changes in the project consortium." Over 15% strongly agreed, and 40.4% rather agreed that "EC is sufficiently flexible in adapting to the project objectives because of changed circumstances." Similarly, 64.7% of the respondents agreed (18.2% strongly agreed, 46.4% rather agreed) that "EC is sufficiently flexible with respect to changes in the project consortium," demonstrating the highest satisfaction rate among the questions inquired. These responses are similar between coordinators and partners.

The level of satisfaction was also relatively high among unsuccessful applicants. From the *Survey of Horizon Europe unsuccessful applicants conducted in May-July* 2023 (short HE unsuccessful applicant survey), 91.1% agreed to the extent that "The overall effort to prepare a Horizon Europe proposal was acceptable". Similarly, 94.4% also agreed that the "Application costs (total time and resources needed) are proportionate to the volume of funding requested in the proposal". These sentiments are similar to those echoed among the Horizon 2020 unsuccessful applicants.

Key Barriers: Cluster 1

An important aspect of beneficiary satisfaction is the proportionality of the burden of administrative and legal requirements for the granting procedure and project reporting requirements. While there is general satisfaction among the beneficiaries, a portion thought that the administrative burden of the application process was high. Looking at the HE beneficiaries survey, in Cluster 1, 25.6% rather disagreed or strongly disagreed that "The burden of the administrative and legal requirements for granting procedures were proportionate". Specifically, Higher and Secondary Education Institutions disagreed (30.1%) with the statement "The burden of the administrative and legal requirements for granting procedures was proportionate" to the largest extent compared to other types of participants. This might be attributed to the substantial proportion of newcomers in Cluster 1 in contrast to Clusters 2 and 3 (see Implementation State of Play). For instance, as underscored by four Public Consultations and corroborated by the corresponding case studies⁵¹, newcomers and SMEs found the process more intricate and demanding.

⁵¹ Case study 9 "Well-being and Inequalities" and Case study 8 "CCISs for Innovation and competitiveness".

Figure 34. (Cluster 1) Would you agree or disagree with the following statements about the administrative and management processes in your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023.

Another difficulty faced by some beneficiaries was the complexity of documents, such as guidelines and rules to calculate personnel costs and the difficulties in managing the increased workload to meet project reporting requirements. Even though the majority still expressed an overall agreement, some 18.5% of respondents to the HE beneficiary survey disagreed with the following statement: "Rules for calculation of personal costs (esp. daily rate) are adequate and clear". Additionally, 18.8% disagreed (56% expressing agreement) that the "Project reporting requirements require reasonable effort and costs". Here, too, most of the dissatisfaction was among the higher education institutions. A possible explanation may lie in the increased number of policy priorities and the new requirements, including the Gender Equality Plan (GEP), which have been incorporated into the application process. Eight responses to OPCs expressed that these additional requirements have increased the complexity and effort required to submit and follow through with the application. Three of them cited that they felt the need to seek an external expert to finish all the appropriate parts of the application. Therefore, while most beneficiaries found the administrative processes to be clear and proportionate in burden, a significant fraction expressed difficulties and concerns.

Figure 35. (Cluster 1) "Would you agree or disagree with the following statements about the administrative and management processes in your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023.

When looking at "the time the process takes up to the signature of the grant agreement", 17.9% of the beneficiaries strongly disagreed or rather disagreed that they were adequate. The time-to-sign (TTS) indicator calculated by the study team is also somewhat in line with the opinion expressed here. The average TTS of 122.9 days exceeded the target maximum of 91 days by 33 days (see Table 8), which is also significantly longer than the Horizon 2020 Societal Challenge 1 (97.4%). This discrepancy highlights an area for potential optimisation in the future to meet the set targets more consistently and improve satisfaction levels among beneficiaries.

While the majority of beneficiaries found the administrative and management processes satisfactory, the guidance and the adequacy of it could be improved. Almost all of the stakeholders from EC's public consultation expressed concerns regarding the lack of a final version of the Annotated Grant Agreement, which was last updated on 1 April 2023 and is still in draft form. The lack of finalised guidelines caused difficulties in navigating the already complex grant preparation process, posing significant barriers for the applicants. As a result, information was also leaked through informal channels, fuelling a sense of inequality. This may also be seen and reflected in the relatively large volume of ineligible proposals in Cluster 1 (6.1%). For example, additional feedback from EC's public consultation and Case

studies⁵² revealed that many stakeholders felt the vast quantity and range of documents could reduce clarity and lead to a higher risk of errors. As a result, a fraction of unsuccessful applicants found that the effort compared to securing funding was disproportionate.

The issue most often cited by unsuccessful applicants (one out of 5) was that the administrative efforts needed were not proportional to the chances of securing Horizon Europe funding.

The application process had been streamlined under Horizon 2020, creating a single entry point for grant applications called the Funding and Tenders Portal ⁵³. Under Horizon Europe, the portal has enlarged the scope of the Participants Portal, covering most of the EU funding programmes. **Despite this simplification, some beneficiaries still found it difficult and cumbersome**. In Horizon Europe, 28.4% of beneficiaries disagreed (18.3% rather disagreed, 5.5% strongly disagreed) that the "Online reporting platform is user-friendly." Additionally, 17.2% disagreed that "The support of technical issues with the online platform is useful". Similar sentiments were also echoed by the EC's public consultation respondents and various stakeholders. Numerous beneficiaries highlighted frequent technical glitches during proposal submissions and highlighted the interface's complexity. Making the platform more user-friendly and less prone to technical malfunctions significantly improves the quality of the application process. The issues with the user-friendliness of the IT tools used in the grant conclusion stage were also notable. **Overall, the introduction of the platform streamlined the application process; however, further adaptations and improvements are needed to improve its functionality and user-friendliness.**

⁵² Case study 9 "Well-being and Inequalities" and Case study 8 "CCISs for Innovation and competitiveness".

⁵³ https://www.ideal-ist.eu/news/funding-tenders-portal-replacing-participant-portal-now
Figure 36. (Cluster 1 unsuccessful applicants) "To what extent do you agree with the following statements about the effort needed to prepare and submit your Horizon Europe proposal?"



Source: Survey of Horizon Europe unsuccessful applicants, conducted in May-July 2023.

In Cluster 2, similar to Cluster 1, aspects that received positive feedback were the relatively clear and easy application process, transparency in the evaluation process, the satisfactory level of feedback, and EC's relative flexibility. Conversely, some barriers lay in the application burden and difficulty in comprehending some documentation and navigating the online platform — issues notably pronounced for newcomers and higher and secondary education institutions. Much like in Cluster 1, in Cluster 2, the overwhelming feedback is positive in all surveyed questions.

Key drivers of the Application Selection Process: Cluster 2

In Cluster 2, like in Cluster 1, the beneficiaries found the application selection process to be relatively 'clear'. The overwhelming majority (99.8%) of beneficiaries found that, to an extent, they are satisfied with the "Ease to identify relevant funding opportunities across different HE programme parts". These results are relatively similar to the overall satisfaction with "The clarity of the aims and objectives" and "Clarity of "general Conditions and eligibility and funding rules provided in the Funding and Tenders Portal" and are in line with the opinions expressed in Horizon 2020. When looking at the type of beneficiary, no coordinator found it difficult to identify funding opportunities, and only 1.7% of partners did.

Figure 37. (Cluster 2) "To what extent are you satisfied with the following aspects related to your Horizon Europe project application process?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023.

Overall, the study team found the application process's clarity was satisfactory. Over 98% were satisfied with "The clarity of the aims and objectives" and the "Clarity of "general Conditions and eligibility and funding rules provided in the Funding and Tenders Portal". Similarly, high satisfaction rates were also found throughout Horizon 2020.

What concerns 'the transparency of the evaluation process', 96.3% of beneficiaries were satisfied with it, which is also in line with Horizon 2020. The coordinators were twice as likely to be more satisfied with this statement to a very large extent than the partners. In addition, no coordinators expressed dissatisfaction with this statement. This aligns with the theme of coordinators appearing more satisfied with the application processes.

'The timelines of the funding decisions' were also noted to be satisfactory and well in line with the TTI indicators calculated by the study team.

Figure 38. (Cluster 2) "To what extent do you agree with the following statements about the effort needed to prepare and submit your Horizon Europe proposal?"



Source: Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023.

Regarding the level of feedback, an overwhelming majority (95.9%) of Cluster 2 respondents found it satisfactory. While the level of EC feedback is still overwhelmingly satisfactory, a few examples from public consultations revealed that it could benefit from increased directionality and specificity.

In Cluster 2, 64.2% agreed (22.2% strongly agreed, 42% rather agreed) that "The EC is sufficiently flexible with respect to the changes in the project consortium", while 61.5% agreed (19.7% strongly agreed, 41.8% rather agreed) that 'The EC is sufficiently flexible in adapting the project objectives because of changed circumstances" (see Figure 34). However, this general sentiment of perceived 'flexibility' might not extend to all aspects of project management. Evidence from the 'Well-being in Inequalities' case study revealed that some beneficiaries found the long-term planning of project milestones and deliverables challenging. Therefore, while EC is generally viewed as adaptable in its management approach, further flexibility, especially in the area of long-term project planning, could enhance beneficiary satisfaction.

When looking at unsuccessful applicants, satisfaction with the 'proportionality' of resources needed for the application and the volume of funding was also relatively high in Cluster 2. Overall, 93.6% of respondents were satisfied with the following statement: "The application costs (total time and resources needed) are proportionate to the volume of funding requested in the proposal" Similarly, 94.5% were satisfied that "The efforts needed were proportionate to the complexity of the proposed project," mirroring the 96.4% who were satisfied that "the effort needed was proportionate to the number of consortium partners involved.

Key Barriers: Cluster 2

The analysis of both Cluster 1 and Cluster 2 reveals a recurring sentiment among some beneficiaries: the administrative and management processes of grant conclusion are perceived as more burdensome than desired. A substantial fraction of respondents, 26.6%, disagreed (6.4% strongly disagreed and 20.2% rather disagreed) that "The burden of administrative and legal requirements for granting procedures was proportionate." A possible explanation for this could lie in the increased number of requirements that the participants had to meet, as discussed in Cluster 1 analysis. At the beneficiary level, partners viewed the administrative burden as a more significant issue, with 27.9% of partners deeming it disproportionate, compared to 18.9% of coordinators. Since coordinators are the ones who mostly deal with administrative tasks, this may indicate partners' unawareness of the full administrative workload.

Figure 39. (Cluster 2) "Would you agree or disagree with the following statements about the administrative and management processes in your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023.

Across different clusters and case studies, a portion of beneficiaries consistently identified call complexity and unclear guidelines as possible challenges in the Horizon Europe application process. While the majority still feels positive about this, over 23% of beneficiaries disagreed (2.9% strongly disagreed and 17.1% rather disagreed) that "Project reporting requirements required reasonable effort and costs." The Higher or Secondary Education Institutions (HEI) seemed to find this to be a bigger challenge than the rest (27.2%), a number similar to Cluster 1. It seems that clarity was lacking in some of the rules and guidelines; notably, a fifth of the beneficiaries disagreed with the statement that "Rules

for the calculation of personnel costs (esp. daily rates) are adequate and clear." In particular, public bodies (PUB) and other organisations (OTH) felt more strongly about this, with 25.0% and 25.6% respectively. It is important to note that while a quarter of respondents is not significant, among the overwhelming majority of positive responses, it merits further scrutiny.

The feedback from the "Cultural and Creative Industries" and "Well-being and Inequalities" case studies further emphasised the complexity of EU calls and the resource-intensive nature of navigating them. Specifically, the beneficiaries in the "Well-being and Inequalities" case study noted that the requirements in the application process are perceived as an enormous challenge, especially for smaller institutions. Many beneficiaries felt that the chance of success depended on experience in the consortia, meaning that the application process was even more burdensome for the newcomers. The lack of a finalised Annotated Grant Agreement (AGA) could also be another reason more beneficiaries found it difficult to meet the application requirements.

Figure 40. (Cluster 2) "Would you agree or disagree with the following statements about the administrative and management processes in your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023.

The user-friendliness of the online reporting platform remains a challenge for Horizon Europe beneficiaries as it was in Horizon 2020. Around a quarter of beneficiaries (24.4%) disagreed with the statement that "The online reporting platform is user-friendly". As mentioned in the analysis of Cluster 1, to complement this analysis, a number of stakeholders have expressed their concerns regarding the functionality and user-friendliness of the platform. While the initiative to consolidate all necessary documents and processes in one location is notable, there is a need for further enhancements to meet the beneficiaries' needs fully.

Lastly, among the beneficiaries, a fraction of 13.1% disagreed with the statement, "The time the processes takes up to the signature of the grant agreement was adequate." While the majority agreed with this statement, it is noteworthy to comment that the actual Time-to-Sign (TTS), calculated by the study team, exceeded the legal maximum of 3 months in Cluster 2, with an average of approximately 129.9 days. The duration noted is significantly higher than the 102.4 days in Horizon 2020. This discrepancy suggests a need to address and improve the time management within the grant agreement process to align with legal parameters and the beneficiaries' expectations.

Compared to the successful applicants, the unsuccessful applicants found the application process to be relatively difficult. Looking at the HE unsuccessful applicant survey, the study team found that 25.6% of respondents felt that "The efforts needed were not at all in proportion with the chances of securing funding." A larger share of HEIs and Public Bodies - (PUBs) found the effort not proportionate, indicating a relatively significant administrative burden. In response to the same question, only 9% of the successful applicants felt that the efforts were not at all proportionate to the chances of securing funding. While 25% might not seem significant, it shows a noticeable difference when juxtaposed with the figures found among successful applicants.

Figure 41. (Cluster 2 unsuccessful applicants) "To what extent do you agree with the following statements about the effort needed to prepare and submit your Horizon Europe proposal?"



Source: Survey of Horizon Europe unsuccessful applicants, conducted in May-July, 2023.

Cluster 3

The respondents in Cluster 3 also showed overall satisfaction with the various aspects surveyed related to their HE project application process. We pulled out some of the key drivers and barriers from the overwhelmingly positive responses, and we elaborated on them. The barriers and drivers in Cluster 3 were rather similar to Clusters 1 and 2, with a key

difference of slightly smaller in magnitude. 'Clarity' and 'ease' of the application process, as well as EC feedback and flexibility, remain key enables of efficiency, while increased application burden, inadequate time for the grant signature agreement, and the difficulties with navigating the online platform still pose some barriers to be addressed.

Key drivers of the Application Selection Process: Cluster 3

Much like Cluster 1 and 2, beneficiaries in Cluster 3 also found the application selection process to be relatively straightforward. An overwhelming majority (over 98%) felt satisfied with the "Ease to identify relevant funding opportunities across the different HE programme parts". Notably, all coordinators voiced a more positive opinion on this matter.

Figure 42. (Cluster 3) "To what extent are you satisfied with the following aspects related to your Horizon Europe project application process?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July, 2023.

Beneficiaries in Cluster 3 expressed the highest degrees of satisfaction with the "Clarity of the aims and objectives of the call," with no beneficiary citing discontent. Over 99.5% were satisfied with the "Clarity of general conditions and eligibility and funding rules provided in the Funding and Tenders Portal", and 32.3% of those expressed satisfaction to a very large extent and 46.1 to a large extent. Similarly, an overwhelming majority found the "Design of the proposal template" to be satisfactory.

The 'feasibility' of fulfilling the application requirements was generally not seen as challenging, with no beneficiary viewing the objectives outlined in the calls as entirely unachievable. In fact, approximately half of the respondents affirmed that, to a large extent, the "feasibility of addressing the objectives set out in the calls" was quite satisfactory. Similarly, 97.6% of surveyed beneficiaries expressed satisfaction with "The size of the possible project funding as foreseen in the call compared to the objectives set in the call".

Timeliness of the funding decisions (N=174)	27; 16,1%	76; 45,8%		49; 29,2%	10; 5; 6,0 <mark>%</mark> 3,0%
Level of details of the feedback provided in the evaluation report (N=164)	16; 9,7%	65; 40,2%	53; 32,39	% 12	20; <mark>9;</mark> 2,2% <mark>5,5%</mark>
The transparency of the evaluation process (N=163)	28; 17,2%	61; 38,0%	44 27,	4; 0% 1	23; <mark>6;</mark> 4,1%3 <mark>,7</mark> %
Adequacy of the length (n of pages requested) of the proposal template (N=170)	34; 20,6%	80; 47,1%		48; 28,2%	5; <mark>2;</mark> 2; 2,9 <mark>%</mark> ,2%
The size of the possible project funding as foreseen in the call compared to the objectives set in the call (N=166)	13; 7,8%	74; 45,2%	34	58; 1,9%	16; <mark>4;</mark> 9,6%2, <mark>4</mark> %
Feasibility of addressing the objectives set out in the Calls (N=166)	23; 13,9%	81; 49,4%		51; 30,7%	10; 6,0%
C)% 2	0% 40%	60%	80%	100%
 To a very large extent To a small extent Not at all 					

Figure 43. (Cluster 3) "To what extent are you satisfied with the following aspects related to your Horizon Europe project application process?"

Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023.

The timelines of application decisions were also noted to be appropriate, well in line with the TTI indicators calculated by the study team and with the findings in Cluster 1 and 2.

In terms of feedback, the overwhelming majority of Cluster 2 respondents felt that the "Level of details of the feedback provided in the evaluation report" was satisfactory (9.7% agreeing to a very large extent and 40.2% to a large extent). Additionally, when breaking down by beneficiary type, it appears that more coordinators find the feedback less satisfactory (10.5% citing that it was not detailed at all) than partners' opinion (4.8%). This indicates that while

the feedback provided generally meets the needs of applicants, there are opportunities to enhance its usefulness through greater specificity and tailored guidance.

The beneficiaries in Cluster 3 also found the administrative and management processes of granting procedures to be relatively clear and comprehensible. Over 70% agreed (16.1% agreeing strongly and 54.8% rather agreeing) that "The guidance documents related to the project implementation phase were relatively sufficient and clear." Similarly, around 70% also agreed (24.5% strongly agreeing and 45.3% rather agreeing) that "The rules for calculating personnel costs were adequate and clear". This finding is also well in line with Horizon 2020.

Lastly, satisfaction rates among unsuccessful applicants were notably high for certain aspects. Specifically, 96.6% felt (9.4% to a very large extent and 46% to a large extent) that "The efforts were proportionate to the complexity of the proposed project", while 96.9% believed (10.6% to a very large extent and 40.1% to a large extent) "The efforts needed were proportionate to the number of consortium partners involved". Similarly, 95.6% of these applicants expressed contentment with the' proportionality' of "the application costs relative to the volume of funding requested".

Key Barriers: Cluster 3

A portion of the beneficiaries in Cluster 3 also perceive the administrative and management processes involved in finalising the granting procedure to be more burdensome than desirable. In this cluster, 13.7% of the beneficiaries disagreed that "The burden of administrative and legal requirements for granting procedures were proportionate". Similar to Cluster 1 and 2, this burden was mostly felt by the HEIs, where 33% of them expressed this as a challenge. Additionally, 13.2% also disagreed with the statement that the "Project requirements require reasonable effort and costs", with HEIs expressing relatively more difficulties. In both cases, the coordinators tend to be more dissatisfied with the administrative burden than the partners. Much like Cluster 1 and 2, an example of this can be seen in some respondents in the Public Consultations (8) who cite that the increased number of policy targets created more burden for the consortia. This, in turn, made it even more burdensome for small SMEs and newcomers. Hence, despite relatively better perceptions, some Cluster 3 beneficiaries also faced challenges with administrative burdens, indicating a need for simplification and additional support.

Figure 44. (Cluster 3) "Would you agree or disagree with the following statements about the administrative and management processes in your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023.

Examining the perceptions of time-based efficiency indicators, 14% disagreed or strongly disagreed that "The time process takes up to the signature of the grant agreement is adequate". Much like Clusters 1 and 2, our study team's calculations revealed that the TTS typically exceeded the legal maximum. This implies a potential need to refine the grant agreement process to better align with legal stipulations and meet beneficiary expectations.

Figure 45. (Cluster 3) "Would you agree or disagree with the following statements about the administrative and management processes in your Horizon Europe project?"



Source: Survey of Horizon Europe beneficiaries, conducted in May-July 2023:

Similar to Cluster 1 and 2, as well as Horizon 2020, one of the most cited sources of user dissatisfaction remains the user-friendliness of the online platform and the IT tools. Almost 16% of the beneficiaries disagreed with the statement that the "Online reporting platform is user-friendly. This finding also aligns with relatively low satisfaction with the user-friendliness of the IT tools used in the grant conclusion stage of Horizon 2020. While the effort to centralise all necessary documents and processes in one location is commendable, additional improvements are necessary to cater to the users' needs fully.

Concerning the unsuccessful applicants in Cluster 3, a fraction (24.7%) also thought that "The efforts were not at all in proportion with the chances of securing HE funding." Moreover, 13% felt not at all satisfied with the statement that "The overall effort to prepare a Horizon Europe proposal was acceptable". These concerns can also be visible in the notably high rates of ineligible proposals - 11.5%. "While we must interpret these results cautiously, as they could be influenced by biases related to unsuccessful applications, they suggest that some aspects of the application process might have been ambiguous or presented eligibility challenges worthy of further examination.

Figure 46. (Cluster 3 unsuccessful applicants) "To what extent do you agree with the following statements about the effort needed to prepare and submit your Horizon Europe proposal?"



Source: Survey of Horizon Europe unsuccessful applicants, conducted in May-July 2023.

1.4.2. Effectiveness in achieving prescribed objectives

Cluster 1

Cluster 1 is on track to achieving its prescribed objectives, according to its calls in Work Programmes and the surveyed beneficiaries.

The Survey of Horizon Europe beneficiaries, conducted in May-July 2023, asked the respondents, "To what extent, if at all, has your Horizon Europe project achieved/is likely to achieve the following results?". The results are presented in the Table below. 8 out of 13 listed results, according to the survey respondents, will be achieved to a very large or to a large extent (over 50%), such as pushing the frontiers of knowledge, strengthening relationships with leading partners in Europe, increasing international visibility through collaborations with leading global partners; improving the skills, knowledge, and competences of researchers. Around 10% of respondents indicated that 2 of the results would not at all be likely to be achieved – entry to new markets and/or (global) value chains (9.7%) and development of sustainable solutions contributing to green transition (12.4%).

Table 2	2 Horizon	Furone a	chieving th	e results t	from Clu	uster 1 re	snondents
	2. 110112011	Luiope a	ionieving in	e results			soponuenta

	To a very large exten t (%)	To a large exten t (%)	To a moderat e extent (%)	To a small exten t (%)	Not at all (%)	Do not know/Not Applicabl e (%)
Pushing the frontiers of knowledge	33.8	44.8	15.3	2.0	0.8	3.3
Contributing to emerging areas of science and technology	29.7	42.3	18.5	3.8	0.8	4.9
Enhancing capacity to test, demonstrate and prototype new technological developments	25.7	36.4	16.6	6.2	3.4	11.7
Strengthening relationships with leading partners in Europe	38.7	42.2	12.5	3.3	0.0	3.3
Increasing international visibility through collaboration with leading global partners	35.0	41.4	15.9	4.3	0.5	2.8
Increasing research productivity (e.g., the number of peer-reviewed publications)	29.5	40.5	18.3	6.1	0.8	4.8
Improving the skills, knowledge and competencies of researchers	37.1	44.7	14.2	2.3	0.3	1.5
Improving the career prospects of researchers	29.9	38.9	18.9	5.1	1.0	6.1
Improving access to physical and knowledge infrastructures, facilities and data resources	21.1	34.4	25.4	7.4	2.8	8.9
Entry to new markets and/or (global) value chains	9.2	17.6	25.6	12.8	9.7	25.1
Strengthened capacity to attract public or private funding	13.2	31.2	28.1	11.4	2.9	13.2
Development of policymaking and standards-setting measures	16.5	33.0	25.0	8.5	3.6	13.4
Development of sustainable solutions contributing to a green transition	8.6	14.6	18.9	14.6	12. 4	31.0

Source: Compiled by the study team based on the survey programme, n=393, Question: To what extent, if at all, has your Horizon Europe project achieved/is likely to achieve the following results?

In addition to the Cluster 1 objectives, Cancer Mission has its own specific (SO) and operational (OO) objectives⁵⁴. The evidence of the implementation of objectives is provided in Case Study 6 on Cancer Mission. The Table below lists the ongoing projects for each specific and operational objective.

⁵⁴ EU Missions two years on: An assessment of progress in shaping the future we want and reporting on the review of Mission Areas and areas for institutionalised partnerships based on Articles 185 and 187 TFEU, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2023:457:FIN, page 40

Table 23. The track of the implementation of the Cancer Mission's objectives

	SPECIFIC OBJECTIVES
Improve the understanding of cancer (SO1), relating to the creation of high knowledge.	The project portfolio is being built with the UNCAN.eu platform, where the blueprint is expected to be launched at the end of 2023. As indicated in Case Study 6 on the Cancer Mission, the ongoing projects for this SO also include <u>BCAST</u> , working on breast cancer and <u>PrECISE</u> , and understanding disease mechanisms and best strategies for therapeutic intervention.
Prevent what is preventable through screening and early detection (SO2)	Guided terms of reference for consultation of EC proposal for an update of Council recommendations on cancer screening have already been acquired. The Cancer Mission Case Study (CS6) also notes 2 projects related to SO2, including the <u>MyPEBS</u> focusing on breast cancer screening trial and <u>FORECEE</u> , predicting a woman's individual risk of developing female cancers.
Optimise diagnostics and treatment (SO3)	The ongoing projects are being implemented around the Comprehensive Cancer Centers (CCC) (e.g. <u>CraNE</u>). The CCC network will be created by 2025, integrating care, research, training and awareness. In addition, the clinical trials programme on treatment was developed. Two additional projects were mentioned in the Case Study on Cancer Mission – <u>UNCOBIOME</u> and <u>EUROSCARC</u> , working towards the microbiome signatures related to cancer occurrence and response to therapy and innovative clinical trials for patients with bone and soft tissue sarcomas.
Support quality of life (SO4)	The blueprint development of the <u>European Cancer Patient Digital Centre</u> (EDCPC) was launched. The Survivorship Passport (<u>SurPass</u>) was developed to provide survivors with a complete overview of their treatment and personalised recommendations for future health issues.
	OPERATIONAL OBJECTIVES
Foster Innovation (R&I programme) (OO1)	There is ongoing work to build project portfolios.
Living labs (OO2)	Living labs already exist in some countries, e.g. Finland ⁵⁵ , France ⁵⁶ , and Spain ⁵⁷ , and they also work at the European level ⁵⁸ .
Monitoring support and indicators (OO3)	Initial mission-specific targets and indicators were developed per each objective.
Health literacy, communication, citizen engagement (OO4)	Health literacy, communication, citizen engagement (OO4): some focus groups are being organised, as well as a large-scale conference on young survivors (<u>Young Cancer Survivors workshops and Conference</u>).

Source: Compiled by the study team.

⁵⁵ Living lab services Kuopio University Hospital (FI): https://www.psshp.fi/web/en/organisation/living-lab

⁵⁶ Living Labs at INCa (FR): https://gnius.esante.gouv.fr/en/players/player-profiles/living-lab-institut-national-du-cancer

⁵⁷ Living Lab at IrsiCaixa AIDS Research Institute (ES): https://www.scishops.eu/case-study-living-lab-for-health-spain/ 58 European Network of Living Labs (ENoLL): https://enoll.org

Cluster 2

Table 24. Horizon Europe achieving the results from Cluster 2 respondents

	To a very large extent (%)	To a large exten t (%)	To a moderat e extent (%)	To a small extent (%)	Not at all (%)	Do not know/Not Applicabl e (%)
Pushing the frontiers of knowledge	31	37.7	23.2	3.5	1.7	2.9
Contributing to emerging areas of science and technology	20	32.3	22.3	6.7	5.3	13.2
Enhancing capacity to test, demonstrate and prototype new technological developments	8.9	16	15.4	13.1	16	30.6
Strengthening relationships with leading partners in Europe	39	36.5	15.9	3.8	1.5	3.2
Increasing international visibility through collaboration with leading global partners	35.2	35.8	15.2	5.3	2.3	6.2
Increasing research productivity (e.g., the number of peer-reviewed publications)	27.1	37.8	19.8	6.5	2.7	6.2
Improving the skills, knowledge and competences of researchers	39	42.8	12.3	2.3	0.3	3.2
Improving the career prospects of researchers	31.3	35.1	19.3	5.8	1.5	7.0
Improving access to physical and knowledge infrastructures, facilities and data resources	20.1	26.3	25.7	9.4	5.0	13.6
Entry to new markets and/or (global) value chains	4.7	13.4	15.1	11.3	16. 0	39.5
Strengthened capacity to attract public or private funding	14	21.8	29.9	11.6	5.1	17.6
Development of policymaking and standards setting measures	28.7	32.2	20.1	8	2.4	8.6
Development of sustainable solutions contributing to a green transition	10.9	13.6	19.4	12.4	10. 0	33.6

Source: Compiled by the study team based on the survey programme, N=345, Question: To what extent, if at all, has your Horizon Europe project achieved/is likely to achieve the following results?

Cluster 3

CL3, similar to CL1 and CL2, is progressing toward fulfilling its defined objectives as outlined in its calls within the Work Programmes, as indicated by the survey respondents.

The Survey of Horizon Europe beneficiaries, conducted in May-July 2023, asked the respondents, "To what extent, if at all, has your Horizon Europe project achieved/is likely to achieve the following results?". The results are presented in the Table below. According to over 50% of respondents, all of the listed results will be achieved at least to a moderate extent. Enhancing capacity to test, demonstrate and prototype new technological developments, strengthening relationships with leading partners in Europe, as well as Improving the skills, knowledge and competencies of researchers were selected by 80% or more respondents as the results which will be achieved to a large or very large extent.

1.4.3. Main results and outcomes of Horizon Europe programme parts Clusters 1, 2, and 3

This study evaluates the effects of the Horizon Europe program through the assessment of three impacts: scientific, societal, and technological. In this phase of the program, our focus is on the short-term indicators detailed in the Table below, with specific attention given to Key Impact Parameters (KIPs) 4, 5, and 6. While there is a concise overview of other impacts, such as scientific and technological impacts, the comprehensive analysis is presented in the Main Report.

Impact	KIP	Short term indicator
	1. Creating high- quality	Publications: number of peer-reviewed scientific publications resulting from the Programme.Baseline: A number of scientific publications produced without Programme intervention (zero).
	new knowled ge	Benchmark: 101 thousand publications, based on analysis of nearly 169 thousand reported H2020 publications in Q1 2021).
	2. Strength ening human capital in	Skills: A number of researchers have reported on Horizon Europe projects based on EC administrative and monitoring data submitted by Horizon Europe participants. Baseline: number of upskilled researchers without Programme intervention (zero)
	R&I	Benchmark: 78,000 researchers, or around 4.2% of the EU's research workforce.
APACT	3. Fosterin a	Share knowledge: share of research outputs (open data/publication/software, etc.) resulting from the Programme that are shared through open knowledge infrastructures.
FIC IN	diffusion of	Baseline: share of the EU's publications that are in OA (between 42% and 46% between 2016 and 2018).
SCIENTI	knowled ge and Open Science	Benchmark: share of H2020 publications that are in OA (85% of analysed H2020 publications in OA).
SOCIETAL IMPACT	4. Addressi ng EU policy priorities & global challeng es through P&I	Results: number and share of products tracked and reported under Key Impact Pathways 1 to 3 (scientific outputs) as well as 7 to 9 (economic/technological outputs), classified according to the specific EU policy priorities concerned, including the SDGs and climate-relevant results aimed at delivering on the Union's commitment under the Paris Agreement. Baseline: top 3 SDGs by share of total publication output for the EU (excluding the UK) in 2015-2020 that potentially contributed to them (SDG15, ca. 20%; SDG 13, ca. 18%; SDG 12, ca. 16%) Benchmark: top 3 SDGs by share of H2020 projects that potentially contributed to them (SDG3, 45%; SDG11, 26%; and SDG7, 26%)
	5. Deliverin g benefits & impact via R&I missions	R&I mission results: number and share of results under the KIPs 1, 2, 3, 7 and 9 short-term indicators for each identified mission.
	6. Strength ening the uptake of R&I in society	 Co-creation: number and share of all ongoing and completed Horizon Europe projects in which EU citizens and end users contribute to the co-creation of R&I content. Baseline: number of projects in which Union citizens and end users contribute to the co-creation of R&I content without the Programme's intervention (zero). Benchmark: share of H2020 projects in which Union citizens and end users contributed to the co-creation of R&I content (no benchmark value available for H2020; best available estimate – ca. 11% of H2020 projects declared the involvement of stakeholders).

Impact	KIP	Short term indicator
AL/ECONOMIC IMPACT	7. Generati ng innovatio n-based growth	 Innovative results: number of innovative products, processes or methods resulting from the Programme (by type of innovation) and intellectual property rights (IPR) applications. Baseline: total number of patent applications without FP intervention (value: zero – no FP-funded IPR outputs and KERs would be produced without the intervention). Benchmark: 3,195 IPR applications in H2020 (source: Horizon Dashboard, accessed in August 2021).
	8. Creating more and better jobs	 Supported employment: number of full-time equivalent (FTE) jobs created and jobs maintained in participating legal entities for the project funded by the Programme (by type of job). Baseline: number of FP-funded FTE jobs created or maintained without the intervention (value: zero) Benchmark: number of FTE jobs created or maintained under H2020 (value: 234,796 FTEs supported under H2020 projects by August 2021).
TECHNOLOGIC	9. Leveragi ng investme nts in R&I	 Co-investment: the amount of public and private investment mobilised with the initial investment from the Programme. Baseline: the amount of public and private investment mobilised by the beneficiaries without the intervention (zero). Benchmark: amount of own funds contributed to H2020 projects (EUR 14.1 billion by August 2021).

1.4.4. Dissemination exploitation and communication measures

Cluster 1

As the data on dissemination activities is limited to this stage of the project, the study assessed the level of citizens' involvement in Horizon Europe projects and the types of exploitation activities using the Survey of Horizon Europe beneficiaries conducted in May-July 2023.

The Figure below provides an overview of the answers to the Horizon Europe beneficiaries survey conducted in May-July 2023. The respondents were asked, "Are there any exploitation activities (e.g., using project results for commercial purposes, to tackle societal problems or in policymaking) foreseen as a part of your project?". Most of the respondents indicated (53.8%) the use of the results for academic purposes, followed by developing, creating, manufacturing, and marketing products or processes (35.5%) and creating and providing a service (34%). Out of those who selected 'Other' (20 respondents), the answers included the adoption of guidelines, development of Policy Briefs and engagement of stakeholders' forums, E-learning and face-to-face training modules development and implementation, innovation support guides and tools, facilitating research policymaking interaction, informing policymakers, improving the quality of life of patients, share in design professionals' communities, using the results for the future funding programme.



Figure 47. Exploitation activities from Cluster 1 respondents

Source: Compiled by the study team based on the survey programme, n=820. Question: Are there any exploitation activities (e.g., using project results for commercial purposes, to tackle societal problems or in policymaking) foreseen as a part of your project?

Cluster 2





Source: Compiled by the study team based on the survey programme. Question: Are there any exploitation activities (e.g., using project results for commercial purposes, to tackle societal problems or in policymaking) foreseen as a part of your project?

Cluster 3

The data on dissemination activities within CL 3 is not available at this stage of the study, so the results on dissemination and exploitation activities are mainly based on the Horizon Europe beneficiaries' survey conducted in May-July 2023.

The Figure below provides an overview of the answers to the Horizon Europe beneficiaries survey conducted in May-July 2023. The respondents within the CL3 were asked, "Are there any exploitation activities (e.g., using project results for commercial purposes, to tackle societal problems or in policymaking) foreseen as a part of your project?". Around 50% of respondents selected three exploitation activities foreseen as part of their projects: *the use* of the results for academic purposes (50.7%), creating and providing a service (48.7%), and standardisation activities (46%).



Figure 49. Exploitation activities from Cluster 3 respondents

Source: Compiled by the study team based on the survey programme, n=820. Question: Are there any exploitation activities (e.g., using project results for commercial purposes, to tackle societal problems or in policymaking) foreseen as a part of your project?

Contribution to Sustainable Development Goals

The Sustainable Development Goals labels, as was done in Horizon 2020, were assigned using the OSDG tool⁵⁹. The full methodological approach can be found in Annex 3, where SDG analysis results at the level of HE pillars are presented. First, the text corpus was assembled for each project, including all the available monitoring data and project publications. Then, the SGD labels were assigned to each project using the entire project text corpus using the three-stage process: using AI and machine learning models for the primary assignment, using expert-curated ontology for the double-checking and verification of initial labels, aggregating the results from the text-segment level to project level, taking into account the size of project corpus, the amount of SDG-related content in the corpus and the

⁵⁹ For a detailed explanation on the tool please refer here: https://arxiv.org/ftp/arxiv/papers/2211/2211.11252.pdf .

relative distribution of different SDGs. To get an SDG label, at least 15% of text segments in the corpus have to be SDG-related, and each SDG included in the final label must account for at least 10% of all the SDG-relevant content in the project corpus. It is important to note that more than one SDG label can be assigned to the project. The desk research, where relevant, also complements the quantitative analysis.

Cluster 1

Regarding SDGs, in the Horizon Europe Strategic Planning 2021-2024, the Key Strategic Orientations for Cluster 1 underlines that the EU is strongly committed to the SDGs, many of which have an important impact on health and well-being, notably SDG3 (Good Health and Well-being for people) with its nine health-specific targets for universal health coverage for all at all ages by 2030 and ending preventable deaths. EU will work closely with its Member States to achieve these ambitious goals. In addition, Cluster 1 Work Programme 2023-2024 indicates that the EU is reinforced as an internationally recognised driver of research and innovation in rare diseases and AMR, substantially contributing to achieving the SDGs related to rare diseases and AMR. In addition, through the Contribution to the Coalition for Epidemics Preparedness Initiative (CEPI), it is expected that research funders, policymakers and the research community will have better tools and solutions to achieve SDG 3.3⁶⁰ and implement 3. B⁶¹. Similarly to CL1, Horizon 2020 Interim Evaluation also indicated that in SC1 Work Programmes, SDG3 was reflected (e.g., the development of new or improved drugs, vaccines, microbicides, and diagnostics against HIV/AIDS, TB and malaria).

Draft General Budget of the EU for the financial year 2023 indicates that regarding SDG3, the EU is implementing a METAFOAM project, which has a new solution targeting low frequencies and enables acoustic metafoams, new materials leading to the creation of a very efficient sound insulator. That is needed as sound pollution is linked to various health problems, and many Europeans are exposed to high noise levels. Around 50 million people living in urban areas suffer from excessively high levels of traffic noise at night, among which 20 million damage their health.

The Table below presents the overview of the projects' status of Cluster 1. Overall, up until now, out of 316 projects within the Cluster 1, 304 were used for the SDG analysis. No projects were closed at the time of the analysis.

HE Thematic Priority	Total Number of Projects	Number of projects with status = CLOSED	Total number of projects analysed	Total number of projects analysed in projects with status = CLOSED
Cluster 1	316	0	304	0
Total Pillar 2	2 217	3	2 195	3

Table 25. Overview of the projects' status

Source: CORDA database.

⁶⁰ End the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases

⁶¹ To support the research and development of vaccines for the communicable diseases that primarily affect developing countries, and provide access to affordable essential vaccines

Cluster 2

The Table below presents the overview of the projects' status in Cluster 2. A total of 151 projects were used in the analysis, with only one project having closed status.

Table 26. Overview of the projects' status

HE Thematic Priority	Total Number of Projects	Number of projects with status = CLOSED	Total number of projects analysed	Total number of projects analysed in projects with status = CLOSED
Cluster 2	151	1	151	1
Total Pillar	2 217	3	2 195	3

Source: CORDA database.

The comparison between the share of Horizon Europe and Horizon 2020 projects by SDG reveals that both Cluster 2 and Societal Challenge 6 significantly contributed to SDGs (100% and 83.3%, respectively).

Cluster 3

Findings: The table below presents the overview of the projects' status of Cluster 3. Out of 97 projects, 96 were used in the analysis provided below.

Table 27. Overview of the projects' status

HE Thematic Priority	Total Number of Projects	Number of projects with status = CLOSED	Total number of projects analysed	Total number of projects analysed in projects with status = CLOSED
Cluster 3	97	0	96	0
Total Pillar 2	2 217	3	2 195	3

Source: CORDA database.

1.4.5. International cooperation

Cluster 1

The findings of the EC administrative and monitoring data suggest that Horizon Europe's Cluster 1 has a broad international outreach, particularly when considering the participation of Third Countries, but the data should be interpreted with caution.

The study team assessed the share of international cooperation participation (Associated and Third Countries⁶²). We found that, when compared to the results of the mid-term evaluation of the predecessor Horizon 2020⁶³, Horizon Europe, in general, shows an increase in international participation across the programme. However, it is important to note that at the moment of the midterm evaluation under Horizon Europe, the United Kingdom held the status of Third Country, which is one of the reasons why international participation across the programme increased. As can be seen from the Table below, when comparing the

⁶² As of November 2023, the UK is still considered as a Third Country under Horizon Europe

⁶³ Results were taken from the interim evaluation of Horizon 2020 (Annex 2)

predecessor SC1 to Cluster 1 (about three years into the programme), we see an 8.8% increase in Third Country participation.

This is not surprising, as Third Country participation is integral to the Cluster 1 strategic agenda. The health cluster actively seeks synergies with the South, such as Africa. For example, in the African Union – European Union Agenda⁶⁴, it was indicated that Public Health is one of the priority areas, aiming to use key enabling and emerging technologies (e.g., digitalisation, ICT, robotics, AI) to enhance the performance and resilience of public health systems, which were affected by COVID-19 and will be impacted by the global climate crisis. Among the actions, the AU-EU partnership seeks to transfer technology and improve and develop quality vaccines, medicines, health technologies, and production, ensuring affordability, availability, and accessibility. Moreover, it aims to design and implement new innovative methods and tools for AMR pathogens and promote health and precision medicine. In addition, although from high-income country, US participants receive EU funding due to the reciprocity of access to the US health research funding programme.

The participation of Associated Countries has also slightly increased from 6.3% to 8.8% compared to the predecessor SC1, especially around the three-year mark into the programme. Even more, it is crucial to note that the number increased despite the alterations in the UK's legal status following the Brexit negotiations. During the Horizon 2020 programme, the UK held the status of an Associated Country, while at the moment of the midterm evaluation, it holds the position of a Third Country under Horizon Europe⁶⁵. Understanding this transition, our team analysed the UK's participation trends across both programmes. Out of the 361 participants from Third Countries in Cluster 1, a substantial 148 (or 41%) hail from the UK. This suggests the significant contribution and involvement of the UK in this cluster and the key explanation for the increase of Third Country participation compared to the predecessor.

As for the EU contributions, Associated Countries and Third Countries received a higher share of contributions in CL1 (6.7% and 5.8%) than SC1 (2.7% and 2.8%).

Programme part	Associated Countries	Third Countries			
Participation patterns					
Cluster 1	8.8%	15.6%			
Horizon Europe total	8.6%	11.2%			
SC1 (mid-term)	6.3%	6.8%			
Horizon 2020 (mid-term)	7%	1.9%			

Table 28. EU participations and for Associated and Third Countries Cluster 1

⁶⁴ https://research-and-innovation.ec.europa.eu/system/files/2023-07/ec_rtd_au-eu-innovation-agenda-final-version.pdf 65 As off 1/1/2024, the United Kingdom have the status of associated country.

Programme part	Associated Countries	Third Countries
	EU contributions	
Cluster 1	6.7%	5.8%
Horizon Europe total	6.7%	4.4%
Horizon 2020 SC1 (mid- term)	2.7%	2.8%
Horizon 2020 total (mid-term)	6.5%	0.6%

Source: EC administrative and monitoring data.

Horizon Europe's commitment to fostering international collaboration is exemplified through its strategic emphasis on targeted thematic areas within Cluster 1. The European Commission's presentation on International Cooperation66 within Horizon Europe highlighted a strategic approach within Cluster 1's 2021-2022 Work Programme. Specifically, seven targeted topics within Cluster 1 were identified to foster international collaboration, and a total budget of EUR 320 million was allocated to these topics, encouraging international cooperation. The outlined thematic focuses encompass critical areas of research and innovation, namely infectious diseases, mental health, health impacts of climate change, AI for treatment and care, repurposing medicines, and antimicrobial resistance. These selected themes signify a deliberate effort to address pressing global health challenges and advance cooperation among international stakeholders within the Horizon Europe framework. The The Tables below indicate the top 10 Third Countries regarding participation and EU contributions. The percentages in brackets represent the share of participations and EU contributions, counting the total, including Third Countries within Cluster 1. It can be noted that participation of the United Kingdom constitutes 41% of all Third Countries participations, followed by 11.9% from the United States and 4.4% from South Africa. When it comes to EU contributions, the United Kingdom received 18.3% of all contributions for the Third Countries, followed by South Africa (14.5%) and the United States (7.6%).

⁶⁶ https://www.eeas.europa.eu/sites/default/files/1._horizon_europe_introduction_nb.pdf

	Country	Participant count
1	United Kingdom	148 (41.0%)
2	United States	43 (11.9%)
3	South Africa	16 (4.4%)
4	Australia	14 (3.9%)
5	Tanzania	11 (3.0%)
6	Uganda	10 (2.8%)
7	Nigeria	9 (2.5%)
8	Ethiopia	9 (2.5%)
9	Kenya	8 (2.2%)
10	Zambia	5 (1.4%)

Table 29. Participations of the Third Countries (the top 10 countries)

Source: Compiled by the study team.

Table 30. EC contributions for the Third Countries (the top 10 countries)

	Country	EU contribution, EUR million
1	United Kingdom	25.24 (18.3%)
2	South Africa	19.95 (14.5%)
3	United States	10.53 (7.6%)
4	Kenya	7.79 (5.7%)
5	Tanzania	7.74 (5.6%)
6	Uganda	7.56 (5.5%)
7	Ethiopia	7.1 (5.2%)
8	Zamia	5.75 (4.2%)
9	Ghana	5.49 (4.0%)
10	Democratic Republic of Congo	4.64 (3.4%)

Source: Compiled by the study team.

As part of the analysis, the study team has also considered the results of the Cluster 1 beneficiaries that were gathered as part of the Survey of Horizon Europe beneficiaries conducted in May-July 2023.

In the survey, beneficiaries were asked about difficulties including partners from Associated or Third Countries in the proposal. In total, 116 respondents answered this question. After analysing the results, three main difficulties could be identified:

- Delays and issues related to the changed country status of the UK and Switzerland: examples mentioned were the post-Brexit "transition" conditions and procedures and the more challenging conditions for both countries to get research funding as they no longer automatically receive EU funding.
- Issues with Third Country Partners: **the guidance for sharing data is unclear** (e.g., when sharing clinical data with Associated or Third countries, it is not clear whether committing to follow GDPR), and there are uncertainties about funding and procedures.

• Other: Difficulties finding partners outside current networks and needing more timely feedback.

Horizon Europe partnerships play an important role in fostering the programme's openness beyond the EU. According to the Biennial Monitoring Report 2022, as partners, the newcomers were primarily stemming from Norway and Israel, alongside some African countries. Other partnerships also included Brazil, Canada, China, Chile, India, and the US⁶⁷.

Cluster 2

To support the Global Gateway Strategy⁶⁸, projects involving international partners are anticipated to contribute to advancing scientific knowledge and transferring technology between partner countries. This collaboration addresses global challenges worldwide and fosters sustainable growth and job creation. In line with the EU's Global Approach to R&I, the **Cluster's 2 Work Programmes remain almost fully open to non-associated Third Countries** for all Research and Innovation Action (RIA) and Innovation Action (IA) topics. In many calls and topics, international cooperation is encouraged in Cluster 2 to achieve the expected outcomes from projects.

Looking at the first Work Programme of Cluster 2, we see nine topics that encourage international cooperation (thematic areas include politics and governance, cultural heritage, indicators for sustainable development, gender, and migration), which totals EUR 89 million for these topics.

The **destination democracy**, for instance, has a significant participation rate of Third Countries, while international cooperation is strongly encouraged in many topics. In this way, the EU's role in supporting democracy, human rights, and the rule of law beyond its borders is crucial. In contrast, **destination cultural heritage does not demonstrate a strong element of international collaboration**.

According to the Horizon Europe Strategic Plan analysis, **international collaboration is aimed to expand** in Latin America and the Caribbean region in the second half of the programme through the Work Programmes 2025 and 2026–27 through a targeted "LAC **initiative**" whereby specific topics will encourage participation of LAC countries⁶⁹.

The Table below illustrates the participation and budget allocation for Associated and Third Countries in CL2 actions. Comparing CL2 to the SC6 mid-term results in the participation rate, the Associated Countries' participation slightly decreased in CL2 (7.4%) compared to SC6 (7.9%), while participations of Third Counties slightly increased (from 10.1% to 11.7%).

⁶⁷ https://ec.europa.eu/research-and-innovation/en/knowledge-publications-tools-and-data/interactive-reports/performance-europeanpartnerships-2022#chapter7

 $^{68\} https://international-partnerships.ec.europa.eu/policies/global-gateway/global-gateway-overview_en$

⁶⁹ European Commission, Directorate-General for Research and Innovation, Horizon Europe strategic plan 2025-2027 analysis, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2777/637816

Regarding EU contributions, for both Associated and Third Countries, CL2 has not yet reached the percentage within the SC6.

Table	31.	EU	budget	allocation	and	participation	patterns	for	Associated	and	Third
Count	ries	Clus	ster 2								

Programme part	Associated Countries	Third Countries						
Participation patterns								
Cluster 2	7.4%	11.7%						
Horizon Europe total	8.6%	11.2%						
SC6 (mid-term)	7.9%	10.1%						
Horizon 2020 (mid-term)	7%	1.9%						
EU contributions								
Cluster 2	4.8%	0.7%						
Horizon Europe total	6.7%	4.4%						
SC6 (mid-term)	5.0%	2.9%						
Horizon 2020 (mid-term)	6.5%	0.6%						

Source: EC administrative and monitoring data.

Cluster 3

Conducting security research within Cluster 3 necessitates a tailored strategy for international collaboration, aiming to strike a delicate equilibrium between sharing information with vital global allies (including pertinent international bodies) and safeguarding the EU's security interests. This must be done while also honouring the imperative of maintaining open strategic independence, especially in crucial sectors and within a challenging geopolitical context⁷⁰.

International cooperation is particularly **highly encouraged in the Destination 'A Disaster-Resilient Society for Europe'**, particularly extensive collaboration with Third Countries across various security research programs. This collaboration recognises the cross-border nature of diverse natural and human-induced threats, such as climate change-related. Hence, fostering international cooperation is highly encouraged in this context, especially in advancing technologies for first responders.

⁷⁰ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-6-civil-security-forsociety_horizon-2021-2022_en.pdf

In other thematic areas of Custer 3, international cooperation is treated with caution due to its sensitive nature. For example, in the Destinations relating to protecting against crime and terrorism, border management, infrastructure resilience and cybersecurity, international cooperation is explicitly encouraged only where appropriate and specifically supporting ongoing collaborative activities.

From the first Work Programme (2021-2022), we have seen **16 topics that encourage international cooperation, resulting in a total contribution of EUR 91 million** to these topics encouraging international cooperation. Examples of thematic areas where international cooperation takes place include **disaster resilience**, **border management**, **infrastructure resilience**, and fighting crime and terrorism.

The study team observes that this approach aligns with the broader Research and Innovation policy, emphasising reciprocity in partnerships and contributing to the EU's overarching strategic goals. The examples could be noted in light of COVID-19, when international cooperation played a significant role. Moreover, to protect the EU interests within the security (Cluster 3), Article 22.5 of the Horizon Europe regulation⁷¹ serves as a safeguarding instrument.

The Table below illustrates the participation and budget allocation for Associated and Third Countries in CL3 actions. Comparing CL3 to the SC7 mid-term results, both Associated Countries and Third Countries saw an increase in participation. The increase for Associated Countries was minimal (from 7.9% to 8.2%), whereas participation from Third Countries experienced a significant increase (from 0.9% to 6.3%). This notable change can be attributed, once again, to the shift in the UK's status, as explained more extensively in CL1. Regarding EU contributions, contributions to Associated Countries decreased in CL3 (from 6.3% in SC7 to 4.8% in CL3), while EU contributions to Third Countries increased by 0.5%.

⁷¹ https://eur-lex.europa.eu/eli/reg/2021/695/oj

Table	32.	EU	budget	allocation	and	participation	patterns	for	Associated	and	Third
Count	ries	Clus	ster 3								

Programme part	Associated Countries	Third Countries						
Participation patterns								
Cluster 3	8.2%	6.3%						
Horizon Europe total	8.6%	11.2%						
SC7 (mid-term)	7.9%	0.9%						
Horizon 2020 (mid-term)	7%	1.9%						
EU contributions								
Cluster 3	4.8%	0.7%						
Horizon Europe total	6.7%	4.4%						
SC7 (mid-term)	6.3%	0.2%						
Horizon 2020 (mid-term)	6.5%	0.6%						

Source: EC administrative and monitoring data.

1.4.6. Consideration of ethical aspects in health research

Under Horizon Europe, ethical aspects of health research are embedded in the EU regulations (Horizon Europe Framework Programme). Article 19 states that actions carried out under the Programme shall comply with ethical principles and relevant Union, national and international law, including the Charter and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols⁷².

Baseline

Ex post evaluation of Horizon 2020⁷³ **concluded that ethical appraisal processes and procedures adopted under Horizon 2020 SC1 were considered to a high degree.** According to the study findings, the programme ensured that sensitive subject health research, including research using human embryonic stem cells, informed consent and participation of persons unable to give consent, research involving vulnerable persons, Third Country participation and non-human primate studies, were appropriately considered and dealt with.

⁷² Horizon Europe Framework Programme Regulation 2021/695, https://eur-lex.europa.eu/eli/reg/2021/695/oj

⁷³ Evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe -RTD/2021/SC/021

In Horizon 2020, the decentralisation of the ethics appraisal process was promoted. Not only were the European Research Council Executive Agency (ERCEA) and the DG RTD Health Directorate (currently Directorate D: Health & Society) able to run parts of their own ethics appraisal processes, but so were other members of the research family, such as the European Research Executive Agency (REA).

In terms of the lessons learned from Horizon 2020, further efforts may be beneficial to develop an approach to better identify the scientific research fields that are subject to clear legal/ethical regulation, standard practices and well-established norms (through which serious and complex ethics issues can be identified and addressed), and those areas where serious and complex ethical issues are likely to arise in the execution of projects. It was noted that putting more emphasis on demanding and complex issues could be more effective in terms of risk reduction and more efficient in terms of resources and time allocation. The key changes in ethical aspects of Horizon Europe compared to the Horizon 2020 framework programme are discussed in the findings section.

Methodology: To evaluate whether the ethical aspects of health research were appropriately considered and dealt with regarding ethics issues, the study team mainly liaised with the ethics officer in DG RTD Directorate D: Health & Society. The relevant documents and guidelines were analysed, mainly looking at the documents updated and adapted from Horizon 2020 to Horizon Europe and getting additional documentation from the ethics officer or interview participants. To better understand the current situation of the Ethics Appraisal Process and the changes in regard to Horizon 2020, two interviews were conducted - with an EC official from DG RTD Research Ethics and Integrity sector and with an ethics officer in HaDEA. The data collection already performed to this stage used the survey of Horizon Europe beneficiaries conducted in May-July 2023. In addition, ethics-relevant data was extracted/provided the data extracted from the G.6 team (at the project and proposals level). The project-level data was used to see the categories of ethics issues.

Findings

One important change in the ethical aspects of health research was that in Horizon Europe, the related Ethics Appraisal Processes were delegated from the Health directorate of DG RTD to the executive agency HaDEA. For Horizon Europe (as well as the Horizon 2020 'legacy'), the unit HaDEA.A3 'Health Research' is responsible for the entire life cycle of the projects funded under the Health Programme previously managed by the Health Directorate of DG RTD, from evaluation to the management of grants. In other words, implementation has been split from the policy, with the policy staying with the DG. The teaming up of numerous project officers from several health units (that previously covered different policies in the Health directorate) into one single unit in HaDEA that is now in charge of implementation and the integration of the ethics review process was an opportunity to rediscuss the process and implement possible improvements. The interviews with EC officials revealed that, for instance, due to more focused discussions within the HaDEA health unit, a clear temporal split of the two Ethics Appraisal Process phases (screening and assessment, which is discussed in the text below) was introduced. In addition, more consistency and more effective exchanges and communication were achieved. From the perspective of RTD.02 Ethics and Research Integrity Sector, the delegation did not negatively impact the workflows or contacts; thus, the effectiveness of the ethics processes was not affected. Additionally, the delegation of implementation to the agency provided the project officers with more opportunities to build expertise in ethicsrelated areas.

It is important to note that the process of Ethics Appraisal is complex. The effectiveness question for Cluster 1 in this section is based primarily on the data and processes in HaDEA

(which implements a vast share of Cluster 1) and exchanges with the RTD Ethics and Research Integrity Sector. At the same time, some specificities in the Ethics Appraisal Process may apply, for example, in the joint undertakings (such as IHI/IMI and EDCTP) and are beyond this analysis's scope.

According to the Horizon Europe Programme Guide 2023⁷⁴, the Ethics Appraisal Procedure assesses and addresses the ethical dimension of activities funded under Horizon Europe. The procedure ensures that all research activities carried out under Horizon Europe are conducted in compliance with fundamental ethics principles. The important differences between Horizon 2020 and Horizon Europe in the ethics review process are the following:

- Changes to Ethics Issue Table⁷⁵
 - 'Artificial Intelligence' as an ethics issue was added to the Ethics Issues Table;
 - Dual use is no longer included in the Table. Dual use-related concerns are now dealt with under security review;
 - Exclusive focus on the civil application is also removed and now asked scientific evaluators (except for the European Research Council (ERC), who still include it in ethics);
 - Misuse was named a cross-cutting issue, which will be analysed in the relevant ethics sections⁷⁶. Misuse issues from the security perspective, e.g., when the developed knowledge could be channelled into criminal activities, are dealt with by the security review.
- The risk-based approach in the Ethics Appraisal Process: shift and focus on serious and complex cases⁷⁷
 - Key changes appear in the screening stage. Under Horizon 2020, if some ethics issues were identified, it frequently resulted in the formulation of ethics requirements. In Horizon Europe, ethics issues are flagged during screening, and if it is decided that the issues are not serious/complex, no specific ethics requirements are formulated, except for the possibility of formulating the requirement to appoint an Ethics advisor (EA) or Ethics Advisory Board (EAB). Ethics clearance does not imply that the beneficiary has no ethics obligations. The obligations are described in the Grant Agreement, and they need to comply with all local and national laws and regulations, as well as ethics principles.

During the interviews, the move towards the risk-based approach was indicated to simplify the work for researchers. By cutting out redundancies and duplicative paperwork, researchers are expected not to perceive ethics as just additional paperwork. Also, with this

⁷⁴ Horizon Europe Programme Guide 2023, https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

⁷⁵ The Ethics Apprisal Scheme in Horizon Europe, https://www.bbmri-eric.eu/wp-content/uploads/The-Ethics-Appraisal-Scheme-_BBMRI-webinar-september-2021_version-for-dessimination.pdf

 $^{76\} Guidance\ note\ -\ Potential\ misuse\ of\ research,\ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-info/fundities/docs/2021-info/f$

^{2027/}horizon/guidance/guidance-note-potential-misuse-of-research-results_he_en.pdf

⁷⁷ The Ethics Apprisal Scheme in Horizon Europe, https://www.bbmri-eric.eu/wp-content/uploads/The-Ethics-Appraisal-Scheme-_BBMRI-webinar-september-2021_version-for-dessimination.pdf

principle of subsidiarity and proportionality, heavier processes are applied only when needed, not by default, and the Member States do everything in their competencies themselves.

On the question of Artificial Intelligence, the interviewee noted that now, in the last Work Programmes, there are numerous topics focused on AI (health projects included). It was also indicated that in Horizon 2020, the issues related to AI were already discussed and addressed, mainly regarding personal data protection, privacy issues, and the question of misuse. Separating the AI question allows the European Commission to raise awareness and establish a uniform approach where applicants/beneficiaries clearly understand what is expected from them. Significant progress has been made in terms of guidance, and it is tangible in the new guidance documents. Notably, the Ethics By Design and Ethics of Use Approaches for Artificial Intelligence build on the work done by EC-funded projects as well as the previously existing Ethics Guidelines for Trustworthy AI⁷⁸. The RTD.02 Ethics and Research Integrity Sector is working on the development of additional guidance on responsible AI.

Ethics Appraisal Process under Horizon Europe

The Ethics Appraisal Process has four stages. The Table and Figure below illustrate the process.

Activity	Who?	When?	How?
Ethics self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
Ethics screening	Ethics experts (and/or qualified staff in case a pre- screening is conducted)	Evaluation phase	Review of application material
Ethics assessment (for proposals involving hESC/hE or flagged as serious or complex)	Ethics experts	Evaluation/Grant preparation phase	Review of application material
Ethics check/review/audit	Project Officer and/or Ethics officer and/or Ethics experts	Implementation phase	Review of project deliverables/interview with applicants/onsite visit

Table 33. Summary of the Ethics Appraisal Steps

Source: Horizon Europe Programme Guide⁷⁹.

2027/horizon/guidance/programme-guide_horizon_en.pdf

⁷⁸ Ethics guidelines for trustworthy AI , https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai

⁷⁹ Horizon Europe Programme Guide 2023, https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-





Source: The Ethics Appraisal Scheme in Horizon Europe⁸⁰.

Ethics Self-assessment stage. When preparing a proposal, an Ethics Self-assessment is required, starting with the completion of an Ethics Issues Table. Ethics self-assessment for the applicants is based on a thorough 'How to complete your ethics self-assessment' guidance document⁸¹, and all applicants must confirm that they have taken into account all ethics issues and that they will complete the ethics assessment as described in the guidelines '**How to Complete your Ethics Self-Assessment**'.

Ethics issues considered in Horizon Europe:

- Human embryonic stem cells (hESCs) and human embryos (hEs);
- Humans;
- Human cells or tissues;
- Personal data;
- Animals;
- Non-EU countries;
- Environment, health and safety;
- Artificial Intelligence;
- Cross-cutting issue: potential misuse of results;
- Other ethics issues that were not covered by the Ethics issue table.

⁸⁰ The Ethics Apprisal Scheme in Horizon Europe, https://www.bbmri-eric.eu/wp-content/uploads/The-Ethics-Appraisal-Scheme-_BBMRI-webinar-september-2021_version-for-dessimination.pdf

⁸¹ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

Pre-screening and screening stages. The pre-screening stage is an optional filtering step for calls that are unlikely to raise ethics issues and for proposals that did not flag any ethics issues in their application. The proposal moves to the screening stage if any ethics issues are selected as 'yes' during the pre-screening. In health research, the pre-screening step is skipped, and all proposals related to health topics are rerouted directly to screening for efficiency reasons, as almost all pre-screened proposals would have to undergo the screening process as a result.

The Ethics Screening stage's key goal is to identify proposals that raise serious or complex ethics issues and those that must undergo a full ethics assessment where ethics requirements may be defined. In general, proposals that do not raise serious and/or complex ethics issues can be cleared at the screening stage. In health research, ethics screening is performed for all proposals. Screening is performed by at least two external ethics experts and evaluators, who screen the proposals and flag their ethics issues. The novelty under Horizon Europe is that the Ethics Issues Table is simplified for the ethics prescreening and screening, and there are no detailed questions. Only the applicable ethics categories can be flagged. Conditional ethics clearance is only for proposals that are cleared, but an ethics advisor or advisory board must be appointed. As a lesson learned from Horizon 2020, more emphasis was put on the demanding and complex issues, possibly leading to more effectiveness in risk reduction and more efficient resources and time allocation.

Ethics assessment stage. Proposals raising serious and/or complex ethics issues⁸² are submitted to the ethics assessment stage, which is an in-depth analysis of the ethics issues. This includes all proposals involving human embryonic stem cells (hESCs) and human embryos (hEs), for which the Ethics Assessment is mandatory. Each proposal is assessed by a panel of 5 external ethics experts. The aim is to identify the necessary measures to mitigate or address ethics issues that must be implemented during grant agreement preparation or grant implementation. Possible outcomes are ethics clearance, conditional ethics clearance (with the formulation of ethics requirements) or no ethics clearance (after 2nd assessment).

Based on the Regulation, the guidance on how to complete the ethics self-assessment clearly indicates that the following activities are not eligible for funding⁸³:

- Activities directed at human cloning for reproductive purposes;
- Activities intended to modify the genetic make-up of human beings that could make such changes heritable (apart from research relating to cancer treatment of the gonads, which may be financed);
- Activities intended to create human embryos solely for the purpose of research or stem cell procurement, including the technique of somatic cell nuclear transfer;
- Activities that lead to the destruction of human embryos;
- Activities that do not have an exclusive focus on civil applications;
- No funding shall be granted, neither within nor outside the EU, for research activities prohibited in all the Member States;
- No activity shall be funded in a Member State where such activity is forbidden⁸⁴.

⁸² Identifying serious and complex ethics issues in EU-funded research, https://ec.europa.eu/info/fundingtenders/opportunities/docs/2021-2027/horizon/guidance/guidelines-on-serious-and-complex-cases_he_en.pdf

⁸³ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

⁸⁴ Article 18(2) of the Horizon Europe Framework Programme and Rules for Participation Regulation (EU) 2021/695 (OJ L 170, 12.5.2021)

The monitoring stage consists of ethics checks, ethics reviews and ethics audits. It aims to assist the beneficiaries in dealing with the ethics issues raised by their research activities and take preventative and/or corrective measures. The application of these measures depends on the grant's size and the seriousness and complexity of the ethics issue. An ethics check is an internal check by the Project officer or ethics officer whom ethics experts may support. Ethics review is a more elaborated and in-depth procedure consisting of up to 5 external experts (this used to be called an Ethics Check under Horizon 2020). The RTD Ethics and Research Integrity sector performs ethics reviews for projects raising serious/complex ethics issues, and all hESC/hE projects, while ethics checks are done in HaDEA/implementing services. Ethics reviews may be recommended during the ethics evaluations for projects raising serious or complex ethical issues, but they could also be requested for other projects. For the purposes of checks, reviews, and audits, the beneficiaries must be able to produce all relevant supporting documents requested by a project officer/advisor in the EC or agency. By default, and regardless of the granting authority's monitoring, beneficiaries are obligated to keep all supporting documents on file. Ethics checks/reviews may be initiated either because recommended at the evaluation stage or based on the initiative of the Project Officer whenever concerns over ethics issues arise. It could also be initiated at the RTD Ethics and Research Integrity initiative.

Effectiveness of ethical aspects in health research

The Survey of Horizon Europe beneficiaries, conducted in May-July 2023, had insights on the ethics processes in Cluster 1. In addition to that, the question was discussed in interviews.

The effectiveness of the risk-based approach in health research is visible. It was noted during the interviews that Health Research is not going through the pre-screening process now, and the external experts evaluate all proposals that need to be reviewed with the necessary level of scrutiny. This implies that, compared to H2020, the granting authority implements a trust-based, risk-based approach by no longer formulating requirements for every issue. While in H2020, the ethics requirements helped beneficiaries to know in detail what they needed to do, in Horizon Europe, for cleared proposals/projects, more effort is required from them to determine what is expected based on the guidance (how-to). However, this is in line with the Horizon Europe legal framework, as well as with the ultimate responsibility for compliance with the law and the applicable ethics framework, which lies with the beneficiaries. Obligations to beneficiaries in terms of legal compliance are reminded in several instances, enshrined in the Horizon Europe Regulation and incorporated in the grant agreement. Noteworthy, for clinical research – a significant share of projects funded under the health programme - a set of mandatory deliverables is established. The set of mandatory deliverables is treated as scientific deliverables and includes, by default, mandatory ethics and regulatory approval that the beneficiaries need to obtain from competent authorities. This approach now applies to health research by default, while it does not overlap with the ethics appraisal process and ensures that no clinical research is funded if it does not obtain ethics approval.

The participants of the survey were asked, 'What is your experience with the ethics selfassessment in your project'. The answers are illustrated in the Figure below. Overall, the survey results show that a significant number of projects had a positive experience with the ethics self-assessment, either without facing any issues or with minor challenges that were successfully resolved. Most of the respondents (36.5%) had a positive experience with the ethics self-assessment in their project, stating that they did not face any issues. Additionally, 33.1% of respondents reported a positive experience to a moderate extent, indicating that they encountered some challenges during the ethics selfassessment but were able to resolve them. A smaller proportion of respondents (2.9%) had a **rather negative experience**, facing some issues during the ethics self-assessment. Likewise, **1.1% of respondents** reported a negative experience with significant issues encountered during the process.



Figure 51. Experience with the self-assessment from Cluster 1 respondents

Source: Compiled by the study team based on the survey programme, n=378.

When respondents were asked, 'How would you rate the support (e.g., information, guidance) available to you in carrying out the ethics self-assessment of your project?', 20.3% of the respondents rated the support available to them in carrying out the ethics self-assessment of their project as excellent. A significant number of respondents (16.3%) rated the support as fair, and 4.0% rated the support as poor (see Figure below).

Figure 52. Support available for carrying out the ethics self-assessment from Cluster 1 respondents



Source: Compiled by the study team based on the survey programme, n=276.

The areas for improvement concerning the effectiveness of the Ethics Appraisal Process in health research were discussed in the interviews. It was noted that it may be too soon to elaborate on this, as ethics experts involved in the Ethical Appraisal Process are still getting acquainted with its new elements. One of the challenges is that for Horizon 2020 projects, there was a list of ethics requirements to be checked during project implementation. Since in Horizon Europe, ethics requirements are formulated only for projects raising serious and/or complex ethics issues, the performance of ethics checks and reviews for screened projects

requires a modified approach and analysis to monitor compliance. To address this challenge, HaDEA, for example, has already established a practice that requires project officers to add ethics expert(s) to scientific project reviews for projects that raise ethical concerns or questions during implementation.

Furthermore, to help single out the ethics issues to be checked, the project officer can add an ad hoc ethics deliverable during the grant agreement preparation. In addition, for continuous improvements, the challenge of reducing the number of delegated staff per number of projects is addressed by HaDEA through several measures. Also, there is an ongoing exchange and reflection process on the continuous improvements and contact with RTD.02 Ethics and Research Integrity sector for the ethics appraisal process and RTD Directorate D: Health and Society.

Quantitative data analysis

Before analysing data, it is important to note, as it was in Horizon 2020, that data interpretation is based on the extracted data that presents a 'snapshot' of the ethics information that is active in the IT system at the moment of data extraction. The monitoring of the data is an ongoing process. It needs to enable the integration of new information under clearly defined conditions (e.g. during the Grant agreement preparation and for project amendments). It is of utmost importance to highlight this complexity. For instance, even if some ethics issues (such as AI) are indicated in the project description, it does not mean that they will be included in the ethics report if, for instance, the ethics experts conclude that this is an ethics issue that is not applicable. The complex process illustrates that EC officials dedicate much attention to ethics and that project officers within their portfolios keep detailed overviews of their assigned projects. Even more, as project officers are now in one unit in HaDEA, they exchange information intensively, can align their approaches, and involve ethics experts in the reviewing process.

In Horizon 2020, the data on ethics incidences and outcomes (cleared, conditionally cleared or pending) were provided, as well as the type of ethics issues for conditionally cleared projects and the distribution of ethical issues in signed projects. However, in Horizon Europe, to this date, there are no closed projects under Cluster 1; thus, the provided data cannot be directly compared.

The analysis below is performed using the project-level data received from the EC administrative and monitoring data. When looking at categories of ethics issues, it is important to note that the largest share of categories belongs to Other Ethics Issues (OEI). OEI cannot be interpreted since the category by default is OEI for the ethics advisor/board. However, this can be edited by the project officer at a later stage. When the OEI category, comprising 55.5% of all categories, is removed, the distribution of the share of categories is presented in the Figure below. The Figure below illustrates that the most common category is Personal data (33.5%), followed by Humans (23.8%), Artificial Intelligence (19.1%), and non-EU countries (11%). In Horizon 2020, among the signed projects, personal data was also the main ethics issue category (29%), followed by Humans (28%). The main difference is the introduction of Artificial Intelligence in Horizon Europe's ethics issues table, which is now among the top 3 main categories.




Source: Compiled by the study team based on EC provided Horizon Europe project data.

Projects concerning the ethical aspects in the health sector

In addition to the Ethical Appraisal Process, the RTD Ethics and Research Integrity sector also works on various projects concerning the ethical aspects (under Swafs in Horizon 2020 and now under WIDERA Work Programmes), which are directed towards raising awareness for the beneficiaries and indirectly increasing the effectiveness of the process. Some examples of the projects include:

- I-Consent (i-consentproject.eu). The project presents guidelines to improve informed consent in clinical studies. They publish the Guidelines for academia, clinical investigators, the pharmaceutical industry, ethical advisory boards, policymakers and anybody involved in the development of the informed consent process.
- EU-funded HYBRIDA project that aims to contribute to the Embedding of a comprehensive ethical dimension to organoïd-based research and resulting technologies.
- Beyond Bad Apples: Towards a Behavioral and Evidence-Based Approach to Promote Research Ethics and Research Integrity in Europe_(BEYOND), a project aiming to promote the highest standards of research ethics and integrity and to prevent research misconduct. This will be done by clarifying institutional and individual responsibilities for ensuring research environments conducive to ethical research.
- Irecs is a Horizon Europe project training researchers in ethics for new technologies.
- TechEthos preparing the ethical guidelines for ethics by design, bringing ethical and societal values into the design and development of technology from the beginning of the process.
- PREPARED (prepared-project.eu) while focusing on research ethics and integrity embedded in global equity, the project includes the voices of marginalised populations in work, delivering engaging, concise output for optimal training and impact.

A list of key guidance documents that were reviewed in this stage:

Rules & codes of conduct

- HE Regulation 2021/695: Eligible actions and ethical principles (Article 18) and Ethics (Article 19)
- HE Model Grant Agreement: Ethics (Article 14 and Annex 5)
- Statement by the Commission on research activities involving human embryos or human embryonic stem cells
- EU Charter of Fundamental Rights
- Ethics Advisors and Ethics Advisory Boards, Roles and Function in EU-funded Projects, version 2.0

General guidance

- How to complete your ethics self-assessment
- Guidelines on serious and complex ethics issues
- Guidelines for Promoting Research Integrity in Research Performing Organisation

Other

- Guidance note on potential misuse of research results
- Guidance note on research focusing exclusively on civil applications
- Ethics and data protection
- Ethics in Social Science and Humanities
- Guidelines on ethics by design/operational use for Artificial Intelligence

1.4.7. The matching investments of Clusters 1, 2, and 3

Cluster 1

The analysis has shown that during the interim phase of Horizon Europe, **the total sum of matching investment for Cluster 1 projects was around EUR 791.9 million**. This is **approximately 25% of total project costs**. When looking back at the predecessor SC1, around the same time in the programme, the assessment of matching investment was performed slightly differently, where the evaluators looked into the amount of euros mobilised for each EUR of EU contribution. However, at the end of the Horizon 2020 programme, the *Resilient Europe Phase 1 study*⁸⁵ found that Societal Challenge 1 had 2.2 billion matching investments or 26% of total project costs. Considering Cluster 1 is just in an interim evaluation phase, the share of matching investments of the total project costs is similar to that of Societal Challenge 1, which shows **a positive direction towards matching investments**. The breakdown of projects, their total costs, EU contribution and matching investments based on Cluster 1 and Societal Challenge 1 action types are presented in the Table below. As can be seen from the Table below, the majority of the matching investments come from the public body participants.

⁸⁵ European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et

al., Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1, Denham, S.(editor), Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2777/60819

	Cluster 1		Societal Challenge 1				
Action type	Projects (count)	Total cost (EUR) millions	EU contribution (EUR) millions	Sum of matching investments (EUR) millions	Share (%) of matching investment	Sum of matching investments (EUR) millions	% of matchi ng invest ment
COFU ND	268	1 051.2	359.6	691.6	66%	N/A	N/A
CSA	349	58.5	53.2	5.4	9%	70.6	21%
IA	28	17.6	13.6	3.9	22%	34.4	12%
PCP	7	5	5	0	0%	N/A	N/A
RIA	3 567	2 038.1	1.9	91	4%	265.1	7%
Total:	4 219	3 170.4	2.4	791.9	25%	2207.3	26%

Table 34. Cluster 1 and SC1 projects matching investments based on the action type

Source: Calculated by the study team using CORDA data.

The Figure below illustrates the Cluster 1 and Societal Challenge 1 share of matching investments by action types (CSA, IA, and RIA). In Cluster 1, the cofund actions provided 66% of matching investments, followed by the IA (22.4%), CSA (9.2%) and RIA (4.5%). In Horizon 2020, CSA (21%) and IA (12%) provided the highest share of matching investments. The relatively small contribution from research and innovation actions (RIA) in Societal Challenge 1 was explained by the nature of the instrument, as RIA projects were aiming at establishing new knowledge and/or exploring the feasibility of new or improved technology, product, process, service or solution⁸⁶. The EU funding rate for RIA calls in Societal Challenge 1 was 100%. In Horizon Europe, as in Horizon 2020, it is important to indicate that although the RIA attracted only 4% of the total Cluster 1 matching investment, the EU funding covers up to 100% of the project costs⁸⁷.



Figure 54. Cluster 1 and SC1 share of matching investments by action type

Source: Calculated by the study using CORDA data.

When looking at the distribution of matching investments based on the participant type, in the Horizon Europe interim stage, considering Cluster 1, the public body (PUB) attracted the

⁸⁶ https://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/find-a-call/what-you-need-to-know en.htm

⁸⁷ https://rea.ec.europa.eu/horizon-europe-how-apply_en

largest share of the total matching investments (59%). In contrast, the research organisations (REC) participation type had the most significant number of participants (1 170). The table below presents the breakdown of the number of participants, total costs, total EU contributions, the sum of matching investments, and their share of the total matching investments.

	Cluster 1	ter 1 Soc					Societal Challenge 1	
Participant type	No of participant s	Total cost (EUR) million s	EU contributio n (EUR) millions	Sum of matching investment s (EUR) millions	% of matching investme nt	Sum of matching investment s (EUR) millions	% of matching investme nt	
Public Body (PUB)	372	487.5	200.4	287.1	59%	160.5	33%	
Research Organisation s (REC)	1 170	1 142. 9	795.9	347	30%	156.4	11%	
Private for Profit (PRC)	874	474.6	411.7	62.9	13%	105.9	7%	
Other (OTH)	373	122	103.6	18.4	15%	15.5	7%	
Higher or Secondary Education (HES)	1 430	943.4	866.8	76.5	8%	68.2	3%	

Table 35. Matching investments based on participation type

Source: Calculated by the study using CORDA data.

The Figure below illustrates the matching investment contributions based on the participant type for Cluster 1 and Societal Challenge 1. It presents that for the interim stage of Horizon Europe, considering Cluster 1, the **public body participant type attracted the highest share of matching investments (59%)**, followed by research organisations (30%), other types (15%), private for-profit (13%) and higher or secondary education (8%). While in Societal Challenge 1, the share of matching investments for the selected participation types was lower, the trend of public bodies being the main contributors remains the same.





Source: Calculated by the study using CORDA data.

Cluster 2

Findings from previous studies and reports: The Resilient Europe Phase 1 study⁸⁸ concluded the sum of matching investment for SC6 actions leveraged was around EUR 118.4 million, representing 10% of total budget costs. The other type of participant (OTH) contributed the most, with 37% of total matching investments, followed by higher or secondary education institutions with 15% (HES) and private for-profit with 12% (PRC).

Findings: The analysis of the matching investments within Cluster 2 indicated that the total sum of matching investments in the interim stage of Horizon Europe is EUR 4.8 million, comprising 1% of total matching investments. For the Societal Challenge, the share of the matching investment was 10%. It is important to note that under Horizon Europe, more action types were reported, where co-funded actions comprised 70% of all matching investments, followed by SMEs (32%). The Table below presents a detailed breakdown of the Cluster 2 actions, their total costs, the EU contribution, and the matching investments per each action type.

	Cluster 2		Societal Challenge 6				
Action type	Project s (count)	Total cost (EUR) millions	EU contributio n (EUR) millions	Sum of matching investment s (EUR) millions	Share (%) of matching investme nt	Sum of matching investment s (EUR) millions	Share (%) of matching investme nt
CSA	72	14.3	13.4	0.8	6%	4.6	3%
RIA	1 434	415.7	411.7	3.9	1%	9.4	1%
Total:	1 506	429.9	425.2	4.8	1%	118.4	10%

Table 36. Matching investments based on the action type

Source: Calculated by the study using CORDA data.

The Figure below illustrates the share of matching investments by action types in Cluster 2 and Societal Challenge 6. Only two actions – CSA and RIA – are included in the graph, as only these two action types were reported under Cluster 2. The picture depicts that under Cluster 2 and Societal Challenge 6, the RIA actions contributed only 1% of matching investments. As indicated for Cluster 1, this could be explained by the different nature of the RIA action types.

Regarding the matching investments based on the participant type, the largest contributor in Cluster 2 was public bodies, comprising 6% of matching investments from the total costs. The second largest contributor was private for-profit participants, with 2% of matching investments from the total costs. The Table below presents the breakdown of the number of participants, total costs, total EU contributions, the sum of matching investments, and their share of the total matching investments.

⁸⁸ European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al., Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase

^{1,} Denham, S.(editor), Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2777/60819

	Cluster 2			Societal Challenge 6			
Participant type	No of participan ts	Total cost (EUR) million s	EU contributi on (EUR) millions	Sum of matching investmen ts (EUR) millions	% of matching investme nt	Sum of matching investmen ts (EUR) millions	% of matching investme nt
Public Body (PUB)	88	14.2	13.3	0.9	6%	3.4	1%
Research Organisatio ns (REC)	289	88.9	88.3	0.6	1%	892.6	1%
Private for Profit (PRC)	200	49.7	48.6	1.1	2%	23.7	12%
Other (OTH)	219	41.1	41	0.05	0%	44.9	37%
Higher or Secondary Education (HES)	710	236.1	233.9	2.1	1%	33.6	15%

Table 37. Matching investments based on participation type

Source: Calculated by the study using CORDA data.

The Figure above illustrates that in Cluster 2, the biggest contributors were public bodies (6%), private for-profit participants (2%) and higher or secondary education institutions (1%) with research organisations (1%). In Horizon 2020, within the Societal Challenge 6, the biggest contributors were other types of participants (37%), higher or secondary education institutions (15%), and private for-profit participants (12%).

Cluster 3

The matching investments under Cluster 3 during the interim stage of Horizon Europe comprised 10% of total costs (EUR 42.1 million), which suggests a similar trend as the predecessor SC7 reached at the end of Horizon 2020. When looking at the action types, Innovation Actions (IA) comprised 15% of matching investments from the total costs for the given action type. The breakdown of projects, their total costs, EU contribution and matching investments based on Cluster 3 action types is presented in the Table below.

	Cluster	r 3	Societal Challenge 7				
Actio n type	Proje cts (cou nt)	Total cost (EUR) millions	EU contribution (EUR) millions	Sum of matchin g investm ents (EUR) millions	Share (%) of matchin g investm ent	Sum of matchin g investm ents (EUR) millions	% of matchi ng invest ment
CSA	50	10.1	10.1	0.02	0%	2.3	1%
IA	778	258.3	219.2	39.1	15%	135.2	17%
RIA	556	171.6	168.6	2.9	2%	5.1	1%
Total	1 384	439.9	397.9	42.1	10%	171	10%

Table 38. Cluster 3 projects matching investments based on the action type

Source: Calculated by the study team using CORDA data.

The Figure below illustrates the share of matching investments in Cluster 3 based on the action types. It can be seen that Innovation Actions (IA) contributed by 15%, and Research and Innovation Actions (RIA) by 2%.

Regarding the participant type, the private for-profit participants contributed 20% of the matching investments. Other types contributed up to 1% of the matching investments. The breakdown of projects, their total costs, EU contribution and matching investments based on Cluster 3 participation types is presented in the Table below.

	Cluster 3					Societal Challenge 7			
Participant type	No of participan ts	Total cost (EUR) million s	EU contributi on (EUR) millions	Sum of matching investmen ts (EUR) millions	% of matcl inves nt	hing tme	Sum of matching investmen ts (EUR) millions	% of matching investme nt	
Public Body (PUB)	268	33	33	0.02	0%		6.3	4%	
Research Organisatio ns (REC)	284	102	101.4	0.7	1%		10.9	1%	
Private for Profit (PRC)	538	207.2	166.4	40.8	20%		149.5	19%	
Other (OTH)	83	20.1	20	0.03	0%		0.6	1%	
Higher or Secondary Education (HES)	211	77.7	77.1	0.5	1%		10.9	3%	

Table 39. Matching investments based on participation type in Cluster 3

Source: Calculated by the study using CORDA data.

1.4.8. Effectiveness of the Feedback to Policy process

The following section discusses the Feedback to Policy (F2P) process using the following indicators:

- Findings from the agency evaluation (REA and HaDEA) on the efficiency of the policy feedback process,
- Differences in the policy feedback process between H2020 and HE and the advancements made in this direction.

Even though the Inception Report mentions the calculation and the multifaceted comparison of costs associated with F2P activities⁸⁹, the study team was unable to perform such quantitative analysis due to several factors. Interviews and discussions with staff from both the Executive Agencies (EA) and the Commission underscored that F2P knowledge transfer is deeply embedded in the Agencies' operations, without a distinct subset of staff or events dedicated solely to F2P activities. Furthermore, the sensitive nature of the subject matter led to limited data accessibility, constraining the study team's ability to perform a more comprehensive and quantitative analysis. As a result, below we present our findings on the main changes and advancements in F2P processes, the ways F2P contributes to policymaking and some key drivers and barriers. The major sources for this analysis come from desk research, Executive Agency Evaluations, and Annual Activity reports.

Feedback to Policy Strategies and their evolution

Effective policymaking depends on input from programs and projects. The Executive Agencies (EAs) play a critical role in collecting and turning this information into useful feedback for the DGs. For this reason, it is paramount to have efficient and effective tools and mechanisms in place that will allow for timely and adequate communication of key knowledge and information.

Over the recent years, both REA (responsible for Cluster 2 and 3) and HaDEA (responsible for Cluster 1) have invested considerable effort in creating frameworks and systems designed for effective and actionable Feedback to Policy (F2P) aimed at bridging the gap between EU-funded projects and Commission policy goals. Recognising the need for a more structured F2P mechanism, they have taken steps towards creating a more formalised and institutionalised F2P system.

In 2021, REA took part in launching the unified Feedback to Policy Framework for the Research and Innovation (R&I) sector⁹⁰ and in 2022, the Agency further advanced its efforts in the implementation of this policy, with a goal to maximise the impact of EU-funded projects on policymaking for all DGs in the R&I family. To achieve this, the framework serves as a tool for steering, streamlining the methodology and monitoring, and applying expertise to specific

90 Annual Activity Report 2021, Research and Executive Agency (REA).

⁸⁹ The following indicators have been removed due to data limitations: Differences in costs associated with the F2P activities; Comparison of costs associated with F2P activities across different agencies and/or programme parts; Quantification of costs associated with the monitoring and evaluation systems and feedback to policy processes.

requests for data or analysis. Importantly, the framework pivots the orientation of policy feedback efforts to be more in line with immediate policy needs and priorities⁹¹.

Following the dissolution of CHAFEA, its successor agency, HaDEA, adopted the Policy Feedback Framework at the end of 2021. As a new player in the field, it was important for HaDEA to develop an efficient and effective feedback to policy mechanism⁹². Subsequently, in 2022, annual plans for Feedback to Policy were formulated for each of the programs or specific programme parts. According to the 2022 Annual Activity Report, the rate of implementation of these plans surpassed the target of 70% by the end of the year⁹³.

This recent Feedback to Policy Frameworks and subsequent activities, passed by both REA and HaDEA, represent a notable advancement compared to the F2P approaches employed under the previous Horizon 2020 framework⁹⁴. One of the key takeaways from agency evaluations during the Horizon 2020 period was the pressing need for more streamlined and formalised mechanisms for F2P. Evidently, this call for structured F2P has been heeded in the early years of Horizon Europe. More formal policy frameworks are being progressively rolled out, addressing the critiques and fulfilling needs expressed earlier. To complement this, following its recent cost-benefit analysis, Recognising this, the EC is set to bolster the F2P efforts with a 3% staff increase for EAs over the 2021-2027 period⁹⁵. The deliberate implementation indicates a thoughtful evolution toward a more robust F2P approach.

Framework to Policy Channels and Activities

Developing the Policy Feedback Framework is an important advancement in ensuring quality and timely policy inputs and the overall efficiency of this process. The active involvement of the DGs in understanding and setting the necessary goals is essential and directly addresses a broader challenge in determining what projects, outputs and subsequent conclusions would be most useful for making better policy proposals⁹⁶.

Upon the recommendations stemming from Horizon 2020 and EA evaluations, coordinated by unit GH6, different DGs and EAs have worked together to develop the Feedback to Policy Framework. Within this framework, joint teams work together to define policy needs as well as the needed inputs. These inputs are intended to go beyond collecting the information on project conclusions and contribute to a more holistic impact assessment. As a result, the outcomes can take different shapes, such as portfolios of results, analysis of projects, meetings with beneficiaries, etc.⁹⁷.

94 Study supporting the evaluation of CHAFEA, EACEA, EASME, ERCEA, INEA & REA (2017/2018-2021), (2023), Forthcoming.

⁹¹ Annual Activity Report 2022, Research and Executive Agency (REA).

⁹² Annual Activity Report 2021, Health and Digital Executive Agency (HADEA).

⁹³ Annual Activity Report 2021, Health and Digital Executive Agency (HADEA).

^{95 &}quot;Delegation of EU Porgrammes to Executive Agencies for 2021 – 2027", (2021)

 $https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/BUDG/DV/2021/02-01/Point10-Presentation-DelegationPackage_EN.pdf$

⁹⁶ REA Evaluation Study (2023). Forthcoming.

⁹⁷ Interview on Dissemination & Exploitation (D&E) and Feedback to Policy, 24/08/2023 , 14:00-15:00 CET, Ms Teams

However, it should also be noted that in addition to the set conditions by the Feedback to Policy Framework, the exchange of information from EAs to the Commission still occurs through a number of less structured and formal channels⁹⁸. For example, in REA, one of the main high-level channels of interaction between the Commission services and the Agency is the Steering Committee meetings. Occurring at least four times a year, the Agency ensures that all parent DGs involved receive the relevant information. Another significant channel for sharing information relevant to Feedback to Policy is the weekly meetings between REA's Director and the Directors of parent DGs. Similarly, Coordination meetings and Programme committee meetings play a major role in information sharing regarding the programme implementation in REA. Generally, agency reporting mechanisms provide the Commission with a comprehensive overview of the activities and their outcomes as overseen by the Agency. As a result, all of these channels of communication serve as a platform for policy exchange between the Agencies and the parent DGs.

In addition to the ongoing efforts to enhance F2P communication, much like in Horizon 2020, REA and HaDEA also utilised a diverse range of ad hoc communication methods to deliver F2P to its overseeing DGs at every stage of the policy cycle through less formal channels. Feedback was coordinated through corresponding units and persons within both the EAs and the parent DGs.

It appears that REA and HaDEA have followed through with the recommendations issued in the prior and took active steps towards establishing more structured F2P mechanisms while maintaining the existing informal processes. A nexus of this approach will allow for the EAs and DGs to gradually pave a smooth and functioning F2P framework, eventually leading to an effective and efficient transfer of policies.

Feedback to Policy Contribution to Policymaking

The contribution of F2P serves as a vital link in the policymaking process, ensuring that realworld data and experiences inform and shape legislative agendas. The F2P activities enable meaningful exchanges between project participants and policy officers, enhancing the impact of EU-funded projects on policy decisions.

In the early stages of the Horizon Europe framework, several noteworthy instances of F2P activities have made significant contributions to the Commission's policymaking efforts. According to REA's 2022 Annual Activity report, the Agency hosted the MSCA cluster event, bringing together researchers, experts, and EU policymakers to explore how the takeaways from these projects can shape the forthcoming R&I activities. Similarly, REA held its third edition of the Projects to Policy Seminar, where consortia and policymakers discussed the 45 newly funded projects from 2020 calls for proposals for Cluster 3. This opened up an opportunity for policymakers to engage directly with the most up-to-date information regarding novel advancements in civil security. REA also noted that data mining on its project portfolio contributed to some of the key legislative initiatives, such as evaluating the Bathing

⁹⁸ REA Evaluation Study (2023). Forthcoming.

Water Directive, preparing the new deal for Pollinators, and assessing the impact for the upcoming EU Soil Health Law⁹⁹.

HaDEA, too, consistently engaged with DG RTD, providing regular input and specific information regarding its projects in the Cluster 1 portfolio, specifically with regard to COVID-19¹⁰⁰.

REA and HaDEA mention utilising project clustering as an effective tool for establishing synergies between funded projects and boosting their cooperation. For instance, in 2022, HaDEA initiated a thematic cluster project focused on the "Health impacts of climate change, costs and benefits of actions and inaction"¹⁰¹. In collaboration with project beneficiaries, HaDEA agreed to organise joint workshops, facilitate knowledge sharing, and develop collaborative practices and communication activities to ensure maximum efficiency in feedback to policy sharing. In the forthcoming PPMI's Executive Agencies evaluation, project clustering was also something noted to be a valuable addition to the F2P process. So far, we are able to observe a gradual shift towards the positive changes recommended to improve the efficiency and effectiveness of the F2P process.

The communication between the EAs and beneficiaries is just as important as the communication between GDs and EAs. Evidence-based policymaking requires information and knowledge from multiple sources, which is why beneficiary feedback is crucial. Engaging beneficiaries and understanding their project results serve as a fundamental piece of the feedback to policy process. As a result, it is commendable that both REA and HaDEA within the HE framework demonstrate initiatives involving the DG members and the beneficiaries.

While it's too early to pinpoint specific policies that have emerged from the F2P feedback within the Horizon Europe framework program, it's clear that significant progress has been made in refining the F2P feedback mechanism. Given that these are the framework program's formative years, quantifying this process's impact is challenging. However, from an efficiency perspective, substantial improvements seem to have been made in enhancing communication and formalising channels with the European Commission.

Key drivers and barriers

A significant key driver that can't be overlooked is the **importance of maintaining informal communication channels**. While formal processes and mechanisms are needed to streamline the process, many interviewees from the forthcoming REA evaluation report noted that the informal communication between the DG and the EA employees is central to their collaborative work environment. Furthermore, having seconded staff from parent DGs proved to be an important asset in providing the Agency with key knowledge of EU policy activities. These processes allow for more flexible knowledge exchange, which has proven to be valuable for both the EAs and the DG. A downside of this would be the breach of this

⁹⁹ Annual Activity Report 2022. REA.

¹⁰⁰ Annual Activity Report 2021. HADEA.

¹⁰¹ Annual Activity report 2022. HADEA.

knowledge upon key staff turnovers. For this reason, having established formal F2P mechanisms is critical.

Based on interviews conducted for the upcoming REA evaluation study, **preliminary dialogues between parent DGs and EAs were found to enhance mutual understanding**, particularly in the realm of policy exchange. This early communication is another key driver, as it allows for a better understanding of higher policy objectives by the EAs and subsequent alignment with the Commission's needs.

F2P is inherently a multistakeholder process involving many actors whose coordination can be challenging, especially when scarce resources are scarce. According to Agency evaluation reports, this **intricate interplay of multiple actors and the scarcity of resources have been identified as barriers** that can potentially impede the efficiency of the F2P process.

The Commission's general challenge is understanding and determining what projects, outputs, outcomes, and subsequent monitoring information would be most useful for making better policy proposals. As a result, **constant and reliable communication between EAs and the DGs is crucial**. This will enable the GDs and EAs to determine when to take quantitative and qualitative approaches to various questions.

Since the launch of the Horizon Europe Framework Programme, both REA and HaDEA have actively participated in a multitude of F2P initiatives (some listed above). These involved key Commission staff, programme beneficiaries, and other major stakeholders. Agency evaluation interviews highlighted the **positive impact of organising collaborative exercises for enriching F2P exchanges**. The frequency of these events directly correlates with the depth and breadth of information exchange, thereby expanding the scope of shared knowledge. However, this ambitious approach comes with its own set of challenges. Limited resources and staff capabilities within the Agencies, coupled with the often low engagement levels of beneficiaries, pose substantial obstacles to maximising the effectiveness of these collaborative efforts.

In summary, the F2P processes have been given greater attention, most notably through initiating and continuously refining the Feedback to Policy Framework for each programme and programme part. This represents a marked improvement over the approaches employed during Horizon 2020. However, given the program's infancy, it remains challenging to accurately measure the scale, efficiency, and long-term impact of F2P activities on policymaking. While strides have been made, a comprehensive assessment will require further time and data to gauge the efficacy of these efforts.

Annex 2: Intervention logic for analysed programme parts

The subsequent sections present intervention logic for Horizon Europe and the relevant programme parts covered under this study. The intervention logics for the overall Horizon Europe programme, EDCTP2 and IMI2 have been reused from a recent report, whereas intervention logics for Cluster 1, 2, 3, IMI2 partnership and EIT Health have been developed as part of this study.

1.5. Horizon Europe intervention logic

According to the impact assessment accompanying the Commission proposal for Horizon Europe³⁰, the **general objective** is: 'to strengthen the scientific and technological bases of the Union and foster its competitiveness, including for its industry; to deliver on the EU's strategic policy priorities and contribute to tackling global challenges, including the Sustainable Development Goals.'

Horizon Europe has broad lines of activities divided into three pillars facilitating the process when reaching the general objective:

- Pillar 1: Excellent Science (Open Science, including the European Research Council, Marie Sklodowska-Curie's actions, and various Research Infrastructures).
- Pillar 2: Global Challenges and Industrial Competitiveness (divided into five clusters).
- Pillar 3: Innovative Europe (Open Innovation that includes the European Innovation Council, support to the innovation ecosystem, European Institute of Innovation and Technology).

The operational objectives of Horizon Europe are divided according to the Key Impact Pathway Indicators (KIPs):

Scientific impact pathway indicators

- 1. Creating high-quality new knowledge
- 2. Strengthening human capital in R&I
- 3. fostering the diffusion of knowledge and Open Science

Societal impact pathway indicators

- 1. addressing EU policy priorities through R&I
- 2. delivering benefits and impact through R&I missions
- 3. strengthening the uptake of research and innovation in society

Economic/technological impact pathway indicators

- 1. influencing the creation and growth of companies
- 2. creating direct and indirect jobs
- 3. leveraging investments for research and innovation

The specific objectives of Horizon Europe are:

- 1. to support the creation and diffusion of high-quality new knowledge, skills, technologies and solutions to global challenges.
- 2. to strengthen the impact of research and innovation in developing, supporting and implementing Union policies, and support the uptake of innovative solutions in industry and society to address global challenges.
- 3. to foster all forms of innovation, including breakthrough innovation, and strengthen the market deployment of innovative solutions.
- 4. to optimise the Programme's delivery for increased impact within a strengthened European Research.

In addition to the specific objectives, Horizon Europe presents destinations that were not part of the Horizon 2020 programme. Destinations are divided for each cluster to respond to the expected impacts (a more detailed overview of each cluster's Intervention Logic is below). Destinations are addressed in EU calls for proposals, reflected in each Cluster's Work Programmes.

Figure 56. Horizon Europe intervention logic



Source: European Commission, DG Research and Innovation³¹.

1.5.1. Cluster 1 – Health intervention logic

The Figure below illustrates the developed intervention logic of **Cluster 1 – Health**. It is divided into five parts – needs, objectives, activities, destinations and expected impacts. The strategic orientations are also listed.

First of all, Cluster 1 has the needs that lead to the specific objectives. The needs, according to the Horizon Europe Strategic Plan 2021-2024, are advancing knowledge and capabilities, improving the understanding of health and diseases, developing innovative methodological and technological solutions to better manage health and diseases, designing sustainable approaches for the digital transformation and delivery of integrated, person-centred and equitable health and care services.

Cluster 1 has the specific objectives:

- Unleashing the full potential of digital tools and data-enabled research and innovation;
- Europe fit for the digital age;
- Convergence of pharmaceutical, digital and medical technologies;
- Data-driven manufacturing of tailor-made products;
- Increasing productivity and supporting the sustainability of the health-related industry and SMEs;
- Mainstreaming of personalised healthcare services (Triple Aim³² approach).

Some activities support the realisation of the objectives and needs. For instance, the EU4Health programme was adopted as a response to COVID-19 and is expected to contribute to building stronger, more resilient and more accessible health systems in the EU. Within the Cluster 1 scope, EU4Health works with Europe's Bearing Cancer Action Plan to support Member States in improving cancer prevention, control and care. Moreover, to achieve the expected impacts, the vital activity is to ensure cooperation among the Member States and mobilise researchers, academics, healthcare providers, SMEs, large companies, and citizens. Additionally, the One Health approach is selected within Cluster 1 as one of the actions facilitating the impact on citizens' health and well-being related to environmental crises, such as pollution, zoonotic diseases, and climate change.

Following the objectives, needs and activities, Cluster 1 has six destinations listed in the Horizon Europe Work Programme 2021-2022, Section 4. Health.

- 1. **Staying healthy in a rapidly changing society.** The destination contributes to the impact area 'Good health and high-quality, accessible healthcare' and leads to the expected impact 'citizens of all ages stay healthy and independent in a rapidly changing society thanks to healthier lifestyles and behaviours, healthier diets, healthier environments, improved evidence-based health policies, and more effective solutions for health promotion and disease prevention'.
- 2. Living and working in a health-promoting environment. The destination contributes to the impact area called 'A resilient EU prepared for emerging threats' and leads to the expected impact: 'living and working environments are health-promoting and sustainable thanks to a better understanding of environmental, occupational, social and economic determinants of health'.
- 3. Tackling diseases and reducing disease burden. The destination contributes to the impact area called 'Good health and high-quality, accessible healthcare' and leads to the expected impact 'healthcare providers are able to better tackle and manage diseases (infectious diseases, including poverty-related and neglected diseases, non-communicable and rare diseases) and reduce the disease burden on patients effectively thanks to better understanding and treatment of diseases, more effective and innovative health technologies, better ability and preparedness to manage epidemic outbreaks and improved patient safety.'
- 4. Ensuring access to innovative, sustainable, and high-quality healthcare. The destination contributes to the impact areas 'Good health and high-quality, accessible healthcare' and 'A resilient EU prepared for emerging threats'. It leads to the expected impact 'Healthcare systems provide equal access to innovative, sustainable and high-quality healthcare thanks to the development and uptake of safe, cost-effective and people-centred solutions, with a focus on population health, health systems resilience, as well as improved evidence-based health policies'.
- 5. Unlocking the full potential of new tools, technologies and digital solutions for a healthy society. The destination contributes to the impact area 'High-quality digital services for all' and also leads to the expected impact 'Health technologies, new tools and digital solutions are applied thanks to their inclusive, secure and ethical development, delivery, integration and deployment in health policies and health and care systems effectively'.
- 6. Maintaining an innovative, sustainable and globally competitive health industry. The destination contributes to the impact area called 'A competitive and

secure data economy and leads to the expected impact 'EU health industry is innovative, sustainable and globally competitive thanks to improved up-take of breakthrough technologies and innovations, which makes the EU with its Member States more resilient and less dependent from imports with regard to the access to and supply of critical health technologies'.

These impacts of Cluster 1 will ultimately contribute to the broader strategic orientations:

- Increase Europe's autonomy in delivering healthcare by contributing to safe, trusted, more effective, efficient, affordable and cost-effective technologies and solutions for improved health promotion and disease prevention, diagnosis, treatment and monitoring for better health outcomes and well-being by integrating people in the design and decision-making.
- 2. Improve the knowledge of the impacts of environmental degradation and occupational lifestyle risk factors on human health and well-being.
- 3. Deliver cleaner, greener and circular design health technologies to make the EU more sustainable and competitive.
- 4. Promote and protect human health and well-being, preventing communicable and non-communicable diseases and decreasing the burden of diseases and disabilities on people and communities; disease prevention and fair access for everyone.

Figure 57. Intervention logic (Cluster 1)



Source: Compiled by the study team, based on Horizon Europe Strategic Plan for 2021-2024³³ and Cluster 1 WP 2021-2022³⁴. Note: *Triple Aim refers to the following three aims: i) improving the patient experience of care (including quality and satisfaction), ii) improving the health of populations, iii) reducing the per capita costs of healthcare.

1.5.2. Cluster 2 – Culture, Creativity & Inclusive Society intervention logic

Cluster 2 – Culture, Creativity and Inclusive Society aims to enhance democratic governance and citizen participation; safeguard and promote cultural heritage; respond to and shape multifaceted social, economic, technological and cultural transformation; and mobilise multidisciplinary expertise of European Social Sciences and Humanities.

Cluster 2 also addresses the unprecedented societal consequences caused by the outbreak of the COVID-19 pandemic. To this end, it will mobilise social sciences, researchers and scientists to provide evidence-based policies that will contribute to recovery and enhance resilience and responsiveness to future crises.

Cluster 2 addresses EU priorities that give a new push to European democracy, Promote the European way of life, a stronger Europe in the world, make Europe fit for the digital age, and support an economy that works for people; the European Green Deal, protect our European way of life, make Europe stronger in the world; better management regarding migration and mobility, Protection of European cultural heritage and stimulation of creativity.

The activities of Cluster 2 entail an enhanced budget (from EUR 1.3 billion under Horizon 2020 to EUR 2.3 billion in Horizon Europe) and emphasize democratic governance, cultural heritage, the creative economy, and economic transformations. All these challenges are interconnected and address EU citizens' most pressing socio-economic, cultural, and political concerns.

As the Figure below demonstrates, Cluster 2 is composed of three impact areas or destinations: Democracy and Governance (DEMOCRACY), European Cultural Heritage and the Cultural and Creative Industries (HERITAGE) and Social and Economic Transformations (TRANSFORMATIONS).

Figure 58. Cluster 2 intervention logic

Destination 1: DEMOCRACY More fragile and vulnerable democracies than in the	OBJECTIVES	INPUTS		EXPECTED OUTPUTS		EXPECTED	IMPACTS	-/-
pass Declining levels of trust in the political institutions of democracy Multilateral global governance is under historic stress	To enhance democratic governance and	ACTIVITIES		Policy recommendations New innovative tools and methods	Societal impacts: 1. Democratic governance is reinvigorati improving the accountability, transparr effectiveness and trustworthiness of		acts: is reinvigorated by lity, transparency, orthiness of	OCRACY
Destination 2: HERITAGE Huge challenges on cultural heritage related to distance hange, polition, natural, man-made distances. Access to cultural resources requires high-quality digitalization and curation of digital assets. Europe's CGS not sufficiently manage digitalization and curation of digital assets. Eroding social fabric and consciousness of societies sterogherupe's CGS not sufficiently may be the sense of belonging and fostering sterogherupe's CGS not well-being How to exploit ongoing changes to create more inclusive societies. Creating a more resilient, inclusive and dieno the divergement of levy digital, enabling and menging technologies, sectors and value chains Creating a more resilient, inclusive and democratic European recovery Promoting in opers strategic autonomy by leading the divergement of levy digital, enabling and energing technologies, sectors and value chains Creating a more resilient, inclusive and democratic European recovery Promoting in Operand many of the Astronger European way of the Astronger European way of the Astronger European way of the Astronger fur on twois for people Green & Digital transitions Better manage migation and mobility Protect our cultural heritage and stimulate creativity	citizens' participation To safeguard and promote cultural heritage To respond to and shape multifaceted social economic	Cluster 2 Work Programme 2021-2022 Protecting and nurturing democracies Reshaping democracies I &	Research and innovation actions Coordination and support actions	Community-based and evidence-based innovations Policy approaches and tools to tackle antidemocratic tendencies Forecasts and scenario of geopolitical phenomena	rule-of-law based institutions and poli 2. The full potential of cultural heritage, and cultural and creative sectors		al heritage, arts sectors	CULTURAL DEM
	Social economic, technological and cultural transformation To mobilise multidisciplinary expertise of European social sciences and Humanities To provide evidence-based policy options for a socially just and inclusive European recovery	vition in the search and innovation on cultural heritage and CCIs I is at II and the stage and CCIs I is at II and the stage and CCIs II and the stage and CCIs II and the stage and CCIs II inclusiveness in times of change statistical future for Europe I & II Cluster 2 Work Programme 2023-2024	Innovation actions Grant to identified beneficiaries	Innovative on-site and remote methods in Cultural Hentage Cultural Iteracy Better-informed decision-making and policy implementation Innovative cligital technologies and datasets Skills development Workshops and networking events	1. Soci sust 2. Inclu vuln throi prot eduu ineq soci COV	Economic impacts: Social and economic resilience and sustainability. Inclusive growth is boosted and vulnerabilities are reduced effectively through evidence-based policies for protecting and enhancing employment, deutation, social fairness and tackling inequalities, including in response to the socieeconomic challenges due to the COVID-19 pandemic.		SOCIAL AND ECONOMIC
	European recurvery Standing up for democracy Past, present and future of democracies Research and innovation on cultural heritage and CCIs – 2023 & 2024 A European Collaborative Cloud for Cultural Heritage Inclusiveness in times of change A sustainable future for Europe		Citizens' participation Farget group Policymaiers Research co Experts, Cult heratage prof and stakehol Local/region Civil society	bs in mmunity, ural essionals ders, al/national itizens,	External and internal factors Demographic trends Globalisation Technological change	Other EU policies Creative Europe, Erasmus-, Global Europe, the EU's Neighbourhood, Development and International Coope Instrument, DEP, R Support Programm CERV, ESF+, EPD EAFRD, InvestEU,	ration eform a, AMIF	

Source: Compiled by the study team based on Strategic Research and Innovation Agenda.

1.5.3. Cluster 3 – Civil Security for Society intervention logic

The Figure below illustrates the developed intervention logic of **Cluster 3 – Civil Security** for **Society**. It is divided into 4 parts – needs, objectives, destinations and expected impacts.

The needs that lead Cluster 3 to the specific objectives to enhance EU responses to security challenges while safeguarding free movement and the integrity of the Schengen area. This entails promoting a resilient and stable Europe, supporting a competitive European civil security industry sector, and utilising security research to transition from a reactive to a proactive approach based on foresight, prevention, and anticipation, particularly in light of rapidly evolving challenges and complex social and technological developments.

Cluster 3 has the specific objectives:

- Developing and using effectively EU and Member States' capabilities in digital technologies supporting the protection of data and networks aspiring to technological sovereignty in this field while respecting privacy and other fundamental right;
- Losses from natural, accidental and man-made disasters are reduced;
- Legitimate passengers and shipments travel more easily into the EU, while illicit trades, trafficking, piracy, terrorist and other criminal acts are prevented;
- Crime and terrorism are more effectively tackled while respecting fundamental rights;

• Resilience and autonomy of physical and digital infrastructures are enhanced, and vital societal functions are ensured.

Following the needs and objectives, Cluster 3 foresees 6 destinations listed in the WP 2021-2022³⁵ guiding and leading the work of Cluster 3 to the expected impacts:

- 1. Better Protect the EU and its Citizens against Crime and Terrorism. This destination responds to the expected impact: 'Crime and terrorism are more effectively tackled, while respecting fundamental rights, [...] thanks to more powerful prevention, preparedness and response, a better understanding of related human, societal and technological aspects, and the development of cutting-edge capabilities for police authorities [...] including measures against cybercrime'.
- 2. Effective Management of EU External Borders, responding to the expected impact of 'Legitimate passengers and shipments travel more easily into the EU, while illicit trades, trafficking, piracy, terrorist and other criminal acts are prevented, due to improved air, land and sea border management and maritime security including better knowledge on social factors.'
- 3. **Resilient Infrastructure.** The expected impact of this destination is that '[...] resilience and autonomy of physical and digital infrastructures are enhanced, and vital societal functions are ensured, thanks to more powerful prevention, preparedness and response, a better understanding of related human, societal and technological aspects, and the development of cutting-edge capabilities for [...] infrastructure operators [...].'
- 4. Increased Cybersecurity. Expected impact: "Increased cybersecurity and a more secure online environment by developing and using effectively EU and Member States' capabilities in digital technologies supporting the protection of data and networks aspiring to technological sovereignty in this field, while respecting privacy and other fundamental rights; this should contribute to secure services, processes and products, as well as to robust digital infrastructures capable of resisting and countering cyber-attacks and hybrid threats."
- 5. Disaster-Resilient Society for Europe. The destination's expected impact is that 'losses from natural, accidental and man-made disasters are reduced through enhanced disaster risk reduction based on preventive actions, better societal preparedness, and resilience and improved disaster risk management in a systemic way.'
- 6. **Strengthened Security Research and Innovation.** This destination has three expected impacts:
 - 'generate knowledge and value in cross-cutting matters in order to avoid sector specific bias and to break silos that impede the proliferation of common security solutions';
 - 'strengthen key pillars of the research and innovation cycle to increase the effectiveness and efficiency of its contribution to the development of security capabilities';
 - 'support innovation uptake and go-to-market strategies with the aim of paving the way towards an increased industrialisation, commercialisation, adoption and deployment of successful outcomes of security research, thus

contributing to reinforce the competitiveness of EU security industry and safeguard the security of supply of EU products in key security areas.'

These impacts of Cluster 3 will ultimately contribute to the broader strategic orientations:

- To contribute to establishing, deploying and stewarding resilient critical digital and physical infrastructure, both private and public. Strengthened European cybersecurity industrial capacities and the uptake of architectural principles of 'security-by-design' and 'privacy-by-design' in digital technologies will create increased open strategic autonomy, competitive edge, and leadership in global markets vis-à-vis foreign technologies.
- 2. To defend the EU's high standards concerning the right to privacy, protection of personal data, and the protection of other fundamental rights in the digital age on the global stage.
- 3. To support EU responses to security challenges while ensuring free movement and protecting the integrity of the Schengen area.

Figure 59. Cluster 3 intervention logic

NEEDS	OBJECTIVES				
Support wider EU responses to the security challenges	Developing and using effectively EU and Member States' capabilities in digital technologies supporting protection of data and networks aspiring to technological sovereignty in this field, while respecting privacy and other fundamental rights				
Ensure free movement and	Losses from natural, accidental and man-made disasters are reduced				
Schengen area- supporting 'a resilient and more stable Europe that protects'	Legitimate passengers and shipments travel more easily into the EU, while illicit trades, trafficking, piracy, terrorist and other criminal acts are prevented				
Support a competitive European	Crime and terrorism are more effectively tackled, while respecting fundamental rights				
Civil security industry sector	Resilience and autonomy of physical and digital infrastructures are enhanced and vital societal functions are ensured				
DESTINATIONS	EXPECTED IMPACTS				
Better protect the EU and its citizens against Crime and Terrorism	me and terrorism are more effectively tackled, while respecting fundamental rights, [] thanks to more verful prevention, preparedness and response, a better understanding of related human, societal and hnological aspects, and the development of cutting-edge capabilities for police authorities [] including asures against cybercrime.				
Effective management of EU external borders	jitimate passengers and shipments travel more easily into the EU, while illicit trades, trafficking, piracy, orist and other criminal acts are prevented, due to improved air, land and sea border management and ritime security including better knowledge on social factors				
Resilient infrastructure	resilience and autonomy of physical and digital infrastructures are enhanced and vital societal functions ensured, thanks to more powerful prevention, preparedness and response, a better understanding of ated human, societal and technological aspects, and the development of cutting-edge capabilities for [] astructure operators [].				
Increased Cybersecurity	reased cybersecurity and a more secure online environment by developing and using effectively EU and mber States' capabilities in digital technologies supporting protection of data and networks aspiring to hnological sovereignty in this field, while respecting privacy and other fundamental rights; this should htribute to secure services, processes and products, as well as to robust digital infrastructures capable to ist and counter cyber-attacks and hybrid threats.				
A Disaster-Resilient Society for Europe	sses from natural, accidental and man-made disasters are reduced through enhanced disaster risk duction based on preventive actions, better societal preparedness, and resilience and improved disaster k management in a systemic way.				
Ge	enerate knowledge and value in cross-cutting matters in order to avoid sector specific bias and to break os that impede the proliferation of common security solutions				
SSRI (Strengthened Security Research and Innovation)	Strengthen key pillars of the research and innovation cycle to increase the effectiveness and efficiency of ts contribution to the development of security capabilities.				
Su inc res	pport innovation uptake and go-to-market strategies with the aim of paving the way towards an reased industrialisation, commercialisation, adoption and deployment of successful outcomes of security search, thus contributing to reinforce the competitiveness of EU security industry and safeguard the curity of supply of EU products in key security areas.				

Source: Compiled by the study team based on Horizon Europe Strategic Plan for 2021-2024³⁶ and Cluster 3 WP 2021-2022³⁷.

Annex 3: Methodologies used

On 1st December 2021, the Directorate General for Research and Innovation initiated an Evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe. This report focused on Phase 2 and supported the interim evaluation of Horizon Europe.

With the support of a Working Group drawn from the services of the R&I family DGs and an InterService Group also comprising other Commission services, the study was implemented by external experts PPMI, in collaboration with Prognos, VTT and the Maastricht University. Phase 2 of the study began in 2023 and was guided by the Tender Specifications under the Specific Contract under the Multiple Framework Contract N° 2018/RTD/A2/OP/PP-07001-2018.

1.6. Main data sources

The study was based on the key methods including:

- **Desk research** Desk research was a key source of evidence involving reviewing strategic documents, policy documents, reports, CORDA administrative data, evaluations and assessments.
- Interview programme The interview programme for Phase 2 was comprehensive, representative and balanced. The interviews were designed around evaluation questions to cross-analyse, validate, and supplement quantitative data and qualitative findings from desk research and literature overview. >200 interviews were used to analyse specific programme parts and assess partnerships covered under the study. The information gathered through the interviews was integral to all inputs during the study period, including the interviews contributed to the analysis of the five evaluation criteria (i.e., relevance, coherence, efficiency, effectiveness, EU added value), as well as the partnership-specific criteria of the programme.
- **Surveys** The two surveys (1 successful applicant organisation and 2 unsuccessful applicant organisations) enabled the comparison of organisations that benefited from participation in Horizon Europe and similar organisations that did not benefit from participation in Horizon Europe, "the treated group" and "comparison/control group", respectively. The surveys were launched on 22 May and 19 May 2023, respectively.
- Online Public Consultation (OPC) As part of our data collection activities, the study team analysed the raw data of the OPC published by the EC in April 2023. The OPC covered several evaluation questions focusing on the performance of Horizon Europe, the Strategic Plan of Horizon Europe, key lessons learned, and messages for the future. The Factual Summary Report and Synopsis Report published by EC are incorporated in the findings.
- **Case studies** 15 case studies contributed to the supporting study's analysis. The case studies are included in Annex 4 of this report.

- **Benchmark reports** In total, 4 benchmark studies were completed in Phase 2 of the study. Completed benchmark reports are included in this report in Annex 5.
- Additional methods In addition to the data sources mentioned above, the study team carried out several quantitative methods, such as bibliometric analysis, network analysis, analysis of synergies with programmes outside of Horizon Europe, analysis of unstructured company data (FET scores), and SDG analysis.

1.7. Overview of the interview programme

The primary purpose of the interviews was to contribute to findings linked to case studies, benchmarks, specific programme parts, and the assessment of partnerships covered by the study. The overall goal for Phase 2 of the study was to complete >200 interviews. **The study team completed 210 interviews**, of which 30 were EC Officials.

As seen in the Table below, 21 exploratory interviews with EC officials were conducted during the inception stage. During the interim stage, the interviews with EC officials were conducted for CL1, CL2, CL3, case studies and benchmarks (30 interviews). Interviews with stakeholders and beneficiaries were conducted for case studies and benchmarks (159 interviews).

Phases of the evaluation (Horizon Europe)	Purpose	Approximate number of interviews
Inception stage	Explanatory interviews with EC officials	21
Interim stage	Interviews with EC officials	30
	Interviews with stakeholders and beneficiaries	159
Total		210

Table 40. Number of interviews conducted during inception and interim stages

Source: Compiled by the study team.

The Table below presents a detailed breakdown of the completed interviews. It is divided into three parts – interviews for specific programme parts (CL1, CL2, and CL3), interviews for Co-funded partnerships, and other programme parts.

	Breakdown of the complete inte	erviews for specific programme	parts	
Programme part	Exploratory interviews	Stakeholder	Number of interviews	Total
Cluster 1	Cluster 1	EC officials, some interviews dedicated to the whole cluster, e.g., the interview for Cluster 1 discussing all the relevant case studies and benchmarks	2	7
	CS1&2: IMI2/IHI	EC officials, IHI team	3	
	CS5: EDCTP3	EC official	1	
	CS6: Cancer Mission	EC official	1	
Cluster 2	Cluster 2	EC officials, some interviews dedicated to the whole cluster, e.g., the interview for Cluster 2 discussing all the relevant case studies	2	4
	CS8: CCIs	EC official	1	
	B3: Measuring societal impact in Cluster 2	EC official	1	
Cluster 3	Cluster 3	EC officials	2	4
	CS12: Cybersecurity	EC officials	2	
Co-funded	CS13: THCS	EC official	1	4
partnerships	CS14: ERA4Health	EC official	1	
	CS15: PARC	EC official	2	
Other	Partnerships	EC official	1	2
	Gender equality	EC official	1	
Programme part	Interviews	Stakeholder	Number	Total
Cluster 1	Cluster 1 (effectiveness and ethics)	EC officials, some interviews covered different parts of the study	5	77
	Cluster 1 (Coherence)	EC officials, some interviews covered different parts of the study	2	
	CS1&2: IMI2/IHI	IHI stakeholders/beneficiaries, EC officials	18	
	CS3&4: EIT Health	EIT stakeholders, EC officials	16	
	CS5 & partnership: EDCTP3	GH EDCTP3 JU stakeholders, EC officials	14	
	CS6: Cancer Mission	Beneficiaries, National contact points, EC officials, some interviews covered different parts of the study	13	
	B1: NIH response to Covid- 19	NIH stakeholders/beneficiaries	7	

Table 41. Breakdown of the completed interviews for specific programme parts

	B2: Gender equality and inclusion practices	Stakeholders	2	
Cluster 2	CS7: Research on democracy	Stakeholders	10	33
	B3: Measuring societal impact in Cluster 2	Stakeholders	2	
	CS9: Well-being and Tackling Inequalities	Beneficiaries	7	
	CS8: CCIs	Beneficiaries, EC official	7	
	B3: Measuring societal impact in Cluster 2	Stakeholders	7	
Cluster 3	CS10&11	Beneficiaries	23	47
	CS12: Cybersecurity	Beneficiaries	17	
	B2: Gender equality and inclusion practices	Stakeholder & beneficiaries	2	
	B4: Civil Security Programme	Stakeholders	5	
Co-funded partnerships	CS13: THCS	THCS stakeholders, EC official	10	31
	CS14: ERA4Health	ERA4Health co-funded partnership stakeholders, EC officials	14	
	CS15: PARC	Beneficiaries	7	
Other	Programme level	EC official	1	1

Source: Compiled by the study team.

The Table below serves as an evidence matrix outlining the source of information utilised for each evaluation criterion and corresponding evaluation question. The matrix details the specific data sources (i.e., desk research, interviews, surveys, OPC, case studies, benchmark reports, and additional methods) linked to each evaluation question.

Table 42. Evidence matrix

Evaluation question	Source	s of infor	mation				
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods
RELEVANCE							
RV1: How relevant has the support to innovation by the Framework Programme been given the stakeholders' needs and considering the scientific, technological and/or socio-economic problems and issues identified at the time of its design and over time?	Х		Х	Х	Х		X

Evaluation question	Source	Sources of information					
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods
RV2: To what extent have the supported thematic areas ¹⁰² taken into account the latest technological, scientific and/or socio-economic developments at the national, European and international levels? RV2.1: What are the emerging needs in this area that the Framework Programme has not covered?	Х			X	X	X	
RV3: Has the Framework Programme tackled the right issues given the positioning of European Union in this area since the programme started and over time?	Х			х	Х	х	х
RV4: To what extent has the Framework Programme support to innovation addressed the needs of groups targeted for application/participation in terms of tools and thematic areas covered? RV4.1: Are the activities as they exist today appropriate to address the needs? RV4.2: What is missing?	Х		Х	Х	X		Х
RV5: To what extent has the Framework Programme demonstrated to be flexible to cope with changing circumstances in Europe and in the world?	Х			х	Х	х	х
RV6: To what extent have the objectives of the partnerships been, and are still relevant regarding the challenges and needs addressed in this area by the Framework Programme? RV6.1: How flexible partnerships in this area have proved to be, in updating the Strategic Research Innovation Agendas, or equivalent strategic documents, adjusting objectives, activities and resources to changing market and/or policy needs?	X				X		

¹⁰² Thematic areas identified in the Horizon work programmes

Evaluation question	Sources of information						
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods
RV7: In which areas is the participation of international partners and Associated Countries the most relevant? RV7.1: How does this participation fit into the objectives of the Framework Programme, including to reinforce Europe's relative positioning?	X		X		X		X
RV8: What was the timeliness of the performed research and innovation activities in comparison with scientific and technological progress in the Resilient Europe area and the emergence of new research needs? RV8.1: How reactive was the programme in this context?	Х				Х		Х
RV9: Did the health research and innovation activities funded under Horizon Europe align/lead the state- of-art in the respective field of research and drive at the international level the emergence of new research approaches/tools/methodologies	X				Х		Х
RV10: To what extent have security- related research and innovation activities funded under Horizon Europe met stakeholders' needs?	Х		х	Х	х		х
	COHI	ERENCE					
 CH1: How coherent has the Framework Programme been in this area, in particular: between Framework Programme parts covered by this study with other parts of the Framework Programme not covered by this study with other EU programmes serving similar objectives with relevant national, regional or international initiatives. 	X		X		X		

Evaluation question	Source	Sources of information					
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods
CH2: What is the positioning of the Framework Programme in this area within the overall European research and innovation landscape (incl. R&I funds at national, regional and European levels) and beyond (at international level)?	Х				Х		
CH3: What could be done to improve the coherence of the Framework Programme interventions in this area with other initiatives to better deliver on the European Union policy objectives?	x		x		x		
CH4: How is the level of coherence among partnerships, and between partnerships and the Framework Programme activities in this area? CH4.1: Are partnerships more effective in achieving synergies, compared to other modalities of the programme?	Х	X		X	Х		
CH5: What was the usefulness and impact of the development of -or participation to international programme-level cooperation multilateral initiatives, e.g., European or International consortia of health research funding agencies, such as the International Human Epigenome Consortium (IHEC), the Global Alliance for Chronic Diseases (GACD), the preparedness research funders network (GlopID-R), the International Traumatic Brain Injury Research consortium (InTBIR), the International Rare Disease Research Consortium (IRDiRC), HIRO (Heads of International Biomedical Research Organisations), the International Consortium for Personalised Medicine (IC-PERMED), the Coalition for Epidemic Preparedness Innovations (CEPI)?	X	X					
CH6: What was the internal coherence of Cluster 1 in terms of adequacy of the instrument (grants, loans, innovation procurements, ERANET cofunds, grants funded	Х						х

Evaluation question	Sources of information						
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods
under the main brand (Clusters), JPIs or under institutional partnerships? CH6.1: Did the different instruments cover different grounds? CH6.2: Did they adequately spread over the different phases of the innovation cycles?							
CH7: How coherent have the Cluster 2 interventions been with the 'Rights, Equality and Citizenship' programme, the 'Europe for Citizens' programme' (or their successor, the ('Citizens, Equality, Rights and Values' programmer), the 'European Neighbourhood Instrument' or other related programmes?	Х			Х	X		Х
CH8: How coherent have the security related research and innovation activities funded under Horizon Europe been with the Justice Programme, the Asylum, Migration and Integration Fund, the Internal Security Fund, the Border Management and Visa Instrument (BMVI), the Common Customs Equipment Instrument, the European Defence Fund, the Digital Europe Programme and the EU Civil Protection Mechanism?	X	X	X				X
CH9: To what extent did the research and innovation security related activities funded under Horizon Europe build synergies and complement activities of other relevant programmes, such as Horizon 2020 ICT-LEIT, CEF and the Digital Europe Programme?	Х	Х	Х				Х
	EFFI	CIENCY					
EFF1: How efficient have implementation processes of the Framework Programme in this area been in terms of administration and management, project application and selection processes, funding allocation, forms of implementation (e.g. partnerships, collaborative	Х	Х					

Evaluation question	Sources of information						
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods
research, blending; bottom-up/top- down actions)?							
EFF4: To what extent are project application, management, and reporting being performed by organisations other than those performing the research and innovation activities? What are the underlying reasons and implications (e.g. in terms of costs, quality of applications, R&I activities) for the beneficiaries and for the Commission?	Х		X				
EFF6: How "proportionate" were the costs of application and participation borne by different stakeholder groups, taking into account the associated benefits?	х	х	х				
EFF6.1: Are the administrative costs borne by applicants and participants lower, higher or constant if compared with the previous Framework Programme?	Х	х	х				
EFF7: How to lower costs of applications and increase benefits from participation for the applicants (i.e. cost of writing proposals) and Commission services (i.e. cost of administrating and running the programme)?	Х	Х	Х	Х			
	EFFEC	TIVENES	SS				
EFC1: What are the main results and (expected) outcomes and impacts from the projects supported in this area?	Х	Х	Х	х	Х		х
EFC1.1: Is the delivery of the projects' results all together leading to the achievement of the programme's objective(s) in this area? EFC1.2: What is needed to be able to reach the objectives and by which timeframe? EFC1.3: What internal or external factors have influenced progress or lack of progress of the Framework Programme interventions in this area	X	X	Х				

Evaluation question	Sources of information						
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods
towards their impact? EFC1.4: What could be done to address these in the short and longer term? EFC1.5: Are there any factors that are more or less effective than others, and, if so what lessons can be drawn from this?							
EFC1.6: To what extent dissemination, exploitation and communication measures have enabled to reach these outcomes and impacts? EFC1.7: What further actions are needed to maximise the impact of the Framework Programme interventions in this area? EFC1.8: To what extent the implementation processes (Art. 20 HE regulation) have enabled the protection of sensitive and classified information within Horizon Europe? EFF8: (a part of EFF8) To what extent does the programme communication/ valorisation strategy allow identifying, capitalising upon and (possibly) transferring good practices/ results?	X		X		X		X
EFF2: How did these [implementation processes] processes cater for flexibility needs in implementation? What have been the barriers or drivers? How could they be improved or what else could be done to maximise the benefits of the Framework Programme implementation in this area? To what extent the programme implementation processes in this area have influenced the types of projects selected?	X	X	X		X		
EFC2: To what extent has the Framework Programme in this area contributed to achieving the European Union policy priorities and the Sustainable Development Goals (SDGs)?	х						x
EFC3: To what extent has gender equality, including the integration of gender dimension in the R&I content and the requirement of a gender equality plan as an edibility criterion,	х	х	х			Х	Х

Evaluation question	Sources of information						
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods
been effectively integrated in the programmes parts covered under this study, and what impacts has this had at Framework Programme level?							
EFC4: To what extent has international cooperation and, more specifically, association of Third Countries to the EU Framework Programme made a difference in achieving the objectives of the Framework Programme in this area? EFC4.1: Has international cooperation, and specifically association, increased the economic impact for the EU in this area?	Х	Х	Х				X
EFC5: To what extent have the partnerships achieved their objectives and the objectives of the Framework Programme in this area?	Х				Х		
EFC6: What was the impact on the European Health Research Area in terms of structuring effects on specific research areas, the creation of resources, infrastructures, including open access to data, guidelines for FAIR data and standard operating procedures for research purposes, creation of scientific societies or structures, effectiveness of Joint Programming activities?	X	X	X				
EFC7: What were the impacts and outcomes of the collaborative nature of projects (joint publications, joint activities, mutual training, etc.)? EFC7.1: Did this nurture durable networks (development of long term collaboration)?	Х	x					Х
EFC8: What was the impact on public health policies? EFC 8.1: Did any project produce outcome used for shaping policies or general change of practice? EFC9: What was the influence of health research and innovation activities funded under Horizon Europe on the priority setting	Х	Х					Х

Evaluation question	Sources of information						
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods
in the MS and in other world major health research funding agencies?							
EFC10: Were the ethical aspects in health research appropriately considered and dealt with, regarding ethics issues such as research using human embryonic stem cells, informed consent and participation of persons unable to give consent including children in clinical trials, concerns in social science research (e.g. research involving vulnerable person), Third Country participation, where no local ethics structures exist, non-human primate studies, or protection of personal data, etc.?	X	X	X				
EFC11: What were the matching investments, i.e., for an € spent of public money, how much additional money has been spent on a project (providing% of EU funding vs. total project, checking differences by areas, etc.)? EFC11.1: How did this leverage materialise? EFC11.2: Did it include additional use of national funding, structural funds, own resources of entities participating in projects etc?	X						X
EFC12: How effective was the market and innovation uptake of EU Security research actions after the end of a research project? EFC14: To what extent did the research and innovation in the area of security contribute to creating tools, processes or solutions effectively responding to the needs of end users and practitioners? EFC14.1: To what extent the KPIs related to achievement of objectives and impacts as defined in the DoA are respected and ultimately fulfilled? EFC15: What was the impact of security research in terms of capability requirements being met and new knowledge/tools being used by practitioners?	X						
EFC13: To what extent did the research and innovation actions of	Х						

Evaluation question	Source	Sources of information									
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods				
Cluster 3 contribute to implementing relevant EU policies? e.g. Security Union Strategy, the Counter Terrorism Agenda, the border management and security dimensions of the New Pact on Migration and Asylum, EU Disaster Risk Reduction policies, the new EU Climate Adaptation Strategy, the EU Maritime Security Strategy and the EU Cybersecurity Strategy.											
EFC16: To what extent did Horizon Europe projects contribute to build or reinforce EU autonomy in key strategic areas?	х				Х						
EFF3: What can be learned in terms of implementation processes from the experience of applicants and participants? What were the key barriers and drivers towards progress they have experienced at application stage and during the implementation of the projects, and their consequences for the researchers and organisations involved?	X		Х								
EFF8: To what extent have the Framework Programme monitoring and evaluation systems and feedback to policy processes been efficient to ensure evidence-based policymakingin this area? Were adequate systems put in place to share lessons learned from implementation and results achieved between Framework Programme interventions in this area?	Х	Х									
EFF9: Which enablers/barriers exist for security-related project for the further development of an end- product or service after the end of a project life-cycle? How can these be strengthened (in the case of enablers) or overcome (in the case of barriers)?		X									
Evaluation question	Sources of information										
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	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods				
	EU ADD	ED VAL	UE								
EAV1: What is the EU added value of the Framework Programme interventions in this area? EAV1.1: What would have happened if the Framework programme had not existed? EAV1.2: Could the stakeholders have implemented their research and innovation in another way, including through other EU, national or regional support?	X		Х		Х	Х					
EAV2: What is the value resulting from partnerships in this area that is additional to the value that could result from interventions carried out at regional or national level?	Х				Х						
EAV3: What was the EU added value of participating to a security-related research and innovation activity funded by the Framework Programme for project beneficiaries such as first responders / end users / public authorities / SMEs?	Х	Х	Х		Х						
EAV4: What was the EU added value of security research to EU Open Strategic Autonomy?	Х	х	х		х						
EAV5: To what extent have the security-related research and innovation activities funded by the Framework Programme improved conditions for industrial exploitation by providing a coherent European framework for common approaches and solutions in the Area of Border Management, Fighting Crime and Terrorism, Infrastructure protection and Disaster resilient societies to the varying social preferences?	Х	Х	X		X						
PARTNE	RSHIPS	SPECIFI	C CRITE	RIA							
PSC1: ADDITIONALITY PSC1: How much private and/or public R&I contributions has been	Х	Х			Х		Х				

Evaluation question	Sources of information									
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods			
mobilised on EU priorities thanks to partnerships? PSC1.1: What is the partnerships' budget leverage factor, in mobilising additional resources, on top of contribution from partners? PSC1.2: How do partnerships facilitate the creation and expansion of R&I networks that bring together relevant and competent actors from across Europe, thus contributing to the realisation of the ERA?										
PSC2: DIRECTIONALITY PSC2: What is the progress towards the strategic vision of the European Partnership? PSC2.1: Do partnerships clearly demonstrate progress in the delivery of results for the EU and its citizens, notably global challenges and competitiveness, which cannot be achieved by traditional calls alone?	X	X					X			
PSC3: INTERNATIONAL POSITIONING & VISIBILITY PSC3: To what extent are partnerships acting as global ambassador for the European R&I system/establish global relevance/ achieve scientific and technological reputation in the international context/ serve as hubs for international cooperation, where appropriate? PSC3.1: What is the level of international cooperation at partnership and project level and how does this result in visibility for the European Partnership?	X	X			X		X			
PSC4: TRANSPARENCY & OPENNESS PSC4: How open are partnerships to new participants? PSC4.1: Are there procedures / mechanisms in place to expand the partnership to involve new members	Х	Х			Х		X			

Evaluation question	Sources of information									
	Desk research	Interviews	Surveys	OPC	Case studies	Benchmark reports	Additional methods			
at partnership and project level, as well as gradually engage a broader set of stakeholders across Europe? What is the extent of gender balance in the governance structures of the partnership?										
PSC4.2: Are there open and transparent processes for consulting all relevant stakeholders and constituent entities in the identification of priorities?										
PSC4.3: What is the level of openness in use of research result? PSC4.4: To what extent are partnerships (notably with industry										
participation) accessible for SMEs?										
PSC5: Are there procedures/mechanisms in place to expand the EDCTP2 partnership and EDCTP3 Joint Undertaking to involve new members at partnership and project level, as well as to gradually engage a broader set of stakeholders across Africa?	Х				Х		X			
PSC6: PHASING OUT PREPAREDNESS	Х				Х		Х			
PSC6: What are the foreseen measures and conditions set for the orderly phasing-out of the Partnership from the Framework Programme funding? PSC6.1: Are these measures appropriate with regards to a possible phasing-out (or renewal) of the partnership?										

Source: Compiled by the study team.

1.8. Additional methods

The following section further details the additional methods used in the study, explaining approaches, techniques and tools employed to support the research findings.

Presented additional methods:

- Bibliometric analysis;
- Network analysis;
- Analysis of synergies with programmes outside of Horizon Europe;
- Unstructured data analysis: Future Emerging Technologies score;
- SDG analysis.

Bibliometric analysis

Research trend analysis of the H2020 programmes: Topic and Funding Comparison

Introduction

In this analysis, we aim to provide the reader with information on the topical focus of the H2020 programme parts and the Social Challenges as defined by the Framework Programme. Next to this, the analysis looks to discover topical overlaps between H2020 Programmes and Social Challenges and topical overlaps on the national and supra-national levels. However, this analysis could also, in part, be defined as investigating funding overlap, where the focus is on topics that have received, overlapping, funding from different programme parts, funders and other (national) funding sources¹⁰³.

The idea of analysing the disciplinary and topical focus of funders and nations has a long history in bibliometrics as well as in the economics of innovation and science of science fields where the idea of smart specialisation (in industry) has a partial overlap with STI studies looking at basic science as an enabler of industrial specialisation.

Next to this, there is literature on funding programmes¹⁰⁴ in S&T forecasting. One of the main goals here is identifying and assessing emerging S&T capabilities, followed by analysing funder priorities and other foresight indicators.

In this report, we combine the two using comparable topic definitions and metrics that measure both topic prominence ("Hot Topics") and topic emergence ("New topics"). As it is notoriously difficult to predict the future, the results of the latter metric are open to interpretation.

Topics

In science, a topic represents a body of literature that is defined by its focus on a specific problem or issue, a common methodological focus or perhaps a specific scientific viewpoint. This body of literature is also defined by its own language, using keywords, key phrases, and a combination of these peculiar to the scientific topic¹⁰⁵. At a higher level, a collection of topics might represent a subject area, which in turn, as a collection of subject areas, might

¹⁰³ These sources can be specific funding programmes, but could also be an aggregate of national funding.

¹⁰⁴ https://www.iarpa.gov/research-programs/forest

¹⁰⁵ Becher & Trowler, 2001

represent a research domain or scientific discipline. The top level in this tree is represented by the distinction between Alpha and Beta¹⁰⁶, STEM¹⁰⁷ and SSH¹⁰⁸.

The classification of science depends on the vocabularies and classifications that are employed to distinguish these topics, subject areas, etc., from one another. Although uncontrolled keywords and key phrases are the norm at the micro-level, once established as part of a literature, these will be added to controlled vocabularies and classifications as representative of a certain topic, subject area, etc.

As we are using the Scopus citation index and the databases connected, Scival and ScienceDirect, as our data source, we can describe the collection of vocabularies and classification used as follows.

Vocabulary	Control	Source
Free text (keywords mined from title, abstract, full text)	Uncontrolled	ScienceDirect, Scopus
Author Keywords	Semi-controlled	Scopus
Index Keywords	Controlled	Scopus
TopicName	Controlled	ScienceDirect ¹⁰⁹ , Scival
TopicCluster	Controlled	Scival
Subject Area	Controlled	Scopus ¹¹⁰ , Scival

Table 43. Short overview of vocabularies and sources

Source: Author's own interpretation.

Through extensive and iterative testing and analyses, we have decided to use the TopicName controlled vocabulary as our main source of topic data. The reasoning behind this is that contextualising separate keywords is rather difficult without in-depth domain knowledge due to (among others) semantic issues (i.e., homonym/synonym problems¹¹¹). Even though we understand that new topics emerge from the natural language as instances of new combinations and interpretations of often already existing keywords, at this stage and for this purpose, we find that using controlled vocabularies makes more sense in terms of interpretability. In addition, we use a method similar to the network theoretic concept of triadic closure¹¹², where we use a combination of three keywords in close proximity to define a

¹⁰⁶ The top level classification we are using in our analysis assigns research output across five classes: Health Sciences, Life Sciences, Physical Sciences, Social Sciences & Humanities and Multidisciplinary Research.

¹⁰⁷ STEM: Science, technology, engineering, and mathematics

¹⁰⁸ SSH: Social sciences and humanties

¹⁰⁹ https://www.sciencedirect.com/topics

¹¹⁰ https://service.elsevier.com/app/answers/detail/a_id/12007/supporthub/scopus/

¹¹¹ https://en.wikipedia.org/wiki/Homonym

¹¹² Wasserman & Faust, 2012: https://www.cambridge.org/core/books/abs/social-networkanalysis/triads/2E61DF0F9CF8EB680BBD8A3B76F7E26C

topic¹¹³. This further enhances the interpretability of the results. A downside of using a controlled vocabulary for calculating certain metrics is that a sort of aggregation problem seems to exist here. The main compounders of this effect are an insufficient number of publications and, as such, topical keywords or an insufficient number of years present in the (sub-) dataset to enable the emergence algorithm to run (even with a dummy). This means that for some programme parts, we have been unable to calculate an emergence score.

Using a refinement of the topical analysis of the H2020 Programmes and Social Challenges (SCs), we calculate the topical overlap, in terms of the number of overlapping programme parts and SCs, for each of the top 200 topics¹¹⁴. With this, we try to pinpoint those topics for which EC-sponsored outputs have been distributed across several programme parts and SCs. As an additional measure, we use the ProminencePercentile per topical triad to approximate the current importance of the topics. A colour scale is used to highlight the amount of EC-sponsored outputs per programme part, SC, and topic.

Next, we have collected additional data on topical productivity per country for the EU-27 countries, a select number of G7 and BRICS countries (China, Japan, South Korea, United Kingdom and the United States), and the world as a whole¹¹⁵. In the analysis, we have also calculated the total for the EU-27 and EU-28 and added a column representing the EC-sponsored outputs¹¹⁶ in the Top 200 topics as calculated for the EU-27 and selected Third Countries. As an additional measure, we use the ProminencePercentile per topical triad to approximate the "momentum" of the topics¹¹⁷.

Data

For our analysis, we depend on three datasets: the EC-reported publications data, the Scopus/Scival generated data and EC administrative data. The EC-reported data has been validated using Scopus and is used for the internal comparison, while the Scopus/Scival generated data is used for the external comparison. Both datasets are comprehensive and of high quality; however, there is an important difference in that the EC-reported data has a funding connection by virtue of being reported, while the Scopus/Scival-generated publications can only be attributed to a funder by virtue of having that information in the acknowledgement. There will then undoubtedly be a discrepancy between the data reported and the data acknowledged. That said, we have separated the comparison of those data that have the same source, i.e., are generated from affiliation data, and those that stem from the reported outputs. As we used EC-sponsored data in the external comparison, we highlighted this by separating this data column¹¹⁸ from the others in the analysis. The same applies to

¹¹³ Here we diverge from the method used to calculate the FET Score (in Phase 1 of the Excellent Science Study). The FET Score method has used free text keywords denoting technologies, while here we aim to define topics using a taxonomy and keyword triads.

¹¹⁴ The top 200 ranking is achieved by looking at research productivity per topic for the whole of H2020; so publication totals per topic

¹¹⁵ Scival uses a full count method for distributing country affiliations across TopicNames as opposed to a fractional count method (Perianes-Rodriguez, Waltman, Van Eck, 2016). To overcome the issue of "over count" we resorted to aggregating the affiliation counts of all countries. As such we reach a TopicName count higher than in reality but end up with a percentage count closer to reality.

¹¹⁶ Please note that the output total for the EU-27, EU-28, and EC columns (columns N,L&J) have not been added to the "Publications per Topic" column (column B), as these number represent a product of the outputs already counted per EU-27/EU-28 country as well as outputs sponsored by the EC and also counted as a national output. To signify this difference we have "corralled" these two columns by bars as well as highlighting them in bold.

¹¹⁷ A color scale is used to highlight the amount of sponsored outputs per country, country group and topic.

¹¹⁸ Column J, https://doi.org/10.34894/DNWIXV

the total EU-27 and EU28 outputs, which, as a construct, can be found in separate $columns^{119}$.

For the reported outputs, we have for Phase 2 a significantly bigger publication set, with 196712 unique DOIs versus the 138888 DOIs that we worked with in Phase 1, which is approx. 40% increase. This is great news because, especially for NLP¹²⁰-based work, the more data points that are available, the more robust the analysis and results.

In terms of the data collected on the topics, we have collected data on 23793 unique topical triads, of which 23765 were matched to EC-funded outputs. On top of this, data was collected from Elsevier's Scival module¹²¹ for each of the analysed countries and institutes/funders. As the full set resulting from the above is a vast matrix, we decided to confine the analysis presented here to the top 200 topics, ranked on the basis of the total number of outputs published for each topic and related to the focal variables of the analysis (be it programme parts and social challenges or countries and institutions or funders).

The same process of assessing, cleaning, matching, and validation has been used in Phase 1 to ensure a similar, high-quality dataset with all the attributes necessary to perform a proper analysis. The dataset has been similarly enriched with specific data and metrics as in Phase 1. In addition, we have used project-level H2020 administrative data in order to collect the funding-related variables needed to calculate the funding amounts per topic. Other information, such as specific Subject Areas and Disciplinary classifications¹²², has been used to create the appropriate concordances.

Metrics

In the above text, we mention that we are testing two relatively new metrics, or indicators, specifically devised for measuring the visibility, momentum, and novelty or emergence of research topics. These are the "Prominence Percentile" for measuring momentum and the "Emergence Score" to define the novelty of a certain topic. Next to this, we also employ the Top1% and Top10% percentile indicators (PPTop¹²³) as used in the bibliometric analysis in Phase 1.

Indicators:

- 1. **The Prominence Percentile**¹²⁴ is an indicator of the momentum or visibility of a particular Topic. Prominence does not signify 'importance'. Calculating a Topic's Prominence combines three metrics to indicate the momentum of the topic:
 - Citation count in year n to papers published in n and n-1;
 - Scopus views count in year n to papers published in n and n-1;
 - Average CiteScore¹²⁵ for year n.

¹¹⁹ Column L&N, https://doi.org/10.34894/DNWIXV

¹²⁰ NLP: Natural language processing

¹²¹ https://www.scival.com/landing

¹²² https://service.elsevier.com/app/answers/detail/a_id/15181/supporthub/scopus/ &

https://service.elsevier.com/app/answers/detail/a_id/12007/supporthub/scopus/

¹²³ Bornmann, 2014: https://doi.org/10.1093/reseval/rvu002

¹²⁴ Klavans & Boyack, 2017: https://doi.org/10.1016/j.joi.2017.10.002

¹²⁵ https://en.wikipedia.org/wiki/CiteScore

Due to the nature of certain research fields, there are Topics which will never become "prominent". However, this does not mean the Topic is not important. However, there is a correlation between the prominence (momentum) of a particular topic and the amount of funding per publication for that topic. The higher the momentum, the more money per publication is available for research in that Topic.

In order to come up with a single and stable percentile score, we have smoothed the yearly figures from 2016-2021, averaging these. For reference purposes, please find that all Topics' overall average Prominence Percentile is 78.

- The Emergence Score¹²⁶ looks at four S&T attributes novelty, persistence, community, and growth, and seeks to identify emergent terms i.e., topical content that evidences these four attributes. To do so, topical content is extracted to discern terms or phrases that show high growth, along with evidence of novelty, persistence, and community:
 - Novelty newness; can pertain to technologies, technical sub-systems, functions, and/or uses;
 - Persistence indicating some identity and momentum e.g., shared use of acronyms, ongoing community interest;
 - Community as in "community of practice," implying multiple players, not all within some single unit, and connected in some manner – e.g., citation connections in R&D literature or patent analyses;
 - Growth increasing R&D outputs and/or gains in other facets (e.g., funding, players).
- 3. The Top Percentiles indicator looks at the impact of science and measures worldclass science by using the citations accrued to calculate the number and share of peer-reviewed publications resulting from the projects funded by the EC-funded programmes, and that is a core contribution to scientific fields, calculated as a percentage of top-cited publications (PPTop¹²⁷):
 - Top 1% Publications that are in the top 1% of the most highly cited publications in their field;
 - Top 10% Publications that are in the top 10% are the most highly cited publications in their field.

The Top Percentiles (PPTop) indicators are also part of the KIPs (Key Impact Pathways) framework for KIP1: Creating high-quality new knowledge^{128,129}.

We use these indicators to show how many EC-sponsored publications are leading in their field. We do this by calculating the percentage of EC-sponsored publications that are in the top percentiles as a proportion of the total EC-sponsored publications for each topic. As such,

¹²⁶ Porter, Garner, Carley and Newman, 2019: https://doi.org/10.1016/j.techfore.2018.04.016

¹²⁷ Waltman & Schreiber, 2013: https://doi.org/10.1002/asi.22775

¹²⁸ See: https://research-and-innovation.ec.europa.eu/strategy/support-policymaking/shaping-eu-research-and-innovationpolicy/evaluation-impact-assessment-and-monitoring/horizon-europe-programme-analysis_en

¹²⁹ European Commission, Directorate-General for Research and Innovation, Nixon, J., Study to support the monitoring and evaluation of the framework programme for research and innovation along key impact pathways – Indicator methodology and metadata handbook, Nixon, J.(editor), Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2777/44653

we can see the share of EC-sponsored output that is published on a certain topic while also denoting the topic's momentum using the prominence percentile.

4. To signify the overlap, we show **the number of overlapping H2020 Programmes and Social Challenges** out of a total of 22. To enhance the interpretation of the presented results, we use colour scaling. The scale denotes the number of outputs per programme, social challenge, country, funder and country bloc per topic covered.

Practicalities

Similarly, as with the Bibliometric Report from Phase 1, the data used is of such size that its representation in this report only serves to show the main results. We have decided to share the results in full, in spreadsheet format, using our Dataverse¹³⁰. The datasets containing the full results can be found at:

- First Interim Report Results: https://dataverse.nl/dataverse/research_trend_analysis_H2020;
- Second Interim Report Results: https://dataverse.nl/dataverse/Research_Trend_Analysis-Funding_and_Topical_Overlap;
- Final Report Results: https://dataverse.nl/dataverse/Excellent_Science_Phase_2_Final_Report.

Results

(a) H2020 Internal Topical Analysis

In the Figure, we show the top 35 topics in relation to the programmes and the number of EC-sponsored outputs¹³¹ reported for each of these topics.

The first thing to notice is that the assignment of a topic to a single programme or challenge is the exception in this listing. Let's look at the number of overlapping topics (in column E), we find that, on average. There is a 6.3 programme/challenge overlap per topic (for the Top 200), with a 21 programme/challenge overlap as a maximum and 1 programme/challenge per topic as the (obvious) minimum.

A maximum of 95% overlap (21 programmes/challenges) is achieved for the topic "Object Detection; Deep Learning; IOU (Intersection Over Union)", which could be interpreted as a general purpose technology (GPT) and as such might find application across a large number of funding areas. Combining this information with the high ProminencePercentile of 99.98 for this topic might explain the interest of a diverse set of areas and funders in technology with high momentum/visibility. That said, one could wonder whether fragmentation of funding for a single high-prominence GPT is in the interest of the funder and of research in the area as a whole. The Flagship projects (as analysed in Phase 1) have shown that concentrating funding works well, and one can wonder if this would also apply to the above.

¹³⁰ https://dataverse.nl/dataverse/UNU-MERIT

¹³¹ Please note that the number of unique publications (in column B) is lower than the number of combined publications for all programmes and challenges (the sum of each row). This is due to the double reporting of same outputs by multiple projects and across multiple programmes and challenges.

Top 20	0 TopicName	15			1	2	3	4	5	6	:	7 8	9	10	11	12	13
		Publications per Programme/Social	Challenge		71320	42690	16197	11632	11242	9589	8174	6671	5176	4600	4409	3486	1724
No.	Publicati	o Topic names	Av. Promi	#Overlap	ERC	MSCA	LEITs-ICT	FET	SC1	SEWP	INFRA	EURATOM	SC2	SC5	SC3	SC4	SC7
	1 96	9 Perovskite Solar Cells; Solar Cell; Fo	100.00	11	419	313	12	123		10	4	9 1			117		
	2 89	5 Molybdenum Disulfide; Monolayer;	99.99	9	349	179	11	470		7	5	8			1		
	3 81	4 Object Detection; Deep Learning; IO	99.98	21	206	129	261	40	40	19	1	7 4	10	6	3	27	30
	4 48	9 Exoplanets; Kepler; Atmosphere	99.72	5	401	92		1			14	4					
	5 37	7 Nasopharyngeal Swabs; Serologic Te	96.09	13	57	42	1	7	202	11	76	5	6				
	6 37	5 Mobile Communication Systems; Sli	98.89	8	4	23	336		5	1	1	3				1	4
	7 37	4 Cavity; Mechanical Oscillators; Reso	99.54	5	185	70	2	178			9	9					
	8 36	0 Quantum Optics; Thermalization (En	99.47	4	252	58		75		1							
	9 34	5 Network Function Virtualization; Tra	99.28	6	9	17	312		1		2	2					10
	10 32	9 Planet; T Tauri Star; Pre-main Seque	98.99	4	238	129						5					
	11 31	8 Intestine Flora; Ruminococcaceae; N	99.99	10	165	74			39	15		2	36				
	12 31	8 Topological Insulators; Topology; Qu	99.76	5	197	66		93		2							
	13 31	1 Integrated Assessment Model; Carb	99.85	11	41	5		2			:	1	6	248	16	2	
	14 30	3 Human-Robot Interaction; Humanoi	99.41	10	66	105	64	8	63	3							1
	15 30	2 Edge Computing; Internet Of Things	99.78	11	7	73	202	6	2	2	4	4	1			5	4
	16 29	5 Divertors (Fusion Reactors); Berylliu	92.37	3		2				2		294					
	17 29	4 Boson; Partons; Higgs Bosons	99.84	4	185	133				3	2	2					
	18 29	4 Ion Temperature; Turbulence; Stella	93.49	3		1					1	7 291					
	19 29	2 Bitcoin; Ethereum; Internet Of Thing	99.58	14	33	31	124	1	15	9	14	4	2		16	7	46
	20 28	8 Precoding; Millimeter Waves; Anter	99.74	5	45	88	149			1						10	
	21 28	7 Exosomes; Extracellular Vesicles; Mi	99.98	9	69	98		38	34	46	(6	2				
	22 28	4 Neutron Stars; Mergers; Gravitation	99.74	5	199	77		17			19	9					
	23 27	6 Demand Response; Demand Side Ma	99.93	9	14	42	24			16					176		1
	24 27	5 Divertors (Fusion Reactors); Poloida	92.89	1								275					
	25 27	5 Graphite; Terahertz; Photodetectors	99.84	8	105	40	5	170		1	:	2			1		
	26 26	8 Internet Of Things; Traffic Engineeri	99.82	10	45	14	187	1	2	1	1	8			1	4	12
	27 26	6 Weyl; Metalloids; Paul Adrien Mauri	99.88	7	204	49	1	32		3	5	5					
	28 26	1 Star Formation; Galaxies; Molecular	98.84	4	207	65					10	0					
	29 25	7 Connectome; Functional Magnetic R	99.93	6	97	48	3	79	40	10							
	30 25	6 Origanum; Superconductivity; Topol	99.37	5	205	31		40		1		4					
	31 25	6 Plastics; Marine Debris; Litter	99.97	16	78	54	1	1	15	4	1	3	63	22	1		
	32 25	5 Fiberoptic Cable; Radio over Fiber; F	98.68	3	44	24	204										
	33 24	8 Homomorphic Encryption; Compute	97.27	6	81	7	89	3	3								87
	34 24	3 Color Centers; Nitrogen; Nanodiamo	99.63	7	110	37		124	13	2		7					
	35 24	0 Genome; CRISPR Associated Endonu	99.98	11	128	45		5	24	10	4	4	5		1		

Figure 60. Top 35 Topics x H2020 Programs and Social Challenges

Note: The set of top 200 topics can be retrieved at https://doi.org/10.34894/QIJZK8.

We can also see that the high incidences of overlap (40% overlap or more, i.e. 10 or more programmes/challenges overlapping) occur almost exclusively with very high prominence topics. This underlines an earlier finding that shows that there is a correlation between the prominence (momentum) of a particular topic and the amount of funding available for that topic: On average, the higher the prominence or momentum, the more funding is available for research on that topic. In our sample, the notable exception is the topic "Nasopharyngeal Swabs; Serologic Tests; COVID-19", which obviously has a different kind of urgency and, although of lower prominence, has received funding from a diverse set of programmes and challenges.

The above conclusion is further exemplified by EURATOM, which, although producing high numbers of outputs in a diverse set of topics, covers a relatively low amount of high-prominence topics. It, however, is also usually the sole funder of these topics.

We find that there is a high incidence of overlap of funding between ERC and MSCA. Also, SEWP and INFRA share a large number of topics with the aforementioned, although the number of outputs differs significantly. LEITs-ICT, FET, and SC1 also share topics with MSCA and ERC, and although the incidence of overlap seems to be lower, the number of publications on shared topics is larger than those for SEWP and INFRA.

Although seemingly lacking in efficiency, the reason for the overlap between the ERC and MSCA can be explained by the breadth of research covered by both programme parts. In addition, instances of MSCA fellows working on ERC-funded projects can contribute to this higher incidence of overlap. We can also explain the lesser overlap for the other programme parts by looking at their more singular focus. LEITs ICT obviously researches ICT-related topics, which are then also visible in Figure 60, and such focus is applicable to many of the

other programme parts, with EURATOM again being the prime example. The above reasoning is confirmed by the more macro-level analysis of Subject Areas and Disciplinary divisions as described below.

(b) H2020 Internal Subject Areas and Disciplinary Analysis

Next to the above micro-level analysis, we would also like to look at more higher-level classifications of the research funded through H2020 and the meso-level "Subject Areas" and macro-level "Disciplines" this research covers. For this, we employ the ASJC (All Science Journal Classification) scheme¹³² and coding¹³³, used by the Scopus citation index. Again, we link the reported DOIs to the subject area codes and the disciplines these subject areas adhere to. As a paper can be linked to multiple projects and as such programme parts, there is some double counting in this dataset¹³⁴. By contemplating that a single piece of knowledge can result from a number of linked experiments, i.e., projects, one can imagine the occurrence of such double counts. Especially as we are analysing knowledge constructs, i.e. topics or concepts, instead of productivity or impact metrics, as in Phase 1, we believe this is a justifiable approach. However, as one paper can cover multiple subject areas, we have employed a fractional count for these. Again, this is justified by the fact that one topic or concept can intersect with several subject areas.

In our dataverse, available at <u>https://doi.org/10.34894/1PUX77</u>, one can see the subdivision of Subject Areas and Disciplines across each of the 22 programme parts and social challenges. The percentage of research is visualised for each Subject Area and Discipline, and then, of course, for each of the programme parts and challenges. In the Figure below, one can see this disciplinary division for the H2020 programme parts.

	ERC	FET	FTI	INFRA	InnoSMEs	LEITsBio	LEITSICT	LEITsMan	LEITsMat	LEITsNan	LEITsSpa	MSCA	SEWP	SWAFS	EURATOM
Disciplines	% of Total														
Health Sciences	6.0	2.7	10.1	5.7	30.5	5.3	1.5	0.4	2.3	7.6	0.3	6.7	10.2	8.3	0.7
Life Sciences	17.7	11.8	16.7	14.2	23.9	49.6	2.2	0.9	6.1	23.5	3.3	16.1	26.0	4.6	0.4
Multidisciplinary	5.3	5.8	0.6	4.9	5.2	2.6	0.9	0.4	2.6	3.2	2.6	3.6	3.6	4.2	0.6
Physical Sciences	62.6	78.0	70.4	72.3	39.6	41.4	91.3	92.9	87.5	64.7	92.6	67.2	55.0	38.0	98.0
Social Sciences & Humanities	8.4	1.8	2.1	2.9	0.8	1.0	4.1	5.3	1.5	1.0	1.2	6.4	5.2	44.9	0.2

Figure 61. Division of H2020 research across the main Disciplines

From the Figure, we can deduce some interesting insights that emphasise the H2020 programmes on the Physical Sciences and the Life Sciences, with Health and SSH seemingly less well covered. However, if we look at the meso-level data next, we see that this is somewhat more nuanced. For instance, for Health and Medical Sciences, we indeed find less attention from most programmes, but some do focus on the Medicine subject area (Innovation in SMEs) or on Immunology and Microbiology (LEITs Nanotech). That said, it does corroborate the findings of the external funder comparison, which shows that the EC programmes have little overlap with the topics covered by the research funded by more Health Sciences focused funders such as the National Institutes of Health (NIH) in the US.

¹³² See https://service.elsevier.com/app/answers/detail/a_id/12007/supporthub/scopus/

¹³³ See https://service.elsevier.com/app/answers/detail/a_id/15181/supporthub/scopus/ 134 Approx. 4.5%

Figure 62. Division of H2020 research across the ASJC Subject Areas

	ERC	FET	FTI	INFRA	InnoSMEs	LEITsBio	LEITSICT	LEITsMan	LEITsMat	LEITsNan	LEITsSpa	MSCA	SEWP	SWAFS	EURATOM
Subject Area	% of Total														
Agricultural and Biological Sciences	2.6	0.6	4.8	2.6	2.2	. 7.7	0.3	0.3	0.3	1.1	2.3	3.2	6.5	1.1	0.0
Arts and Humanities	2.0	0.2	0.0	0.4	0.0	0.4	0.3	0.1	0.5	0.1	0.0	1.3	0.4	3.0	0.1
Biochemistry, Genetics and Molecular Biology	10.0	5.6	7.0	8.9	13.8	26.9	1.0	0.4	3.5	10.0	0.8	8.0	12.4	2.3	0.3
Business, Management and Accounting	0.3	0.1	0.4	0.1	0.0	0.0	0.5	1.4	0.2	0.0	0.1	0.5	0.6	7.4	0.0
Chemical Engineering	2.7	2.9	2.7	2.3	1.8	9.6	0.6	6.9	8.4	7.1	0.2	3.1	. 2.7	0.3	0.4
Chemistry	6.8	8.0	4.0	7.0	4.3	9.9	0.8	4.2	14.0	12.5	0.9	7.0	6.2	0.4	1.2
Computer Science	7.8	9.8	7.4	8.3	5.6	i 1.9	46.1	20.7	3.9	1.5	8.4	9.1	8.3	14.7	1.3
Decision Sciences	0.3	0.2	0.3	0.4	0.2	0.0	1.6	2.4	0.1	0.0	0.3	0.4	0.4	1.9	0.0
Dentistry	0.0	0.0	0.0	0.0	0.4	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Earth and Planetary Sciences	7.0	0.6	1.0	11.4	1.1	0.2	0.4	1.1	0.1	0.1	40.5	4.5	2.4	0.9	0.6
Economics, Econometrics and Finance	0.8	0.1	0.0	0.3	0.0	0.2	0.1	0.3	0.1	0.0	0.0	0.4	0.8	0.8	0.0
Energy	0.8	1.0	11.5	1.3	1.0	1.4	0.7	6.8	4.6	1.0	0.7	2.0	2.4	3.4	14.3
Engineering	5.6	9.2	19.6	4.7	9.0	5.5	22.8	34.4	13.9	8.5	9.8	10.0	10.8	4.9	14.0
Environmental Science	1.9	0.5	1.9	3.1	1.2	7.3	0.3	3.6	3.3	8.9	5.2	3.5	4.5	7.3	0.9
Health Professions	0.1	0.1	0.4	0.1	0.2	0.1	0.1	0.0	0.2	0.1		0.2	0.2	0.3	0.1
Immunology and Microbiology	1.8	0.5	1.4	1.7	2.2	13.5	0.1	0.0	0.2	1.6	0.1	1.4	2.3	0.3	0.0
Material Science	6.0	13.7	7.8	6.6	5.9	2.9	5.2	5.9	25.7	18.1	2.6	7.2	6.7	1.5	13.0
Mathematics	5.8	3.2	3.9	3.4	1.0	1.5	7.8	4.0	0.8	0.7	2.7	4.7	2.6	2.3	3.3
Medicine	5.8	2.6	9.7	5.2	29.6	5.1	1.4	0.4	2.1	7.2	0.3	6.2	9.6	6.5	0.6
Multidisciplinary	5.3	5.8	0.6	4.9	5.2	2.6	0.9	0.4	2.6	3.2	2.6	3.6	3.6	4.2	0.6
Neuroscience	2.7	4.8	2.6	0.3	2.7	0.3	0.8	0.2	. 0.1	0.3	0.0	1.9	2.0	0.8	0.0
Nursing	0.1	0.0	0.0	0.2	0.3	0.1	0.0	0.0	0.0	0.1	0.0	0.2	0.2	1.6	0.0
Pharmacology, Toxicology and Pharmaceutics	0.6	0.3	1.0	0.7	3.0	1.1	0.1	0.0	2.0	10.6	0.0	1.6	2.7	0.1	0.0
Physics and Astronomy	18.1	28.9	10.6	24.1	8.7	1.2	6.6	5.3	12.7	6.4	21.7	16.0	8.4	2.2	49.0
Psychology	1.1	0.7	0.3	0.2	0.3	0.0	0.2	0.1	0.0	0.0	0.0	0.7	0.3	1.8	0.0
Social Sciences	3.8	0.4	1.1	1.6	0.4	0.2	1.4	1.1	0.5	0.8	0.7	3.0	2.6	29.9	0.1
Veterinary	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.2	0.0	0.0

Internal funding comparison

Below, we showcase a selection of the topics that perform well in terms of impact as well as interesting "hot" and emerging topics for a number of funding programmes and social challenges. More can be found on our dataverse, available at https://doi.org/10.34894/Q1NT0D.

We can see from the comparison of topic clusters (Topic_TOP200) that topics are largely concentrated in the "appropriate" programmes, with the most obvious examples being EURATOM and Swafs. But also, foci in material science and engineering for the LEITs, FET and INFRA, as well as those matching each of the Social Challenges. ERC, MSCA and SEWP are the ones that are broadest in the range of topics, but this is to be expected, as explained earlier.

What is interesting to note from this internal comparison of funding programme parts is that **there is a surprising overlap of topics across the programme parts and Social Challenges**. This is not an issue, especially for those topics that need an amount of funding which one programme alone cannot cover¹³⁵ (without reverting to a near-singular topical focus) or for topics that can be researched from different angles¹³⁶. This requires higher-level coordination to ensure efficiency of effort, which could be a potential policy issue.

For instance, work on sustainable energy, drug development and therapies, and geneticsrelated work seem to span multiple programme parts. Obviously, COVID-19 has greatly impacted the work done in the final year of H2020. It is quite interesting to see that the **EC** has been able to mobilise not just the resources but also to effect this sudden change in direction as a reaction to the pandemic.

The above conclusions are magnified once we continue our analysis by looking at the number of publications per topic in relation to the overall EC funding these topics receive¹³⁷. From this data, it is clear that ERC has been most efficient in allocating funding across a large spectrum of topics while also safeguarding sufficient funding for those topics that are not as prominent or productive as some of the leading topics (leading in terms of total productivity). This is less evident in most of the other programme parts, except for MSCA. Again, this will be an effect of the concentration of topics and funding in the "appropriate" programs, but it could also be influenced by those topics that require large research infrastructure and which one can assume to be also concentrated in more topically focussed programme parts.

Below, we present a selection of findings for a number of the programme parts and social challenges. We will be looking especially at productivity in terms of publications and impact in terms of Top 1% and 10% cited publications. Next, we look at the momentum and visibility of a few funded topics using the prominence and emergence scoring from our calculations.

ERC – As a programme funding a broad array of research, we find an equally broad number of topics that are receiving input. Quite a number are leading in terms of impactful, highly cited research, with a large share of the funded research in these topics featuring the top 1%

¹³⁵ One could think of topics for which' research involves large or costly infrastructures, such as special laboratory set-ups or computational facilities with unique specs.

¹³⁶ Multidisciplinary, mixed methodologies and such.

¹³⁷ Please find the data and analysis at: https://doi.org/10.34894/M9JGU2

and top 10% of the world's most highly cited publications in their field. From the Top200 we select:

In terms of topical impact:

- Work on solar energy production and solar cells (Perovskite Solar Cells; Solar Cell; Formamidine), of which 63% of the EC-sponsored research on this topic features in the Top 10%;
- Work in the area of astronomy (Neutron Stars; Mergers; Gravitational Waves) has produced EC-sponsored work, of which 71% of the research funded by the ERC features in the Top 10% and 20% of the funded output in the Top 1%;
- Work in the area of photocatalysis (Alkene; Cross-coupling Reactions; Photocatalysis) has a staggering 84% of the ERC-funded research features in the Top 10%;
- Work on immunotherapy and drug development (Nivolumab; Pembrolizumab; Immunotherapy) has 34% of the ERC-sponsored research in the Top 1% of the world's most highly cited publications on that topic.

In terms of momentum and novelty:

- Work on groundwater and water storage (GRACE; Groundwater; Water Storage) has both a high emergence score and a high average prominence percentile;
- Work on thermoacoustics has a similarly good emergence score and high average prominence percentile;
- In terms of the number of publications funded, high emergence scores and high average prominence percentiles, the ERC-funded research on Beyond 5G (Beyond 5G; Massive MIMO; Intelligent Reflecting Surface) and on Migration (Transnationalism; Human Migration; Dual Citizenship) scores high.

FET - This programme specifically funds frontier research. Although basic science is funded, there is a certain focus on applied science. Here, we find research on topics similar to those funded by the ERC, but also on material science and engineering-focused topics that are of a more applied nature.

In terms of topical impact:

- Work on solar energy production and solar cells (Perovskite Solar Cells; Solar Cell; Formamidine), a topic also sponsored heavily by ERC, of which 69% of the FETsponsored research on this topic features in the Top10%, and 29% in the Top1%;
- Work on organic polymers (Organic Polymers; Triazines; Porous), of which 68% of the FET-sponsored research on this topic features in the Top 10%, and 29% in the Top 1%;
- Work on electrochemical capacitors (Electrochemical Capacitors; Silicon Nanowires; Graphite), of which 87% of the FET-sponsored research on this topic features in the Top10% in this field, and a staggering 57% in the Top1%;
- Work in the field of mechanotransduction¹³⁸ and the topic (Mechanotransduction; Focal Adhesions; Extracellular Matrix), even though the number of FET-funded

¹³⁸ https://www.sciencedirect.com/topics/medicine-and-dentistry/mechanotransduction

publications is not that large, has managed to get 83% of the FET-sponsored research on this topic to feature in the Top10% in this field, and 26% in the Top1%.

In terms of momentum and novelty:

- Work on adsorption properties (Effective Properties; Random Sequential Adsorption; Fiber);
- Work on elastomers (Elastomers; Actuator; Nematic);
- Work on photonics (Filamentation; Terahertz; Supercontinuum Generation).

INFRA – this programme seems to be most successful in sponsoring material science-related research.

In terms of topical impact:

- Work in the area of materials science (Neural Networks; Potential Energy Surfaces; Materials Science) with a relatively high number of publications sponsored, of which 64% of the INFRA-sponsored research on this topic features in the Top 10% in this field and 24% in the Top 1%;
- Work in the area of materials science and high-entropy ceramics¹³⁹ (Thermal Conductivity; Solid Solution; High-Entropy Ceramics) reveals that 86% of the INFRA-sponsored research on this topic features in the Top10% in this field, and a staggering 43% in the Top 1%;
- Work on COVID-19 (Pharmacotherapy; Prolongation; COVID-19) shows that 77% of the INFRA-sponsored research on this topic features in the Top 10% in this field and a staggering 31% in the Top 1%.

In terms of momentum and novelty:

• Work in the field of astronomy (Asymptotic Giant Branch Stars; Iron; Dwarf Galaxies) seems to catch attention, with an exceptionally high emergence score as well as a high prominence percentile.

SEWP – the Spreading Excellence and Widening Participation programme has seen successful collaborations on a number of topics.

In terms of topical impact:

- Work in the field of health and medicine (Multifactorial Inheritance; Summary Statistic; Single Nucleotide Polymorphism) reveals that a staggering 88% of the SEWP-sponsored research on this topic features in the Top10% in this field, and 32% in the Top 1%;
- Work in the same field (Anthocyanins; Gene; Dihydroflavanol 4-Reductase) has a similar impact, with 73% of the SEWP-sponsored research on this topic featuring in the Top 10% in this field and 18% in the Top1%.

¹³⁹ https://www.sciencedirect.com/topics/materials-science/high-entropy-ceramics

In terms of momentum and novelty:

• Work in the field of medicine again on MicroRNA (Exosomes; Extracellular Vesicles; Microrna) has a prominence percentile of nearly 100%, denoting a very "hot" topic, with a very high emergence score as well. From the interpretation of the indicators, this would be a highly fundable topic.

SC1 – This Social Challenge, focusing on "Health, demographic change and well-being", has funded a large body of health-related research.

In terms of topical impact:

- Work on COVID-19 (ARIMA; Mathematical Modeling; COVID-19) has generated SC1-funded research, of which 74% features in the Top 10% in its field and 29% of the funded research features in the Top 1%;
- Work, again on COVID-19 (Interleukin 6; Rheumatology; COVID-19) has generated SC1-funded research, of which 73% features in the Top10% in its field, and a staggering 54% of the funded research features in the Top1%.

In terms of momentum and novelty:

 Work in the area of chemical engineering (Fluorocarbon; Fluorochemicals; Perfluorooctane) has a prominence percentile of nearly 100%, denoting a very "hot" topic, with a very high emergence score as well. Similar to the SEWP-funded example above, this seems to be a highly fundable topic.

Note to the Prominence and Emergence analysis: In the spreadsheet retrievable at <u>https://doi.org/10.34894/Q1NT0D</u>, and under the tab "Topic_TOP200", there are the main topics (Top 200) published in, by number of publications per H2020 sub-programme and Social Challenge. These topics consist of three closely connected keywords, as explained earlier. Furthermore, one can find the number of highly cited publications in the Top 1% and Top 10% (in red, in the columns denoted by a 1) as a share of the total EC-sponsored publications for each topic, signalling the impact EC-sponsored research in these topics has. Under the tab "TopicKeywords_TOP200" there are the single keywords that make up the topics, with the same calculations and metrics as for the "Topic_TOP200".

Under the tab "TopicEmergence", one can find the keyword constructs that define a "topic. These topics are made up of three keywords that are connected through similarity and instances of appearance in the same publications. The topics, as defined, also add some initial context to the keywords by virtue of "connectedness" and can then also be seen as a rudimentary S&T concept. Added are both "emergence scores" as well as average "prominence percentiles", denoting resp. novelty and momentum of a certain topic. Under the tab "TopicKeywordEmergence", one can find the different "emerging" topic keywords as distributed across each H2020 sub-programme and Social Challenge and the publications in which they appear. Added are the "emergence scores", which denote the novelty value for each. Interestingly, one can see that for these "new" topics, there is little difference in the publication count of the keyword constructs and the individual keywords.

H2020 External Topical Analysis

In the Figure, we show the top 35 topics in relation to countries, both EU-27 and 5 selected Third Countries, and the number of "sponsored" outputs reported for each of these topics.

Top 200 To	pic Names																				
	Publicatio	ons per Ent	4175593	952724	107970	1563552	4800991	196332	9282691	7719139	196652	260045	35089	46756	23961	176187	230650	28195	174353	920805	139577
No.	Publicatio Topic Nar	Av. Promi	China	Japan	South Kor	United Kir	United Sta	European	EU-28	EU-27	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Rep	Denmark	Estonia	Finland	France	Germany
1	71093 Object De	99.98	25355	3484	172	4258	17631	814	24451	20193	344	350	36	84	62	262	304	63	398	2146	440
2	35454 Perovskit	100.00	14298	2034	58	1976	6233	969	12831	10855	73	279	13	19	30	148	105	5	142	751	204
3	34058 Nivoluma	99.99	5106	3036	41	1710	11103	140	14772	13062	297	474	14	27	22	181	275	9	81	2343	212
4	27983 Boson; Pa	99.84	1243	623	1110	1850	1915	294	23092	21242	1046	623	700	495	486	1129	581	516	560	1407	217
5	27251 Microrna;	99.99	20550	434	28	421	3012	90	3227	2806	75	77	10	5	3	65	94	5	31	210	61
6	27147 Intestine	99.99	6316	1077	74	1377	7373	318	12307	10930	198	470	20	18	19	134	564	38	466	1179	126
7	25473 Molybder	99.99	8401	1672	69	1011	6213	895	9118	8107		320	5	18	6	152	218	10	195	673	154
8	23060 Nasophar	96.09	1751	970	179	2514	7996	377	12164	9650	162	251	10	37	54	133	270	32	110	1179	170
9	22569 Radiologi	93.34	5193	678	321	2070	5277	77	11100	9030	124	210	23	59	70	104	204	14	72	860	98
10	21946 Embeddir	99.62	6646	969	92	1538	6121	158	8118	6580	81	. 103	17	38	6	134	201	25	104	785	180
11	18144 Exosome	99.98	4989	878	92	831	4824	287	7361	6530	102	152	3	12	8	55	151	46	143	507	83
12	17121 Psycholog	95.82	1382	484	281	2254	4539	76	10435	8181	125	137	21	70	87	102	167	19	116	555	98
13	16890 Microstru	99.98	3463	577	130	1314	4114	163	8606	7292	156	279	11	7	13	307	92	98	146	683	193
14	16278 Connecto	99.93	3079	368	32	1520	6093	257	6706	5186	89	183	4	10	7	49	147	7	130	546	116
15	15834 Bitcoin; E	99.58	3863	421	92	1499	3206	292	8252	6753	226	86	36	37	76	56	211	85	212	604	99
16	15236 Polymer	99.98	6262	657	47	741	2315	103	5955	5214	75	146	9	19	30	57	155	3	44	377	86
17	14892 Electrode	99.99	9972	338	5	339	1162	25	3415	3076	10	21	9	7	5	48	35	1	9	161	24
18	14301 Genome;	99.98	3017	945	29	845	5597	240	4713	3868	80	108	5	12	13	56	223	10	43	398	103
19	13747 Collabora	99.83	6541	466	41	503	2431	67	4268	3765	136	75	18	9	18	51	46	12	80	367	47
20	13183 Transcath	99.81	333	642	44	986	4211	8	7953	6967	160	180	2	5	11	84	291	3	75	871	185
21	12985 Biochar; S	99.97	5612	238	122	613	2088	42	4925	4312	119	128	5	8	26	238	151	12	122	270	72
22	12867 Oxygen P	99.99	6884	522	23	329	1698	164	3740	3411	11	. 39	23	5	1	58	127		33	229	87
23	12807 Cyanoger	99.99	9430	354	25	320	646	52	2352	2032	11	. 29	3	3	2	90	36		31	116	42
24	12739 Exoplane	99.72	289	388	63	1724	3633	489	8366	6642	195	306	23	3	3	72	454	9	44	861	129
25	12395 Plastics; M	99.97	2077	398	103	1216	1678	256	8139	6923	72	111	15	46	36	84	243	36	141	610	118
26	12279 Zinc Air B	99.99	7293	598	21	312	1558	74	2809	2497	17	35	10	1		44	60	119	26	223	41
27	12278 Strain Ser	99.98	4707	602	11	558	2867	146	4091	3533	55	86	6	6	1	23	28	7	89	164	32
28	12264 Edge Com	99.78	4670	399	28	808	2180	302	4987	4179	112	81	42	9	47	36	65	54	231	365	47
29	11766 Thrombu	99.82	1412	514	57	614	3610	45	6173	5559	95	107	7	22	4	224	100	13	126	766	134
30	11715 Fatty Live	99.88	1649	876	38	944	3178	105	5974	5030	101	. 89	12	58	7	45	164	5	77	422	64
31	11665 Cultural E	99.92	2373	179	118	1172	1523	220	7472	6300	188	212	50	13	18	144	158	28	236	475	114
32	11649 Consensu	99.84	7979	239	11	315	1417	33	2003	1688	12	21	7	3	21	40	7		25	273	17

Figure 63. Top 35 National Topic and Funding Overlap

Note: The full set of top 200 topics can be retrieved at https://doi.org/10.34894/DNWIXV.

The analysis presents us with interesting information, some of which might require additional insights to fully understand the implications of these findings. **Out of five topics with the highest output for all H2020 programmes, we find that only two can be found in the top five topics researched and funded**¹⁴⁰ by the EU-27 & EU-28 and selected Third **Countries.** These are "Object Detection; Deep Learning, IOU"¹⁴¹ and "Perovskite Solar Cells; Solar Cell; Formamidine". The third is on COVID-19-related testing. The Nano S&T-related MoS2 topic is in the top 10, while the Exoplanets-related topic is in the top 30. This points to a partial "disconnect" between topics prioritised in, for instance, China or the USA. Whether this is a result of national Smart Specialization¹⁴² strategies or other causes, we cannot ascertain, and this would require additional research.

COVID-19-related research features somewhat more prominently in the comparator set than in the H2020 programmes and SCs set. Another point in the case is Gene and RNA-related research, which features less (high) on the EC-sponsored topic list than elsewhere (with China and, to a lesser extent, the USA being interested in these topics). **Overall, we can say that health and medicine-related topics are somehow less covered by the ECsponsored outputs (and programmes, by extension) than by the EU-27 countries separately.** One can question whether the EC needs to sponsor research that is already well covered, but likewise, the question can be raised whether the EC would want topical gaps in its funding portfolio.

A further observation is that the UK clearly had a substantial role in strengthening the core EU research topics before and during H2020 when we compare EU-27 versus EU-28 topics and publication numbers per topic. Although these topics have remained core

¹⁴⁰By local, national, or other funding

¹⁴¹ Latvia seems to have a keen interest in this topic, contributing almost 22% to the total EU-27 output in this topic, and ranking higher than the UK or Japan in this area. In the EU-27, Germany is a close second on this specific topic. A case of smart specialization?

¹⁴² See Wintjes & Hollanders, 2011: https://ideas.repec.org/p/unm/unumer/2011027.html

topics after Brexit, the departure of the UK has had a noticeable impact on EU publication numbers.

External funder comparison

For this external comparison, we have chosen a select number of large third-country funders from China, Japan, the United Kingdom and the United States:

- National Natural Science Foundation of China (NNSFC, China);
- Japan Science and Technology Agency (JSTA, Japan);
- Engineering and Physical Sciences Research Council (EPSRC, UK);
- National Institutes of Health (NIH, USA);
- National Science Foundation (NSF, USA);
- European Commission (EC, Europe).

Using Scival data, we have generated an overview of the topics funded by each funder, prominence percentiles, and scholarly output generated. By virtue of their calculation by Scival, these final two can differ slightly, but the overall comparison remains valid¹⁴³. To further enable comparison, we have added a percentage of funded publications as a share of total output per topic.

We find that in terms of topics covered:

Funder	total # of topics	# of overlapping topics with EC	# of different topics	# of funded topics, more than 1% of worldwide output	# of plus 1% topics not- shared
EC	984	0	0	68	0
NNSFC	198	198	0	7	0
JSTA	6275	229	6046	1062	1044
EPSRC	197	8	189	14	14
NIH	7164	296	6868	2847	2753
NSF	1483	173	1310	193	172

Table 44. External funder comparison - topics

Source: Author's own interpretation. Note: The dataset can be found at: <u>https://doi.org/10.34894/SKYJTH</u>.

Let's first look at productivity in terms of having a share of 1% or more funded publications in a specific topic. We find that for 7% of all research topics funded by the EC, 1% of the worldwide publications are funded by the EC programmes. Comparing this to the NSF, we

¹⁴³ As mentioned before there is a difference in data gathered via the EC beneficiary survey and through the text-mining of acknowledgements. Here we have attempted to separate the two, with the external comparison relying completely on Scopus/Scival data. This data is retrieved by API. Due to time lag these figures can then differ slightly. This however should not affect the overall robustness of the results and analysis.

find that this is 13% vs the EC's 7%, while for the EPSRC it is 7%. The NIH has almost 40% of all topics funded in this 1% or more bracket. The NNSFC seems to have a rather low share at 3.5%.

What is rather interesting is the similarity with the NNSFC-funded research; all (100%) NNSFC-funded topics are matched by the EC, and the dis-similarity with the EPSRC and JSTA, where only approximately 4% of the research topics match. For the NIH and NSF, these are 4% and 11%, respectively.

Lessons Learned

- From the internal analysis of topical overlap, we find that, indeed, such overlap exists between the H2020 programme parts and Social Challenges. The overlaps differ per topic, which is important to note as we find that topics that represent a more broadly applicable technology (a general-purpose technology, or GPT) or topics that have a certain urgency or can be contributed to by different programme parts and Social Challenges (such as COVID-19) show higher levels of overlap than topics that have a much more narrow focus;
- The internal analysis also shows that programme parts with a broad focus, such as ERC, MSCA and SEWP, support research in many prominent topics. Other programme parts (such as EURATOM or the LEITs) and Social Challenges are more specialised in their focus and policy goals. This is mirrored by the topics they fund, and the overlap with other programme parts and Social Challenges is only minimal, especially when looking at the publication numbers outside of the funding programme part or SC. One can denote that there usually is a clear home for specific topics, with only a small number of publications appearing in other clusters;
- The external analysis shows that **EC-funded research is in line with those topics researched nationally in the broader EU.** EC-funded research also shows a high overlap with Chinese research (both Nationally and with that from the Chinese National Science Fund (NNSFC)) as well as with other Third Countries such as the United States and Japan. A certain differentiation effect can be noticed on the national level, but this should be expected and is in line with the smart specialization strategies employed at the national level;
- The external analysis clearly shows the effect of BREXIT on the funded topics. The UK has been an integral part of the European research area and environment, strengthening topics that are important to the EU-27 and the EC and relying on EU research to fill in domestic gaps. The analysis shows that it is a "no-win" situation, game theoretically speaking, in terms of topical coverage in research;
- The re-admission of the UK as an associate member to HE and the ERA has been a necessary step for both sides, as the analysis shows, and an extension beyond 2027 is called for;
- The external analysis points out that the EC seems to be lagging with respect to research funded in Health Science topics.

Potential areas for improvement

 One can say that ERC and MSCA produce the bulk of H2020's new knowledge in a large number of topics, while other programme parts and the SCs are trying to boost competitiveness or are solving specific societal challenges. The programme part and SCs' foci and funding are proportionate and cover programme-specific topics. This excludes Health Sciences and, to some extent, also SSH related topics; • A gap in the EC's funding portfolio, in terms of Health Science related research, might require attention, especially as it is the core of the first Social Challenge (3.1). Compared to the US and China, the EC is lagging, so funding for research in these topics is required.

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Network analysis

Methodology

In Phase 2, the study team conducts a network analysis of participating organisations and individuals. The basis for this analysis is the administrative data on Horizon Europe, with analyses through individual researchers done using participating researchers' projects' data¹⁴⁴ and analyses through entities done using participating entities' data¹⁴⁵. In addition, Tracking of Research Results (TRR) data for FP7 and H2020 was used to trace participation over time.

The analysis encompasses two main sections, split by the two main data sources: The first section uses the participating entities' data to find highly networked entities throughout the framework programme and measure collaborations within Pillar 2, Clusters 1-3. Individual PICs were used to denote the entities, and official HE project numbers were used to denote the connections between them.

The second section uses data from individual participating researchers. It encompasses a geographic dimension, an internal dimension and a continuity dimension.

Geographic analysis uses research projects to trace ties between countries, given the individual researcher's nationality. Nationality, as opposed to country of residence, was chosen in this case because the data on nationality was complete, but there was no data on country of residence. This part of the analysis provides outputs on the most central countries and regions across different programme parts and feeds into the evaluation questions regarding effectiveness.

The internal dimension uses individual researchers to trace ties between different programme parts within the current framework programme, while the continuity dimension uses individual researchers to trace ties between the current and previous framework programmes. These results feed into the analyses on coherence and effectiveness. It was noted in the inception report that ORCID numbers would be used to identify and connect researchers. However, ORCID numbers were not available in the data for 6,808 (11.2%) individuals; therefore, full names were used instead. Full names present their own complications, as there is no perfect way to ensure that two individuals with identical full names will not be treated as one. It may be tempting to tie individuals to research institutions in order to guarantee their uniqueness. However, this would then treat the same individual as two separate people in the case that he or she changed research institutions. To mitigate the risk of overestimating the number of connections due to identical full names, we repeated the analysis using a subset of the data where ORCID numbers are available and found similar results, which speaks to the method's robustness. Because full name data is more complete, it is what is shown in this report.

In each case, we first present the analysis of HE as a whole, followed by the analysis of Pillar 2 where relevant.

Concepts related to network analysis

Three statistics are considered to understand connectedness in our data: **degree**, **closeness and betweenness centrality**. Centrality measures each node's level of "central-ness", which

¹⁴⁴ Latest update: 14-04-2023.

¹⁴⁵ Latest update: 20-06-2023.

are countries or programme parts. The meaning of "central" varies by the type of centrality measurement used, and a highly central node by one measurement can be low by another. Therefore, it is important to look at all three measurements.

- 1. **Degree centrality** is a simple measure of how many connections or "edges" each node has. For example, in the geographic analysis, each country's degree tells how many different countries the node was connected to through Horizon Europe research projects.
- 2. Closeness centrality, as the name implies, looks at how close each node is to every other node in the network. It is the average shortest path of the node to every other node in the network, normalized so that the score is between 0 and 1. A score closer to 1 indicates that the paths from that node to every other node are, on average, short, and a number close to 0 indicates longer average paths. The closeness centrality can inform which nodes are good information broadcasters and can reach other nodes most quickly.
- 3. Betweenness centrality takes the ratio of the shortest paths that go through the node over the shortest paths between two nodes. In simpler terms, betweenness centrality measures how important a node is to the information flow of the network. The number is reported as an absolute, unweighted value and will increase in size as the size of the network increases. Therefore, it is impossible to compare the betweenness scores across different network analyses; however, we can compare the rankings.

In addition, the density of each graph is given. Density is a number between 0 and 1, which tells us about the connectedness of the network as a whole. For example, if every country was connected to every other country through at least one project, the density would be 1. If no country was connected to any other, for example, if researchers worked exclusively with researchers from their nationality, the density would be zero.

Horizon Europe entities analysis

Using the participating entities' administrative data, we analysed the connectedness of different entities across the funding programmes. First, we examine the way that collaboration between participating entities contributes to regional disparities within the European Research Area (ERA), followed by the analysis of the top 1% of most networked entities.

Concentration of R&I activities

Regional disparity in innovation activity was noted as a challenge in *A New Horizon for Europe – Impact assessment of the 9th EU framework programme*. The divide across Member States is sharp and has been increasing in recent years, most notably after the pandemic¹⁴⁶. Regional disparities in R&I can lead not only to economic disparities, as each euro invested by EU funding is predicted to generate up to EUR 11 in GDP over the next 25 years, but also to consequences for the diffusion of breakthrough technologies, which is currently sub-optimal due to under-utilisation of interregional linkages and regional innovation ecosystems¹⁴⁷. Below, we examine the collaboration of entities within EU Member States as one facet of this issue.

¹⁴⁶ European Commission, Directorate-General for Research and Innovation, A new horizon for Europe – Impact assessment of the 9th EU framework programme for research and innovation, Publications Office, 2018, https://data.europa.eu/doi/10.2777/194210.

Entities, here referring to individual organisations, including higher and secondary educational institutes, private and public research organisations, and other institutions which conduct scientific research, collaborate with one another through HE projects. Each instance of collaboration between two entities is counted as a single "degree" for each of those entities, as described by degree centrality in the Methodology section above. The more times that an entity collaborates, the higher its degree will be. To examine the regional disparities within the ERA, we have summed up all the degrees of all entities within each Member State and visualised this in Figure 64. The map presents an aggregation of all instances of collaboration by all entities within each Member State. For example, if W University in Germany collaborated twice with Z University in the Netherlands, then Germany would have a total degree of 4, and the Netherlands would have a total degree of 2. The interpretation of this map is that regions with higher aggregate degrees are host to entities that collaborate more (in absolute numbers). Spain has the highest number of collaborations, followed by Germany, Italy, and France, meaning that entities within those countries collaborate the most.

Collaboration between researchers across disciplines and regions hastens the flow of knowledge and improves the quality of scientific research¹⁴⁸. Therefore, we expect regions with a higher degree of collaboration also produce high-quality scientific output. One way to measure the quality of scientific output is through highly-cited publications.

¹⁴⁸ Ibid.

Figure 64. Aggregate instances of collaboration (degree) by Member State



Source: Compiled by the research team using eCORDA data.

Figure above **Figure 65** shows a map of highly-cited publications created for the report, *Science, Research and Innovation Performance of the EU 2022*, where we see a clear concentration of highly-cited publications across Western Europe. Many regions whose entities collaborated often also produced a high concentration of highly-cited publications. We also see a high concentration of highly cited publications coming from the Nordic Member States and from Cyprus, Estonia, and Slovenia, which is not reflected on our map above. However, a similar trend emerges if we normalise the degree of collaboration by each Member State's population density.



Figure 65. Percentage of highly cited publications (top 10%) in 2018 per NUTS 2 level

Source: European Commission, Directorate-General for Research and Innovation (2022), Science, research and innovation performance of the EU 2022 – Building a sustainable future in uncertain times, Publications Office of the European Union, Luxembourg, https://data.europa.eu/doi/10.2777/78826.

The Figure above**Table 45** provides the density of the degree weighted by each country's population to add nuance to the picture. When population density is accounted for, Cyprus, Luxembourg, Slovenia, and Estonia emerge at the top of Member States and Associated Countries, meaning their entities collaborated more with other institutions relative to the size of the countries' populations. Cyprus and Estonia saw the greatest increase in innovation index scores between 2016 and 2023, according to the European Innovation Scoreboard (EIS), so seeing them near the top of the list is not surprising.

Name	Total degree	Weighted degree
Cyprus	7 459	0.82
Luxembourg	4 839	0.74
Slovenia	12 291	0.58
Estonia	6 372	0.47
Iceland	1 583	0.41
Finland	22 620	0.41
Belgium	46 076	0.39
Greece	38 089	0.37
Norway	19 436	0.36
Malta	1 881	0.35
Austria	28 874	0.32
Denmark	18 065	0.31
Netherlands	51 702	0.29
Ireland	13 939	0.27
Switzerland	22 094	0.25
Portugal	25 923	0.25
Latvia	4 604	0.24
Sweden	23 778	0.23
Spain	92 156	0.19
Lithuania	4 764	0.17
Croatia	6 256	0.16
Czechia	15 072	0.14
Italy	79 999	0.14
Bulgaria	7 244	0.11
France	74 114	0.11
Germany	90 371	0.11
Slovakia	5 412	0.1
Hungary	8 223	0.09
Montenegro	413	0.07
Serbia	4 188	0.06
Liechtenstein	24	0.06
Romania	10 951	0.06
Poland	16 285	0.04
North Macedonia	626	0.03
Moldova (Republic of)	801	0.03

Table 45. EU member states and Associated Countries total and weighted degree

Source: Compiled by the research team using eCORDA data.

In contrast, some regions are doing poorly by any measure. Romanian and Hungarian entities are collaborating less in absolute as well as relative measures, and their concentration of highly-cited publications is also low. Romania was also given the lowest score of all Member States by EIS.

Our findings, therefore, support the assertion by A New Horizon for Europe that regional disparities exist in the European R & I ecosystem. The next section looks in detail at specific entities and examines the extent to which those entities dominate participations and funding in Horizon Europe.

Top 1% most networked entities

The top 1% subset was created by identifying the participating entities with the highest (top 1%) closeness centrality. A node with a high closeness centrality indicates not only that it has a large number of direct connections to other nodes in the network but also that it has short paths to other nodes with which it lacks direct connections. We can, therefore, interpret the "top 1% most-networked" as entities with the strongest connections to other entities within Horizon Europe, i.e., well-established. The individual entities were given by their PIC, and collaboration was defined as two or more entities being listed under the same project number. There were 18,017 total unique entities; therefore, the top 1% was a set of 180 entities.

So far, 34.5% of Horizon Europe has gone to just 1% of participating entities. This implies that the remaining 65.5% of all funding was distributed among 17 837 entities. The top 1% of most networked entities are primarily located in Western Europe, with Italy, Germany, the Netherlands, Spain, the United Kingdom and France hosting half of them. In addition, 9 member states (Bulgaria, Croatia, Cyprus, Latvia, Lithuania, Hungary, Malta, Romania and Slovakia) do not host any top 1% most-networked institutions. This finding further supports the evidence in the previous section that regional disparities exist in the European research area. Highly influential and well-established entities are concentrated in Western Europe and receive disproportionately more funding. This may lead to deepening disparities and slower diffusion of research results as time goes on.

Pillar	Total top 1% participations	Share of top 1%	Total top 1% funding (eur mil)	Share of funding to top 1%
HEU overall	14 591	26.3	7 886.29	34.5
Pillar 1	6 122	38.0	3 572.42	51.0
Pillar 2	7 369	20.8	3 718.83	26.5
Pillar 3	652	31.6	357.73	36.1
WIDERA	448	23.8	237.31	28.0

 Table 46. Participations and funding to the top 1% most-networked

Source: Compiled by the study team using eCORDA data.

The participation of the 180 most networked entities is presented in the three Tables below by programme parts, region, and member state. In each Table, total participations by top 1% of most networked entities are compared with total participations in that programme part, region, or country. A higher share of participations by the top 1% indicates that HE resources may be disproportionately funnelled towards a small number of well-established institutions. To give an idea of these highly networked and well-established entities, Table 50 provides the names of the 18 most networked entities.

The participation by the top 1% varied across the different programme parts but was highest among Pillar 1 due to its focus on excellence. EIE saw the smallest share of the top 1% participations of any HE programme, meaning that EIE calls may be more accessible to institutions without strong existing networks.

Part name	Total participations by Top 1%	Total participations (HE overall)	Share (%)
ERC	1 686	3 277	51.4
MSCA	624	10 986	34.1
INFRA	3 812	1 832	34.7
WIDERA ERA	319	1 175	27.1
WIDERA Widening	129	705	18.3
Cluster 1	1 063	4 758	22.3
Cluster 2	412	1 760	23.4
Cluster 3	272	1 606	16.9
Cluster 4	2 174	9 312	23.3
Cluster 5	2 018	10 295	19.6
Cluster 6	1 430	7 656	18.7
EIC	622	2 083	37.8
EIE	30	420	7.1
HEU Overall	14 591	55 865	26.3

Table 47. Participations of top 1% by programme part

Source: Compiled by the study team using eCORDA data.

Table 48 gives an overview of the share of participations by the top 1% most networked by region. Non-Widening countries experienced the highest share due to their stronger research infrastructure.

Table 48. Participations of the top 1% by region

REGION	TOTAL PARTICIPATIONS BY TOP 1%	TOTAL PARTICIPATIONS (HE OVERALL)	SHARE (%)
Widening	1 487	9 303	16.0
Non- Widening	11 083	36 706	30.2
Associated	1 567	6 155	25.5
Third	454	3 264	13.9

Source: Compiled by the study team using eCORDA data.

Over half of Denmark's participations came from the top 1% of most networked entities, while Poland only saw a single participation by such entities. Sweden and the Netherlands also saw a high percentage of participations by the top 1% entities (40% and 36.8%). This is in line with the findings of the European Innovation Scoreboard, which ranked Denmark highest among member states in 2023 in the overall innovation index, while Sweden and the Netherlands were the next highest among member states¹⁴⁹.

¹⁴⁹ European Commission, Directorate-General for Research and Innovation, Hollanders, H., European Innovation Scoreboard 2023, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2777/119961

MEMBER STATE	TOTAL PARTICIPATIONS BY TOP 1%	TOTAL PARTICIPATIONS (HE OVERALL)	SHARE (%)
Denmark	756	1 371	55.1
Luxembourg	119	256	46.5
Sweden	680	1 506	45.2
Netherlands	1 493	3 654	40.9
Finland	512	1 288	39.8
Ireland	374	1 056	35.4
Greece	773	2 369	32.6
Slovenia	196	611	32.1
Italy	1 658	5 367	30.9
Belgium	928	3 011	30.8
France	1 367	5 141	26.6
Austria	434	1 634	26.6
Germany	1 560	6 270	24.9
Spain	1 202	6 152	19.5
Estonia	66	369	17.9
Portugal	257	1 490	17.2
Czechia	126	737	17.1
Poland	69	876	7.9

Table 49. Participations by top 1% by member state

Source: Compiled by the study team using eCORDA data.

A further subset of the top 0.1% of entities with the highest degree is presented in Table 50. These 18 entities represent the most well-connected entities across Horizon Europe. Because the closeness centralities of these entities are very similar, degree is presented instead for comparison. The degree represents the number of shared HE projects given by project number.

None of these entities were newcomers to EU funding programmes. The Fraunhofer Society tops the list with 3 354 shared HE projects, which is not surprising considering it is the biggest organisation for applied research in Europe.

Country	Participant	Entity type	Degree
Germany	FRAUNHOFER GESELLSCHAFT ZUR FORDERUNG DER ANGEWANDTEN FORSCHUNG EV	REC	3 354
Spain	AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS	REC	2 554
France	CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE CNRS	REC	2 552
Italy	CONSIGLIO NAZIONALE DELLE RICERCHE	REC	2 344
Belgium	KATHOLIEKE UNIVERSITEIT LEUVEN	HES	2 076
France	COMMISSARIAT A L ENERGIE ATOMIQUE ET AUX ENERGIES ALTERNATIVES	REC	2 040
Netherlands	TECHNISCHE UNIVERSITEIT DELFT	HES	1 921
Greece	ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS	REC	1 917
Finland	TEKNOLOGIAN TUTKIMUSKESKUS VTT OY	REC	1 774
Italy	ALMA MATER STUDIORUM - UNIVERSITA DI BOLOGNA	HES	1 690
Denmark	DANMARKS TEKNISKE UNIVERSITET	HES	1 686
Germany	DEUTSCHES ZENTRUM FUR LUFT - UND RAUMFAHRT EV	REC	1 560
Italy	POLITECNICO DI MILANO	HES	1 524
Switzerland	EIDGENOESSISCHE TECHNISCHE HOCHSCHULE ZUERICH	HES	1 521
Netherlands	NEDERLANDSE ORGANISATIE VOOR TOEGEPAST NATUURWETENSCHAPPELIJK ONDERZOEK TNO	REC	1 519
Netherlands	WAGENINGEN UNIVERSITY	HES	1 463
Norway	SINTEF AS	REC	1 452
Denmark	AARHUS UNIVERSITET	HES	1 451

Source: Compiled by the study team using eCORDA data.

Unique collaborations between entities

We analysed the unique collaborations between entities within Clusters 1, 2, and 3 and within the subset of Cluster 1: Mission Cancer calls and Cluster 3: Cybersecurity calls. We define "unique" collaborations as those which did not occur elsewhere in the HE framework programme.

There were 8 225 collaborations within C1 Mission: Cancer, 7 110 (86%) of which were unique to this call. The visualisations show all Mission: Cancer collaborations between entities. The Figure below shows the collaborations within Mission Cancer by entity type. The different colours of dots represent different legal entity types. The bigger the dot is, the stronger collaborations there are. For instance, it can be noted that most collaborations appear between RES types. However, it can also be noted that collaborations go widely and appear among all legal entity types, even if these are weaker ones.

Figure 66. Collaborations within C1: Mission Cancer by entity type



Source: Compiled by the study team using eCORDA data.

When it comes to the collaborations of Mission Cancer by country association, the most collaborations appeared between the Member States (light blue dots), followed by Associated Countries (green dots). The Third Countries were also indicated as having some collaborations; however, these are smaller dots.

Figure 67. Collaborations within C1: Mission Cancer by country association



Source: Compiled by the study team using eCORDA data.

The Table below illustrates the top 10 unique collaborations within Cluster 1 on the Mission of Cancer. Cancer Mission has unique collaborations between and within the Member States, mostly including HES and REC entities. Among the top 10 unique collaborations, Lithuania is indicated six times, collaborating with other Member States, including Norway, Hungary, Finland, Estonia, Poland, and Sweden.

Unique	Partner 1 name	Partn	Partn	Partner 2 name	Partn	Partn
ns		count	er i entity		er∠ count	er ∠ entity
		ry	type		ry	type
4	HUS-YHTYMA	FI	REC	OSLO UNIVERSITETSSYKE HUS HF	NO	HES
3	OSLO UNIVERSITETSSYKE HUS HF	NO	HES	NACIONALINIS VEZIO INSTITUTAS	LT	REC
3	Orszagos Onkologiai Intezet	HU	REC	NACIONALINIS VEZIO INSTITUTAS	LT	REC
3	HUS-YHTYMA	FI	REC	NACIONALINIS VEZIO INSTITUTAS	LT	REC
3	SIHTASUTUS TARTU ULIKOOLI KLIINIKUM	EE	REC	NACIONALINIS VEZIO INSTITUTAS	LT	REC
3	NARODOWY INSTYTUT ONKOLOGII IM. MARII SKLODOWSKIEJ- CURIE - PANSTWOWY INSTYTUT BADAWCZY	PL	REC	NACIONALINIS VEZIO INSTITUTAS	LT	REC
3	KAROLINSKA INSTITUTET	SE	HES	NACIONALINIS VEZIO INSTITUTAS	LT	REC
3	EREVNITIKO PANEPISTIMIAKO INSTITOUTO SYSTIMATON EPIKOINONION KAI YPOLOGISTON	EL	REC	MINISTRY OF HEALTH	EL	PUB
3	EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER AISBL	BE	REC	SYREON KUTATO INTEZET KORLATOLT FELELOSSEGU TARSASAG	HU	PRC
3	INSTITUT GUSTAVE ROUSSY	FR	REC	UNICANCER	FR	REC

Table 51. Top ten unique collaborations within C1: Mission Cancer

Source: Compiled by the study team using eCORDA data.

There were 2 468 collaborations within Cluster 3 Cybersecurity calls, 2 097 (85%) of which were unique to this call.

Figure 68 shows a visualisation of the collaborations between entities within the cybersecurity call. PRC types (light green dots) and RES types (darker blue dots) were the most connected entities. There is also an isolated cluster of entities (on the right-hand side) that collaborate with one another but not with any other entity within cybersecurity.





Source: Compiled by the study team using eCORDA data.

Below are the top 10 unique collaborations within Cluster 3 cybersecurity calls.

Unique collaboration s	Partner 1 name	Partne r 1 countr y	Partne r 1 entity type	Partner 2 name	Partne r 2 countr y	Partne r 2 entity type
4	AEGIS IT RESEARCH GMBH	DE	PRC	CYBERALYTIC S LIMITED	CY	PRC
4	SPHYNX TECHNOLOGY SOLUTIONS AG	СН	PRC	CYBERALYTIC S LIMITED	CY	PRC
3	MAGGIOLI SPA	IT	PRC	CYBERALYTIC S LIMITED	CY	PRC
3	HOSPITAL DO ESPIRITO SANTO DE EVORA EPE	PT	PUB	METAMIND INNOVATIONS IKE	EL	PRC
3	MONTIMAGE EURL	FR	PRC	METAMIND INNOVATIONS IKE	EL	PRC
3	PDM E FC PROJECTO DESENVOLVIMENTO MANUTENCAO FORMACAO E CONSULTADORIALD A	PT	PRC	METAMIND INNOVATIONS IKE	EL	PRC
3	DIMOSIA EPICHEIRISI ILEKTRISMOU ANONYMI ETAIREIA	EL	PRC	METAMIND INNOVATIONS IKE	EL	PRC
3	AEGIS IT RESEARCH GMBH	DE	PRC	SECURITY LABS CONSULTING LIMITED	IE	PRC
3	SPHYNX TECHNOLOGY SOLUTIONS AG	СН	PRC	SECURITY LABS CONSULTING LIMITED	IE	PRC
3	POLYTECHNEIO KRITIS	EL	HES	SECURITY LABS CONSULTING LIMITED	IE	PRC

Table 52. Top ten unique collaborations within Cluster 3: Cybersecurity

Source: Compiled by the study team using eCORDA data.

Horizon Europe geographic network analysis

Using Horizon Europe administrative data (from the CORDA database), we were able to trace the connectedness of EU-funded research on a global scale.

The full dataset consists of 63 083 rows, each representing a unique researcher/project pair. Each project (represented by a nine-digit number) may have multiple researchers associated with it, and each researcher may be involved in multiple projects. Importantly, we use the nationality data provided for each researcher to connect nations through projects.

It was, therefore, possible to connect different nations through the research projects, as most projects had multiple researchers from different backgrounds working together. To prepare the data, 2 653 values with no nationality information were removed, of which 2 580 were from the MSCA programme. What concerns the Resilient Europe study scope is that only six values were removed from Cluster 1.

Programme part	Count	Percent
Cluster 1	6	0.0
Cluster 4	3	0.0
Cluster 5	10	0.0
Cluster 6	3	0.0
EIC	4	0.0
INFRA	1	0.0
MSCA	2 580	1.0
WIDERA	3	0.0
NA	43	0.0
Total	2 653	1

 Table 53. Missing nationality information by programme part

Source: Compiled by the study team using eCORDA data.

A total of 155 countries have been participating in Horizon Europe thus far. Two countries, Brunei and Myanmar, were dropped due to having only a single nationality participating in the project. Therefore, **the analysis uses a total of 153 countries.**

Figure 69 shows a visualisation of the top collaborations between Member States and Associated Countries in Horizon Europe. The top collaborations for this visual are the edge weights that lie two log standard deviations above the log mean edge weight for the dataset. All edges visualised represent more than 10 938 collaborations. The size of the label corresponds to the country's betweenness centrality, and the thickness of the lines corresponds to the number of times that researchers from the two connected countries participated in a research project together. The countries are colour-coded by Non-Widening (blue), Widening (green), and ssociated (purple). Table 54 shows the network statistics for all 27 Member States.

The density of the graph is 0.368¹⁵⁰. A high density indicates a high level of interconnectedness between countries. Globally, over one-third of countries are connected through researchers participating in Horizon Europe-funded projects. As this is the first year this particular analysis has been done, there is yet to be a baseline for comparison. In subsequent years, we may be able to compare how the density changes over time.

¹⁵⁰ The density is measured from 0 to 1, where 0 presents networks with no relationships and 1 presents networks with all possible relationships.
Figure 69. Visual representation of countries connected through research projects



Source: Compiled by the study team using eCORDA data.

The Table below shows the centrality measurements for all EU-27 countries. The results from this analysis echo the results of the co-publication network analysis done in Phase 1. **Germany, France, Italy, and Spain remain highly central to the European research ecosystem in the new framework programme, according to all three measures**. Germany and Italy were tied for highest in both degree and closeness centrality, and Italy was highest for betweenness. This tells us that Italy and Germany are the two countries most connected to other countries through Horizon Europe. Furthermore, the graph above shows that the thickest edge occurs between Spain and Italy, telling us that more researchers from those two countries collaborated on Horizon Europe projects than any other two nationalities.

Interestingly, **in all measures of centrality, non-Widening countries scored the highest** in terms of their well-developed research infrastructures. Among the Widening countries, Greece, Portugal, Poland and Czechia were found to be more central. The country with the lowest centrality ranking by any measure was Luxembourg.

Country	Region	Degree	Closeness centrality	Betweenness centrality
Germany	Non-Widening	142	0.9	519.1
Italy	Non-Widening	142	0.9	571.9
Spain	Non-Widening	139	0.9	542.2
France	Non-Widening	137	0.9	446.9
Netherlands	Non-Widening	135	0.9	361.1
Greece	Widening	130	0.9	363.6
Belgium	Non-Widening	129	0.9	285.9
Portugal	Widening	119	0.8	222.9
Austria	Non-Widening	115	0.8	171.1
Finland	Non-Widening	108	0.8	123.9
Poland	Widening	108	0.8	106.4
Czechia	Widening	107	0.8	135.1
Denmark	Non-Widening	106	0.8	126.7
Sweden	Non-Widening	106	0.8	126.3
Ireland	Non-Widening	104	0.8	94.5
Romania	Widening	99	0.7	80.7
Slovenia	Widening	96	0.7	49.6
Bulgaria	Widening	95	0.7	76.9
Hungary	Widening	95	0.7	76.6
Cyprus	Widening	88	0.7	48.2
Croatia	Widening	88	0.7	37.5
Lithuania	Widening	86	0.7	48.3
Slovakia	Widening	81	0.7	37.2
Estonia	Widening	78	0.7	24.6
Latvia	Widening	72	0.7	13.9
Malta	Widening	68	0.6	15.6
Luxembourg	Non-Widening	60	0.6	11.5

Table 54. Centrality statistics for EU-27, all Horizon Europe

Source: Compiled by the study team using eCORDA data.

Horizon Europe programme parts connectedness

The connectedness of programme parts was analysed through individual researchers. Each row represents a unique researcher/project pair and includes the name of the programme part that the project falls under. It was, therefore, possible to trace individual researchers across programme parts.

The full FP dataset contained 62 859 rows. The density was 0.95, meaning that **almost every programme part was connected to every other programme part through at least one researcher**. That means that of the 12 programme parts, all but three achieved the maximum degree of 11. The three parts which did not achieve the maximum degree were Cluster 3, European Innovation Ecosystems (EIE), and ERC, all of which had degrees of 9. Each of these programme parts was connected to 9 of 11 other programme parts.

The Figure below presents a visualisation of the connectedness of programme parts through individual researchers. The programme part names are colour-coded by pillar: Pillar 1 and WIDERA are in blue, Pillar 2 is in green, and Pillar 3 is in purple. The thickness of the edges represents the number of times a researcher had a project in each of the two connected nodes.

Figure 70. Connectedness of programme parts



Source: Compiled by the study team using eCORDA data.

The Table below presents the top 20 thickest edges (according to the number of connections of shared researchers) and their measurements from the above graph. The study team found that Cluster 5 and Cluster 4 shared the most common number of researchers (1 717) out of all Horizon Europe programme parts. Looking at the Resilient Europe study's scope (i.e., Clusters 1, 2 and 3), we observe that Cluster 1 shared the most number of researchers with Cluster 4 (444) and Cluster 5 (191), followed by Cluster 2 with Cluster 4 (221), likewise, Cluster 3 with Clusters 4 (472). As such, of the three clusters within the scope of this study, Cluster 4 appears to have the most researchers in common.

Pair	Connections
Cluster 5 / Cluster 4	1 717
Cluster 6 / Cluster 4	727
Cluster 6 / Cluster 5	668
Cluster 4 / Cluster 3	472
Cluster 4 / Cluster 1	444
MSCA / Cluster 4	302
INFRA / Cluster 4	271
INFRA / Cluster 6	261
Cluster 4 / Cluster 2	221
EIC / Cluster 4	209
WIDERA / Cluster 4	207
WIDERA / Cluster 6	193
Cluster 5 / Cluster 1	191
WIDERA / Cluster 5	185
MSCA / Cluster 5	153
Cluster 6 / Cluster 1	145
INFRA / Cluster 1	138
Cluster 3 / Cluster 1	135
WIDERA / INFRA	135

Table 55. Part connectedness (top 20) 151

Source: Compiled by the study team using eCORDA data.

The Table below shows the bottom 20 – thinnest edges – and their measures. Again, considering the scope of the Resilient Europe study, we observe that the smallest number of connections (shared researchers) were between Cluster 1 and EIE (4), Cluster 1 and ERC (13) as for Cluster 2, the least number of shared researchers were with ERC (2), EIC (2) and EIE (3). Cluster 3 was least connected with EIC (2) and INFRA (21). While the limited connections with EIE, EIC and INFRA are not that surprising, considering their different scope compared to the three programme parts within this study, the relatively small number of connections between Cluster 1 and ERC is a potentially interesting finding. Especially so that the Phase 1 report feeding into the ex post evaluation of Horizon 2020 found that more than two-thirds of health research was implemented outside of SC1, particularly in Pillar 1

¹⁵¹ The numbers will by half of what was reported in ESS Phase 2 First Interim Report Annex 6 (table 27). I accidentally counted each connection twice. It will be corrected in the second interim report. Please use these numbers, as they are the correct ones.

programmes. For example, health research comprised an estimated 39% of the ERC programme.

Pair	Connections
INFRA / Cluster 3	21
MSCA / ERC	16
ERC / Cluster 1	13
EIE / Cluster 6	12
EIE / Cluster 4	11
ERC / Cluster 4	10
EIE / Cluster 5	8
WIDERA / EIE	8
ERC / Cluster 5	6
ERC / Cluster 6	5
ERC / EIC	5
INFRA / EIE	5
EIE / Cluster 1	4
EIE / Cluster 2	3
EIC / Cluster 2	2
EIC / Cluster 3	2
ERC / Cluster 2	1
EIE / EIC	1
MSCA / EIE	1

Table 56. Part connectedness (bottom 20)

Source: Compiled by the study team using eCORDA data.

Continuity of programme parts across the FPs

This section aims to look at trends in the way researchers from previous FPs participate in Horizon Europe on an individual level.

The evaluation of HE is happening early in its life cycle, and sufficient co-publication data is not yet available¹⁵². However, good quality participation data is available at the individual level. On the other hand, individual participation data was not released for FP7 or H2020, but we have abundant publication data. Working under the assumption that project collaborators also publish together, we use both types of data to examine the flow of researchers from the previous two framework programmes into HE. The two analyses below show the capacity in which researchers who *published* under FP7 and H2020 projects went on to *participate* in HE.

The main limitation of this methodology is that those who publish under a project funded by the EU are not necessarily participants in the project. This becomes obvious when looking at H2020's ERC, a mono-beneficiary programme with a single leading PI per project, but sometimes, over 200 researchers publish under that same project. The strength of this method is that it is possible to capture some aspect of the knowledge flow, as researchers

¹⁵² Only around 800 publications have been recorded as of October 2023.

who publish under a project can be assumed to bring their knowledge of that topic to the next project they participate in, a knowledge flow that could not be captured by using pure participations data.

As mentioned earlier in the methodology section above, researchers were identified in both datasets by their full names, as Orcid IDs were only available for around 11% of individuals. Both datasets were encoded with UTF-8 to ensure compatibility between the names. Duplications were removed based on the level of analysis: For pillar-level analysis, a researcher was counted once to see if they had published under or participated in a given pillar. For programme part analysis, each researcher was counted once for their publication under or participation in a given programme.

Pillar level – full framework programme

Here, we examine the ways in which researchers who published under previous framework programme pillars went on to participate in HE. Duplications based on the pillar were removed for this Table, meaning that the subset included only one instance of a researcher publishing under or participating in any given pillar, leading to a clearer interpretation of the results. After removing all duplicates, the merged dataset was 1,843,244 rows. FP7-GA was removed before the analysis because it did not fit well into any of the main pillars; however, it was a small fraction of the data (<1%) and will not affect the conclusions. The results of this analysis feed into the effectiveness analysis in the main report and CS9.

Overall, the continuity, as measured by the number of researchers who published under a previous FP and went on to participate in HE, is low. The largest flow in absolute numbers happened between FP7 Cooperation and HE Pillar 2. Over 7 500 researchers who published under FP7 Cooperation participated in HE Pillar 2, two highly thematically related pillars that feature strong topical overlap in Health and Security. However, this represents only a small fraction, 7 502 out of 386 553, or around 2% of the total number of researchers who published under Cooperation.

Number of	Published under this previous FP	Went on to participate in this HE
researchers:	pillar:	pillar:
7 502	FP7 Cooperation	Pillar 2
5 821	H2020 Pillar 3	Pillar 2
5 812	H2020 Pillar 1	Pillar 2
3 567	H2020 Pillar 2	Pillar 2
3 473	FP7 People	Pillar 2
3 472	FP7 Ideas	Pillar 2
2 568	H2020 Pillar 1	Pillar 1
2 091	FP7 Capacities	Pillar 2
1 764	FP7 Cooperation	Pillar 1
1 485	FP7 Ideas	Pillar 1
1 294	FP7 People	Pillar 1
942	H2020 Pillar 3	Pillar 1
933	FP7 Capacities	Pillar 1
808	H2020 Pillar 1	Pillar 3
672	H2020 Pillar 2	Pillar 1
595	FP7 Cooperation	Pillar 3
568	FP7 Ideas	Pillar 3
512	H2020 Pillar 1	WIDERA
499	FP7 People	Pillar 3
494	FP7 Cooperation	WIDERA
346	FP7 People	WIDERA
299	H2020 Pillar 3	WIDERA
288	FP7 Ideas	WIDERA
265	H2020 Pillar 2	Pillar 3
264	FP7 Capacities	WIDERA
226	H2020 Pillar 3	Pillar 3
217	FP7 Capacities	Pillar 3
213	H2020 Pillar 2	WIDERA
76	FP7 Nuclear	Pillar 2
25	FP7 Nuclear	Pillar 1
9	FP7 Nuclear	Pillar 3
3	FP7 Nuclear	WIDERA

Table 57. Researchers who went on to participate in HE by pillar

Source: compiled by the study team using eCORDA data.

Following the same methodology as above, below are the top 20 most connected HEU parts and the number of researchers shared between them. The lack of Pillar 3 programmes in the Table makes it clear that EIE and EIC have relatively weak connections to previous FPs.

Number of researchers:	Published under this previous FP programme:	Went on to participate in this HE programme:
1 702	H2020-LEITs-ICT	Cluster 4
1 574	FP7-ICT	Cluster 4
1 243	H2020-MSCA	Cluster 4
1 211	FP7-IDEAS-ERC	Cluster 4
1 185	FP7-HEALTH	Cluster 1
1 064	H2020-SC1	Cluster 1
1 043	H2020-MSCA	MSCA
1 000	H2020-ERC	Cluster 4
924	FP7-PEOPLE	Cluster 4
906	H2020-SC2	Cluster 6
886	FP7-ENVIRONMENT	Cluster 6
878	FP7-IDEAS-ERC	Cluster 1
873	FP7-KBBE	Cluster 6
837	FP7-IDEAS-ERC	MSCA
803	H2020-ERC	MSCA
764	FP7-PEOPLE	Cluster 6
756	FP7-IDEAS-ERC	Cluster 6
756	H2020-MSCA	Cluster 6
755	H2020-MSCA	Cluster 5
706	H2020-MSCA	Cluster 1

Table 58. Researchers who went on to participate in HE by programme part (top 20)

Source: Compiled by the research team using eCORDA data.

Pillar 2 geographic network analysis

The geographic network analysis of Pillar 2 was performed using the same methodology as for the overall Horizon Europe analysis in the earlier section. The Pillar 2 dataset comprises 46 100 rows, each representing a unique researcher/project pair. Each project (represented by a nine-digit number) may have multiple researchers associated with it, and each researcher may be involved in multiple projects. Importantly, the study team used the nationality data provided by each researcher to connect nations through projects.

There were 148 countries in Pillar 2, and there were no countries with zero connections (none needed to be removed). As noted in the Table featuring the missing nationality information by programme part, only six values were removed (all from Cluster 1).

Figure 71 depicts the countries with the most collaborations within Pillar 2. As in the HE geographic analysis, the top collaborations for this visual are the edge weights that lie two log standard deviations above the log mean edge weight for the dataset. All edges visualised represent more than 795 collaborations, meaning that only 303, or 7.5% of the edges, are visible. The size of the label corresponds to the country's betweenness centrality, and the thickness of the lines corresponds to the number of times that researchers from the two

connected countries participated in a research project together. The countries are colourcoded by non-Widening (blue), Widening (green), associated (purple), and third (grey). Table 59 shows the network statistics for all 27 Member States.

The density for Pillar 2 is 0.36, which is very close to the overall density of Horizon Europe networks, higher than Pillar 3 (0.263), but slightly lower than Pillar 1, which appears to be the most globally connected Pillar in Horizon Europe. As mentioned in an earlier section, as we do not have baseline measures for density in the predecessors, the study team cannot conclude whether the density of networks is increasing or decreasing over time.

Looking at the different centrality measures, we observe the following:

- Degree centrality: Pillar 2 has the highest degree of centrality in non-Widening countries such as Germany, Italy, Spain, France, and the Netherlands. Essentially, this measure indicates that the countries with the highest degree of centrality score could be considered more central as they are the most connected to others. In the context of Horizon Europe Pillar 2, this could mean that countries such as Germany, Italy, Spain, France and the Netherlands (among others) can potentially have access to and/or deliver more resources¹⁵³.
- Closeness centrality: Our data shows that in Pillar 2, Germany, Italy and Spain were the most central in this measure. The more central the nodes (i.e., greater closeness centrality measure), the faster and easier these nodes (or, in this instance, countries) communicate with each other.
- Betweenness centrality: Similar to the closeness centrality for Pillar 2, Germany, Italy, and Spain have the highest betweenness centrality score. This could mean that those countries with the highest betweenness centrality score are the gatekeepers of information and resources.

¹⁵³ https://visiblenetworklabs.com/2021/04/16/understanding-network-centrality/



Figure 71. Visual representation of countries connected through research projects (Pillar 2")

Source: Compiled by the study team using eCORDA data.

The Table below shows the breakdown in the centrality measurements for all EU-27 countries under Pillar 2. While the three measures are explained in the paragraph above, we also observe a general trend (not exclusive to Pillar 2) that Widening countries are less well-connected compared to non-Widening countries, with some exceptions, such as Luxembourg.

Table	59.	Centrality	statistics	for	EU-27.	Pillar 2	2
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Country	Region	Degree	Closeness centrality	Betweenness centrality
Germany	Non-Widening	139	0.9	514.8
Italy	Non-Widening	138	0.9	502.9
Spain	Non-Widening	135	0.9	489.9
France	Non-Widening	133	0.9	383.2
Netherlands	Non-Widening	131	0.9	326.8
Greece	Widening	128	0.9	333.4
Belgium	Non-Widening	126	0.9	277.3
Portugal	Widening	114	0.8	210.1
Austria	Non-Widening	112	0.8	173.0
Finland	Non-Widening	104	0.8	111.6
Poland	Widening	104	0.8	118.1
Denmark	Non-Widening	103	0.8	119.4
Sweden	Non-Widening	101	0.8	109.6
Czechia	Widening	97	0.7	87.5
Ireland	Non-Widening	97	0.7	83.2
Romania	Widening	97	0.7	89.5
Slovenia	Widening	94	0.7	55.9
Hungary	Widening	91	0.7	72.4
Bulgaria	Widening	87	0.7	63.8
Croatia	Widening	84	0.7	34.1
Cyprus	Widening	83	0.7	50.1
Lithuania	Widening	83	0.7	42.7
Estonia	Widening	75	0.7	28.2
Slovakia	Widening	75	0.7	39.6
Latvia	Widening	69	0.7	15.8
Malta	Widening	60	0.6	13.5
Luxembourg	Non-Widening	55	0.6	9.7

Source: Compiled by the study team using eCORDA data.

Centrality statistics from Cluster 1 show that researchers from the Netherlands are more central when compared with Pillar 2 overall.

Table 60. Centrality statistics for EU-27, Cluster 1

Country	Region	Deg ree	Closeness centrality	Betweenness centrality
Germany	Non-Widening	96	1.0	307.2
Netherlands	Non-Widening	96	1.0	315.4
Italy	Non-Widening	92	0.9	247.4
Spain	Non-Widening	91	0.9	231.1
France	Non-Widening	87	0.9	188.4
Portugal	Widening	78	0.8	112.1
Greece	Widening	76	0.8	110.0
Sweden	Non-Widening	75	0.8	126.8
Belgium	Non-Widening	73	0.8	80.7
Austria	Non-Widening	70	0.8	71.5
Poland	Widening	69	0.8	66.1
Finland	Non-Widening	64	0.7	49.1
Denmark	Non-Widening	63	0.7	50.7
Ireland	Non-Widening	63	0.7	38.4
Hungary	Widening	57	0.7	24.8
Czechia	Widening	56	0.7	25.5
Slovenia	Widening	53	0.7	21.6
Croatia	Widening	52	0.7	15.2
Romania	Widening	50	0.7	22.9
Estonia	Widening	48	0.7	14.2
Lithuania	Widening	48	0.7	17.9
Bulgaria	Widening	47	0.7	12.8
Slovakia	Widening	47	0.7	7.0
Cyprus	Widening	46	0.6	11.5
Luxembourg	Non-Widening	34	0.6	1.8
Latvia	Widening	31	0.6	3.8
Malta	Widening	22	0.6	0.0

Source: Compiled by the study team using eCORDA data.

In Cluster 2, we find that Greek and Polish researchers are more central when compared with Pillar 2 overall.

Country	Region	Degree	Closeness centrality	Betweenness centrality
Germany	Non-Widening	79	1.0	415.9
Italy	Non-Widening	71	0.9	258.5
Greece	Widening	62	0.8	140.0
Poland	Widening	58	0.8	125.3
Spain	Non-Widening	58	0.8	100.3
France	Non-Widening	56	0.8	79.4
Belgium	Non-Widening	55	0.7	72.3
Netherlands	Non-Widening	54	0.7	77.5
Austria	Non-Widening	52	0.7	71.6
Sweden	Non-Widening	50	0.7	89.3
Finland	Non-widening	48	0.7	35.5
Czechia	Widening	45	0.7	39.3
Romania	Widening	45	0.7	36.9
Denmark	Non-Widening	44	0.7	43.4
Portugal	Widening	44	0.7	35.0
Hungary	Widening	42	0.7	18.6
Ireland	Non-Widening	41	0.7	15.2
Slovenia	Widening	41	0.7	18.8
Croatia	Widening	39	0.7	22.0
Estonia	Widening	39	0.7	23.0
Slovakia	Widening	36	0.6	8.0
Bulgaria	Widening	34	0.6	6.8
Cyprus	Widening	34	0.6	12.2
Lithuania	Widening	27	0.6	2.8
Latvia	Widening	24	0.6	1.2
Malta	Widening	18	0.6	2.3
Luxembourg	Non-Widening	13	0.5	0.0

Source: Compiled by the study team using eCORDA data.

In contrast to Clusters 1 and 2, Germans are not the most well-connected within Cluster 3. It is also interesting to note that researchers from Denmark are not well-connected in this Cluster. No researchers from Latvia, Malta or Luxembourg are known to have participated in Cluster 3 as of the release of this data (May 2023).

Country	Region	Degree	Closeness centrality	Betweenness centrality
Italy	Non-Widening	51	0.9	138.3
Spain	Non-Widening	51	0.9	132.8
Greece	Widening	50	0.9	112.9
Germany	Non-Widening	49	0.9	112.9
France	Non-Widening	46	0.9	82.9
Finland	Non-Widening	37	0.8	29.7
Portugal	Widening	36	0.7	34.1
Belgium	Non-Widening	35	0.7	29.2
Romania	Widening	33	0.7	25.5
Austria	Non-Widening	31	0.7	13.2
Poland	Widening	30	0.7	20.5
Netherlands	Non-Widening	29	0.7	17.6
Cyprus	Widening	28	0.7	16.5
Ireland	Non-Widening	27	0.7	18.1
Bulgaria	Widening	26	0.7	10.1
Hungary	Widening	25	0.6	6.0
Sweden	Non-Widening	22	0.6	4.0
Slovenia	Widening	15	0.6	0.6
Croatia	Widening	14	0.6	1.1
Lithuania	Widening	14	0.6	0.0
Czechia	Widening	12	0.6	0.8
Estonia	Widening	11	0.6	0.0
Slovakia	Widening	8	0.5	0.0
Denmark	Non-Widening	3	0.5	0.0

Table 62. Centrality statistics for EU-27, Cluster 3

Source: Compiled by the study team using eCORDA data.

Connectedness of Pillar 2

The Figure below presents a visualisation of the connectedness of Pillar 2 through individual researchers. The methodology for the connectedness analysis of Pillar 2 was the same as that of the overall Horizon Europe. The dataset contained 46 100 rows, and the density for Pillar 2 was 1. This means all six Clusters under Pillar 2 are connected to every other Cluster through at least one researcher. Generally, a network with high density suggests a tightly knit community, which may be beneficial for efficient communication.

The thickness of the edges represents the number of times a researcher had a project in each of the two connected nodes (or Clusters under Pillar 2). The Figure below shows that Cluster 4 and 5 are the most connected parts of Pillar 2. Looking at the scope of the Resilient Europe study, **Clusters 1, 2 and 3 are the most connected to Cluster 4**.

Figure 72. Connectedness of Pillar 2 parts



Source: Compiled by the study team using eCORDA data.

The Table below depicts the connections between different Pillar 2 clusters. As noted above, Cluster 4 and 5 are the most connected, with 1 717 connections through at least one researcher. All three Clusters that are within the scope of the Resilient Europe study (i.e., Cluster 1, 2 and 3) are the most connected with Cluster 4. Cluster 3 has the most connections with Cluster 4 out of the three. This is not surprising, considering that both clusters share some thematic areas like Artificial Intelligence, internet and cybersecurity.

Pair	Connections
Cluster 5 / Cluster 4	1 717
Cluster 6 / Cluster 4	727
Cluster 6 / Cluster 5	668
Cluster 4 / Cluster 3	472
Cluster 4 / Cluster 1	444
Cluster 4 / Cluster 2	221
Cluster 5 / Cluster 1	191
Cluster 6 / Cluster 1	145
Cluster 3 / Cluster 1	135
Cluster 6 / Cluster 2	127
Cluster 5 / Cluster 2	125
Cluster 2 / Cluster 1	115
Cluster 5 / Cluster 3	112
Cluster 6 / Cluster 3	75
Cluster 3 / Cluster 2	50

Table 63. Connections between Pillar 2 clusters

Source: Compiled by the study team using eCORDA data.

Continuity of Pillar 2

This section follows the methodology from the previous section, mapping researchers who published under previous framework programmes to their participation in HE. For this analysis, a subset of only those who participated in HE Pillar 2 was used. We removed duplicates at the programme part level, therefore, each number in Table **64** represents researchers who published in the programme part listed in column 1 and participated in the programme part listed in column 2. The subset contained 79 933 rows of unique researcher/programme part pairs.

Researchers who published under H2020 FP7 Health were the largest group of participants to CL1, followed by H2020 SC1, its thematic predecessor. Cluster 1 received much more participation from those who had published under previous FPs than CL2 or CL3.

Number of researchers:	Published under this previous FP programme part:	Went on to participate in this Pillar 2 programme part:
1 185	FP7-HEALTH	Cluster 1
1 064	H2020-SC1	Cluster 1
878	FP7-IDEAS-ERC	Cluster 1
706	H2020-MSCA	Cluster 1
704	H2020-ERC	Cluster 1
671	FP7-PEOPLE	Cluster 1
431	FP7-ICT	Cluster 1
335	H2020-SEWP	Cluster 1
303	FP7-JTI	Cluster 1
259	H2020-LEITs-ICT	Cluster 1
251	FP7-INFRASTRUCTURES	Cluster 1
243	FP7-ENVIRONMENT	Cluster 1
236	H2020-INFRA	Cluster 1
205	FP7-KBBE	Cluster 1
174	FP7-REGPOT	Cluster 1
174	H2020-LEITs-ICT	Cluster 3
161	H2020-SC6	Cluster 2
157	FP7-IDEAS-ERC	Cluster 2
154	H2020-FET	Cluster 1
152	H2020-SC2	Cluster 1

Table 64. Researchers who went on to participate in Pillar 2 (C1, 2 and 3 only) by programme part (top 20)

Source: Compiled by the research team using eCORDA data.

Figure 73 shows the aggregated sum of connections by those who published under FP7/H2020 and went on to participate in HE by programme part¹⁵⁴. We can clearly see the stark difference between Cluster 1, which saw the participation of many researchers who had previously published under HE, and Clusters 2 and 3, which comparatively saw very few, most likely owing to the smaller scope of Clusters 2 and 3.

¹⁵⁴ Note: because of the way the figures were calculated, this aggregation cannot be interpreted as distinct researchers, but as number of instances that researchers who published under one programme also participated in another.





Source: Compiled by the research team using eCORDA data.

Analysis of synergies with programmes outside of Horizon Europe

This section provides a detailed analysis of Cluster 1, Cluster 2 and Cluster 3 synergies between other EU funding programmes outside of Horizon Europe. The programmes that this analysis has included are as follows:

- <u>Creative Europe programme</u> (CREA2027)
- <u>Digital Europe Programme</u> (DIGITAL)
- European Maritime, Fisheries and Aquaculture Fund (EMFAF)
- Erasmus+ (ERASMUS2027)
- European Social Fund (ESF)
- <u>EU4Health Programme</u> (EU4H)
- Euratom Research and Training Programme (EURATOM2027)
- Internal Security Fund (ISF) only Union Actions are represented here due to methodological limitations, making up about 10-15% of the whole ISF.
- Programme for the Environment and Climate Action (LIFE)
- <u>Single Market Programme</u> (SMP)

To supplement the analysis, the study team carried out the analysis of all the programmes stated in <u>Annex IV of Horizon Europe regulation</u>. These programmes were analysed qualitatively, and the programmes are following:

• Synergies with the European Agricultural Guarantee Fund (EAGF) and the European Agricultural Fund for Rural Development (EAFRD) under the Common Agricultural Policy (CAP);

- Synergies with the European Regional Development Fund (ERDF);
- Synergies with the Connecting Europe Facility (CEF);
- Synergies with the Union Space Programme;
- Synergies with the Neighbourhood, Development and International Cooperation Instrument (NDICI) and the Instrument for Pre-accession Assistance (IPA III);
- Synergies with the InvestEU Programme;
- Synergies with the Innovation Fund under the Emission Trading Scheme (the 'Innovation Fund');
- Synergies with the Just Transition Mechanism;
- Potential synergies with the European Defence Fund shall benefit civil and defence research with a view to avoiding unnecessary duplication and in accordance with Article 5 and Article 7(1);
- Synergies with the Recovery and Resilience Facility.

Methodology

- The analysis of the HE synergies with other EU funding programmes is two-fold; it is categorised as **Complementary funding** (funding received from HE and other EU funding programmes for the thematically related research project);
- Alternative funding (funding received from other EU funding programmes as an alternative to HE).

Complementary funding analysis is performed by comparing the HE projects administrative data (participant PIC numbers and project abstracts) to the administrative data from other EU funding programmes (particularly CREA2027, DIGITAL, EMFAF, ERASMUS2027, ESF, INNOFUND, ISF, LIFE2027, SMP). When PIC numbers match in HE and other EU funding programmes, the project abstracts are compared to find the project similarities (using the semantic textual similarity method). When we find that a signed/ongoing HE project matches a signed/ongoing project in one of the other EU funding programmes, we flag these projects as receiving complementary funding from other EU sources. Alternative funding analysis takes the unsuccessful HE proposals and compares them to the projects funded under other EU funding programmes (particularly CREA2027, DIGITAL, EMFAF, ERASMUS2027, ESF, INNOFUND, ISF, LIFE2027, SMP). Using the same underlying methodology described above, we can flag the unsuccessful HE proposals that secured funding from other EU funding programmes and went ahead with their research projects.

To perform these analyses above, we employed the semantic textual similarity method. It is a data science method that takes two texts (in this case, project abstracts) and decides if and to what extent these texts are similar in meaning. In the cases where we identify the same research-performing organisation (based on their PIC number) to participate in HE and other EU funding schemes, using this method, we assign the similarity score from 0 to 1, where 1 signifies extremely high similarity. For the purpose of this analysis, we set a threshold at the similarity score of 0.6. Projects with a score of 0.59 or lower are not considered similar enough.

The following steps were taken to get the abstract similarity scores: first, every relevant abstract was turned into a word embedding using the "all-MiniLM-L6-v2" model from the

Sentence-Transformers¹⁵⁵ library. The maximum input size, 256 word tokens, was chosen. This means that due to technical limitations, only around 200 words from the start of each abstract are used to compute embeddings. Then, each project from HE was compared with each project from other EU funding programmes to see if it had either a single matching participant or at least two matching participants in a consortium. Finally, projects that had similar authors had their abstract embeddings compared using cosine similarity. This produced a number from 0 to 1. Through a manual analysis of matched abstracts, the study team chose a threshold of 0.6 for abstract similarities. Finally, projects that fulfilled both the consortium similarity metric and the abstract similarity threshold were evaluated in this study.

During the abstract similarity comparison, one project from a different EU funding program could be found to be similar to multiple HE projects. Because of this, projects were deduplicated within the slice, which is calculated for each Table. As a result, the values and totals on different levels (for example, EU funding framework and Pillar levels) may not add up to the same numbers.

Analysis of Clusters 1, 2 and 3

In this analysis, the study team focused exclusively on three specific clusters covered under this study, namely CL1, CL2 and CL3.

(a) Complementary funding Cluster 1, 2 and 3

The subsequent Table provides a detailed breakdown of complementary funding for CL1, CL2 and CL3. According to the data provided below, among the 316 projects in CL1, 20 (or about 6%) of them have received complementary funding, amounting to EUR 38.8 million. In CL3, complementary funding was provided to 12 out of 97 projects in total – this is about 12% of projects. On the other hand, our analysis suggests that for CL2, complementary funding is rather low, with only a single project having received this type of funding. On the one hand, projects receiving complementary funding may have additional resources to enhance their research, innovation, or implementation efforts. On the other hand, **the level of complementary funding could imply that these projects are perceived as having greater alignment with the goals and objectives of the funding entities or stakeholders.**

Pillar	Total no of projects in Horizon Europe	No of the projects received complementary funding	Total amount of EU funds received as complementary funding, in EUR million
Cluster 1	316	20 (6.3%)	38.8
Cluster 2	151	1 (0.7%)	0.1
Cluster 3	97	12 (12.4%)	8.0

Table 65.	The overview	of the	complementary	/ fundina	(in EUR	million)
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Source: CORDA data.

Our analysis was also extended with the aim of looking at complementary funding for Widening countries and HE newcomers. Complementary funding can play a crucial role for Widening countries (e.g., capacity development, opportunities for global cooperation) and newcomers (e.g., access to resources, fostering growth) participating in Cluster 1, 2, and 3 projects within Horizon Europe.

¹⁵⁵ https://www.sbert.net/index.html

The two Tables below show that complementary funding was important for Widening countries, especially under CL1, less important under CL3 and even less critical for CL2. In terms of newcomers, as the Table below illustrates, only a few countries received complementary funding and no complementary funding for CL2.

Table 66. The overview of the complementary funding (in EUR million) for Widening countries

Pillar	Total no participations indicated to participate in HE and other funding programmes	Of which are from Widening countries	Total amount of EU funds received as complementary funding, in EUR million	Total amount of EU funds received as complementary funding by Widening participants, in EUR million
Cluster 1	131	42 (32.1%)	38.8	5.5 (14.2%)
Cluster 2	3	1 (33.3%)	0.1	<0.1 (<100%)
Cluster 3	37	6 (16.2%)	8.0	0.8 (10.0%)

Source: CORDA data.

Table 67. The overview of the complementary funding (in EUR million) for HE newcomers

Pillar	Total no participations indicated to participate in HE and other funding programmes	Of which are newcomers in HE	Total amount of EU funds received as complementary funding, in EUR million	Total amount of EU funds received as complementary funding by HE newcomers, in EUR million
Cluster 1	131	3 (2.3%)	38.8	0.4 (1.0%)
Cluster 2	3		0.1	
Cluster 3	37	1 (2.7%)	8.0	0.6 (7.5%)

Source: CORDA data.

The study team also analysed the distribution of complementary funding by Cluster. However, as only one CL2 project received complementary funding, we did not include any analysis for this Cluster in this section.

For Cluster 1, the EU4H programme stands out as the primary contributor to healthrelated projects, complementing those under CL1. A total of 16 projects under EU4Health have been identified as complementary to CL1 projects, receiving a combined funding of EUR 36.1 million. Of this amount, EUR 5.4 million was allocated to Widening countries. This is not surprising as both Horizon Europe and the EU4Health programme aim to foster maximum synergies, especially in the realm of health research, innovation, and healthcare system strengthening, to ensure a more comprehensive and impactful approach to addressing health challenges. According to the latest EU4Health performance update,¹⁵⁶ synergies with the Horizon Europe programme are sought to maximise outputs and reduce duplication.

¹⁵⁶ https://commission.europa.eu/strategy-and-policy/eu-budget/performance-and-reporting/programme-performancestatements/eu4health-performance_en

EU funding framework	No of the projects flagged as complementary to HE projects	Total amount of complementary to HE funding, in EUR million	Total amount of complementary to HE funding received by Widening countries, in EUR million	Total amount of complementary to HE funding received by HE newcomers, in EUR million
DIGITAL	2	2.2		
ERASMUS2027	1	0.3	0.1 (33.3%)	
EU4H	16	36.1	5.4 (15.0%)	0.4 (7.4%)
EURATOM2027	1	0.1	<0.1 (<100%)	
Total	20	38.8	5.5 (14.2%)	0.4 (7.3%)

Table 68. Complementary funding (in EUR million) by source in Cluster 1

Source: CORDA data.

When we look at complementary funding across the CL1 topics and specific actions (e.g., Cancer Mission, EDCTP3), the analysis suggests that topics on disease and cancer are the health areas to which complementary funding was primarily allocated. Projects on topics such as environment and care have also received complementary funding from EU4Health, although to a lesser extent.

EU funding framework	CAR E	CANC ER	CORO NA	DISEA SE	ENVHL TH	IN D	STAYHL TH	TOO L	UNCA N
DIGITAL						1. 1		1.2	
ERASMUS2 027	0.3								
EU4H	3.4	11.7	0.2	19.2	3.9		0.6		3.8
EURATOM2 027							0.1		
Total	3.7	11.7	0.2	19.2	3.9	1. 1	0.7	1.2	3.8

Table 69. Complementary funding (in EUR million) by source and Cluster 1 topics

Source: CORDA data.

Regarding CL3, complementary funding has been received under the DIGITAL and ISF programmes (Union Actions), indicating some complementarity level between the two programmes. In terms of funding, the highest amount is observed in the DIGITAL and less in the ISF programme. It should be noted that the Integrated Border Management Fund (IBMF), a key European funding programme in border management, is not included in the analysis due to data limitations.

EU funding framework	No of the projects flagged as complementary to HE projects	Total amount of complementary to HE funding, in EUR million	Total amount of complementary to HE funding received by Widening countries, in EUR million	Total amount of complementary to HE funding received by HE newcomers, in EUR million
DIGITAL	6	5.4	0.6 (11.1%)	0.6 (11.1%)
EURATOM2027	1	0.2	<0.1 (<50%)	
ISF	6	2.4	0.2 (8.3%)	
Total	13	8.0	0.8 (10.0%)	0.6 (7.5%)

Table 70. Complementary funding (in EUR million) by source in Cluster 3

Source: CORDA data.

Additionally, the destinations FCT (Fight against Crime and Terrorism) and CS (Cybersecurity) within CL3 have benefited most from the complementary funding from the DIGITAL and ISF programmes. SSRI in the Table below refers to the horizontal actions of CL3.

Table 71.	Complementary	funding (in	in EUR million)	by source and	Cluster 3 destination
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EU funding framework	FCT	CS	SSRI
DIGITAL	2.3	3.5	
EURATOM2027			0.2
ISF	2.0		0.4
Total	4.3	3.5	0.6

Source: CORDA data.

(b) Alternative funding in Cluster 1, 2 and 3

Out of 1 740 unsuccessful CL1 proposals, 23 secured funding from sources other than HE. The total amount requested under the new scheme was slightly lower than what was initially requested under CL1, decreasing from EUR 39.6 million in CL1 to EUR 31.8 million under the new funding. Of the 1 006 unsuccessful CL2 applications, 17 succeeded in obtaining funding through a different programme. As with CL1, the funding granted to these projects was less under the new scheme. Specifically, for CL2, the amount received was a third less than what was requested under HE. For CL3, out of 609 unsuccessful applications, 31 managed to secure alternative funding. Unlike CL1 and CL2, the total alternative funding for CL3 was marginally higher than the amount requested under HE, increasing from EUR 17.3 million under HE to EUR 19 million under the alternative funding scheme.

Pillar	Total no of unsuccessful applications in Horizon Europe	No of projects received alternative funding	Total amount of EU funds received as alternative funding, in EUR million	Total amount of HE grant requested (as unsuccessful HE applicants), in EUR million	Share of alternative funding received as compared to HE requested grant
Cluster 1	1 740	23 (1.3%)	31.8	39.6	80.3%
Cluster 2	1 006	17 (1.7%)	10.1	15.8	63.9%
Cluster 3	609	31 (5.1%)	19.0	17.3	109.8%

Table 72. The overview of the alternative funding (in EUR million)

Source: CORDA data.

For Widening countries, alternative funding was especially important for projects not funded under CL3, as demonstrated in the Table below.

Table 73. The overview of the alternative funding (in EUR million) (Widening countries)

Pillar	Total amount of EU funds received as alternative funding, in EUR million	Total amount of alternative to HE funding received by Widening countries, in EUR million
Cluster 1	31.8	4.3 (13.5%)
Cluster 2	10.1	2.3 (22.8%)
Cluster 3	19.0	4.8 (25.3%)

Source: CORDA data.

For projects submitted under CL1 but did not secure the HE funding, the most important alternative funding has arrived from EU4H. The programme has granted a total of EUR 24.7 million to CL1 projects that did not manage to get financial support under HE. This indicates the substantial investment of EU4H in supporting health research projects.

Table 74. Alternative	funding (in EUR	million) by sou	Irce in Cluster 1
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EU funding framework	No of the projects flagged as alternative to HE projects	Total amount of alternative to HE funding, in EUR million	Total amount of HE grant requested (as unsuccessful HE applicants), in EUR million	Share of alternative funding received as compared to HE requested grant, in EUR million
DIGITAL	4	5.8	7.1	81.7%
ERASMUS2027	2	1.4	2.7	50.22%
EU4H	16	24.7	29.7	83.2%
Total	22	31.8	39.6	80.3%

Source: CORDA data.

As the Table below indicates, out of EUR 24.7 million HE4H granted as alternative funding for CL1, EUR 3.9 million went to Widening countries. DIGITAL and ERASMUS2027 allocated no more than EUR 0.2 million to Widening countries.

EU funding framework	Total amount of alternative to HE funding, in EUR million	Amount of alternative to HE funding received by Widening countries, in EUR million
DIGITAL	5.8	0.2 (3.5%)
ERASMUS2027	1.4	0.2 (14.3%)
EU4H	24.7	3.9 (15.8%)
Total	31.8	4.3 (13.5%)

Table 75. Alternative funding (in EUR million) by source in Cluster 1 (Widening countries)

Source: CORDA data.

When we look at CL1 alternative funding for each topic, we observe **that EU4H programme continues to remain the most important alternative source, especially for CORONA, CARE and CANCER topics**.

EU funding framework	CANCE R	CAR E	CORON A	DISEAS E	ENVHLT H	STAYHLT H	TOO L	IN D
DIGITAL		1.0					2.9	1.8
ERASMUS20 27				0.3		1.0		
EU4H	5.0	7.3	9.4	3.5	3.1	0.4	2.5	
Total	5.0	8.3	9.4	3.8	3.1	1.4	5.4	1.8

Table 76. Alternative funding (in EUR million) by source and Cluster 1 topics

Source: CORDA data.

CL2 has the potential to harness synergies with additional EU programmes like Creative Europe and Erasmus+ to advance the integration of cultural heritage, creativity and innovation into the educational, training and civic engagement of young people throughout Europe. This collaboration aims to nurture social cohesion and enhance cross-cultural understanding. The primary source of alternative funding for CL2 projects predominantly has come from the ERASMUS2027 programme, which has supported 11 projects. This is followed by the CREA2027 programme, funding four projects in total. Notably, for all these alternative funding schemes available to CL2 projects, the final amounts received are significantly lower than the initial amounts requested under HE. This finding is also consistent with Horizon Europe's unsuccessful applicants survey conducted in May-July, 2023. Based on CL2 respondents' feedback, two-thirds claimed that the amount of funding available from other sources was insufficient (42.1% very important and 27% important). This observation highlights the key role of CL2 in financing R&I activities in the Social Sciences and Humanities. In this context, CL2 stands out as the most important source of funding in this area.

EU funding framework	No of the projects flagged as alternative to HE projects	Total amount of alternative to HE funding, in EUR million	Total amount of HE grant requested (as unsuccessful HE applicants) , in EUR million	Share of alternative funding received as compared to HE requested grant, in EUR million
CREA2027	4	0.9	2.6	35.2%
DIGITAL	2	0.4	1.8	22.0%
ERASMUS2027	11	8.7	11.2	77.7%
ESF	1	<0.1	0.1	17.6%
Total	18	10.1	15.8	63.9%

Source: CORDA data.

In terms of Widening countries, the ERASMUS2027 programme emerges as the first alternative option for them.

EU funding framework	Total amount of alternative to HE funding, in EUR million	Amount of alternative to HE funding received by Widening countries, in EUR million
CREA2027	0.9	0.2 (22.2%)
DIGITAL	0.4	
ERASMUS2027	8.7	2.1 (24.1%)
ESF	<0.1	<0.1 (<100%)
Total	10.1	2.3 (22.8%)

Table 78. Alternative funding (in EUR million) by source in Cluster 2 (Widening countries)

Source: CORDA data.

The next Table provides a detailed overview of the sources of alternative funding for CL2 projects, categorised by the three destinations, namely destination 'democracy and governance', destination 'cultural heritage and culture and creative industries' and destination 'social and economic transformation'. Projects within the 'social and economic transformation' destination that were unsuccessful in obtaining initial funding have benefited from alternative sources, especially the ERASMUS2027 programme. This trend demonstrates a significant level of complementarity between CL2 'transformations' destination and ERASMUS2027.

Table 79.	Alternative	funding (in	EUR million) by source	and Cluster	2 destination
				.,,		

EU funding framework	Democracy	Heritage	Transformations
CREA2027		0.9	
DIGITAL	0.4		<0.1
ERASMUS2027	0.3	0.4	8.1
ESF			<0.1
Total	0.7	1.3	8.2

Source: CORDA data.

In the case of CL3, DIGITAL and ISF were the primary alternative funding sources. Contrary to the case of CL1 and CL2, the finding suggests that CL3's alternative funding surpassed the amounts initially requested under the HE programme offered by DIGITAL. One possible explanation for that could be the dynamic and growing emphasis stemming from research and innovation in security and cybersecurity within Europe, which has ultimately led to a high demand for this field. Also, this shows the high level of complementarity between the two programmes as well as alignment in terms of their needs and goals.

Table 80. Alternative funding (in EUR million) by source in Cluster 3

EU funding framework	No of the projects flagged as alternative to HE projects	Total amount of alternative to HE funding, in EUR million	Total amount of HE grant requested (as unsuccessful HE applicants), in EUR million	Share of alternative funding received as compared to HE requested grant
DIGITAL	9	13.0	9.4	138.30%
ISF	12	5.9	7.9	74.68%
Total	21	19.0	17.3	109.83%

Source: CORDA data.

As we can see from the Table below, the destination CS was the one who DIGITAL most benefited, while FCT destination relied on alternative funding from ISF.

EU funding framework	BM	FCT	CS	SSRI
DIGITAL	0.1	1.4	12.7	0.1
ISF	0.2	6.6		
Total	0.3	8.0	12.7	0.1

Table 81. Alternative funding (in EUR million) by source and Cluster 3 destinations

Source: CORDA data.

When considering alternative funding sources for Widening countries, the HE programme, DIGITAL, emerges as the main alternative, followed to a lesser extent by the ISF programme.

 Table 82. Alternative funding (in EUR million) by source in Cluster 3 (Widening countries)

EU funding framework	Total amount of alternative to HE funding, in EUR million	Amount of alternative to HE funding received by Widening countries, in EUR million
DIGITAL	13.0	4.1 (31.5%)
ISF	5.9	0.6 (10.2%)
Total	19.0	4.8 (25.3%)

Source: CORDA data.

Unstructured data analysis: Future Emerging Technologies score (Pillar 2)

Across the funded actions, a strong commitment to developing and applying future technologies can be observed in the Future Emerging Technologies (FET) score trends. The FET score captures the extent to which the analysed actions address new or fast-growing research and innovation topics. 'New' is defined as a topic that first occurred around 2015, while 'fast' is a topic that grew at least two times faster than expected in the entire research and innovation universe, captured by MAG/OpenAlex database. In total, there are around 9 000 FET topics. Actions strongly linked to many FET topics get a higher FET score.

To determine the FET score of the programme parts, the study team took the Description of Action (DoA) of projects funded so far by the HE and matched their text data against the MAG/OpenAlex database. The results are provided below.

Pillar 2 results

The Table below shows the average FET score and the 5 most common topics for Pillar 2 of HE. Analysis of FET-related actions showed that projects in Pillar 2 had a higher-thanaverage FET score (12.22, compared to the average score of 8.59 across Horizon Europe), indicating **a higher percentage of new or fast-growing topics covered**. Mostly, open science keywords are the most used, fast-growing topics in research.

Table 83. Average FET Score

Programme part	Average FET Score	Top 5 corresponding FET topics (and number of corresponding projects)
Pillar 2	12.22	Open science (2039) Open data (942) Findability (805) Deep learning (582) Climate change mitigation (517)
Horizon Europe	8.59	Open science (5877) Open data (1795) Deep learning (1440) Findability (1403) Open peer review (1097)

Source: HE administrative data, MAG/OpenAlex database.

The Table below provides the same data for the Pillar 2 programme parts within the study context (i.e., Cluster 1, 2 and 3). All three clusters had higher average FET scores than average for Pillar 2 and average for the overall framework programme. This suggests that all three clusters are covering highly relevant topics of research.

Programme part	Average FET Score	Top 5 corresponding FET topics (and number of corresponding projects)
Cluster 1	13.71	Open science (269) Middle income country (108) Translational research (99) Open data (95) Electronic health record (79)
Cluster 2	9.96	Open science (145) Open data (73) Findability (52) Citizen science (44) Social innovation (40)
Cluster 3	15.30	Open science (93) Open data (56) Findability (52) Deep learning (46) Supply chain security (36)
Pillar 2	12.22	Open science (2039) Open data (942) Findability (805) Deep learning (582) Climate change mitigation (517)
Horizon Europe	8.59	Open science (5877) Open data (1795) Deep learning (1440) Findability (1403) Open peer review (1097)

Table	84.	Average	FET	Score	Pillar	2
TUDIC	υτ.	Average		00010	i mai	~

Source: HE administrative data, MAG/OpenAlex database.

To enhance the analysis above, we looked into EuroSciVoc taxonomy and the topics each Pillar 2 project corresponds to. The top 20 most frequent topics according to that taxonomy

(level 3) are presented in the Table below¹⁵⁷. In addition, we examined what FET topics most frequently occur according to the EuroSciVoc topic. The results are presented below. While open science-related keywords dominate the list, we also see that some of the field-specific FETs can be identified as emerging trends in the research topics funded by Cluster 1.

Top 20 project topics according to the EuroSciVoc taxonomy, level 3	Top 5 corresponding FET topics (and number of corresponding projects)
Artificial Intelligence	Open science (45) Deep learning (27) Electronic health record (19) Precision medicine (18) Patient engagement (17)
Oncology	Open science (42) Translational research (19) Electronic health record (19) Personalized medicine (18) Deep learning (17)
Pharmacology and pharmacy	Open science (30) Middle income country (13) Precision medicine (11) Personalized medicine (8) Patient engagement (8)
Public health	Open science (29) Middle income country (12) Pandemic preparedness (11) Translational research (9) Findability (9)
Infectious diseases	Open science (25) Pandemic preparedness (13) Translational research (12) Middle income country (12) Open data (9)
Immunology	Open science (19) Translational research (10) Precision medicine (7) Patient stratification (7) Inflammatory biomarkers (6)

Table 85. New or fast-growing research and innovation topics Cluster 1

Source: HE administrative data, MAG/OpenAlex database.

Similarly to the above, topics around open science dominate the list. Nevertheless, we see that FETs directly related to the objectives of the programme part, such as citizen science, social innovation and similar, are among the most frequent FETs.

¹⁵⁷ If the topic had less than 20 articles, it was not included in the table.

Top 20 project topics according to the EuroSciVoc taxonomy, level 3	Top 5 corresponding FET topics (and number of corresponding projects)
Business and management	Open science (35) Open data (19) Social innovation (14) Findability (13) Digital skills (9)
Political policies	Open science (36) Open data (18) Findability (15) Citizen science (13) Citizen engagement (11)
Government systems	Open science (36) Open data (20) Disinformation (19) Citizen science (14) Findability (13)
Governance	Open science (26) Open data (11) Citizen science (10) Citizen engagement (10) Findability (10)
Social issues	Open science (24) Open data (12) Survey experiment (8) Findability (8) Citizen science (6)

Table 86. New or fast-growing research and innovation topics Cluster 2

Source: HE administrative data, MAG/OpenAlex database.

Given the low number of Cluster 3 projects so far, a breakdown by different sub-topics would not be meaningful. Instead, in the Table below, we provide the top 15 most occurring FET topics in Cluster 3. We see open science, data, and findability among the leading topics. Regarding more security-related topics, supply chain security, privacy-preserving, and cyber threats are the leading FETs in Cluster 3.

Table 87. New or fast-growing research and innovation topics Cluster 3

Top 15 FET topics (and number of projects)
Open science (93)
Open data (56)
Findability (52)
Deep learning (46)
Supply chain security (36)
Privacy-preserving (34)
Ai systems (31)
Cyber threats (31)
Blockchain (30)
Digital forensics (23)
Smart city (21)
Industrial security (21)
Citizen science (20)
Disaster risk reduction (20)
Open peer review (20)

Source: HE administrative data, MAG/OpenAlex database.

SDG analysis

Results at the level of HE pillars

This is a methodological Annex dedicated to the analysis of SDG data. Its main aim is to present data and insights into how different parts of Horizon Europe contributed to SDGs. Our initial sample was the full list of HE projects, but we have narrowed it down to observations with data related to SDG available. As the HE programme is ongoing, the share of projects with status closed is insufficient for analysis. Therefore, the sample did not regard the status of the project.

In the breakdowns, we present two values: absolute and relative.

- The absolute value refers to the number of projects/publications/millions of euros from that group (pillar or programme part) contributing to a given SDG;
- The relative value refers to the relative share of that SDG among the overall contribution to all SDGs from that group (pillar or programme part).

The SDG labels were **assigned to the projects using the OSDG tool**¹⁵⁸. We assembled a text corpus for each project using this approach, including all the available monitoring data and project publications. We then assigned the SDG labels for each project using the entire project text corpus. Assigning SDG labels was a three-stage process:

- In the first stage, we used AI and machine-learning models to assign preliminary SDG labels;
- In the second stage, we used our expert-curated ontology to double-check and verify the initial labels;
- In the final third stage we aggregate the results from the text-segment (paragraph) level to the project level, taking into account the size of the project corpus, the amount of SDG-related content in the corpus and the relative distribution of different SDGs. To get an SDG label, at least 15% of text segments in the corpus have to be SDG-related, and each SDG included in the final label must account for at least 10% of all the SDG-relevant content in the project corpus. OSDG tool supports multilabel classification, i.e., it can assign more than one SDG label to relevant projects.

The Table below presents an overview of the projects' distribution in Pillar 2 for the Horizon Europe programme. At the moment of analysis, there were only 3 closed projects (5.4%) in Pillar 2; therefore, the analysis encompassed all projects of Pillar 2 - 195 (24.5%) regardless of status.

¹⁵⁸ For a detailed explanation on the tool please refer here: https://arxiv.org/ftp/arxiv/papers/2211/2211.11252.pdf .

HE Thematic Priority	Total Num Projects	nber of	Number of with status CLOSED	projects =	Total num projects a	ber of nalysed	Total number projects and projects with CLOSED	er of alysed in h status =
	Number	Share	Number	Share	Number	Share	Number	Share
Pillar 2	2 217	23.4%	3	5.4%	2 195	24.5%	3	5.4%
Total for HE	9 459	100%	56	100%	8 964	100%	56	100%

Table 88. Overview of the projects' status

Source: CORDA data, June 2023 data release.

The decomposition of Horizon Europe projects based on pillars and SDGs in Table 89 reveals that overall in Pillar 2, projects were the most intensively focused on: SDG7 – Affordable and Clean Energy (35%); SDG13 – Climate Action (27.4%); SDG9 - Industry, Innovation and Infrastructure (26.6%); SDG3 Good Health and Well-being (24.5%) and SDG16 - Peace, Justice and Strong Institutions (23.5%). The share of projects relevant to a particular SDG tended to be similar in Pillae 2 and overall HE, except for SDGs 12 and 13, which had a higher focus in Pillar 2 and SDG 4, which had a significantly lesser focus.

Table 89.	Number	of HE	projects	by SDG
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Thematic	Pillar 2		Total		
Priority	Number	Share	Number	Share	
SDG1	59	2.7%	301	3.4%	
SDG2	125	5.7%	302	3.4%	
SDG3	538	24.5%	3 948	44.0%	
SDG4	106	4.8%	1 398	15.6%	
SDG5	179	8.2%	988	11.0%	
SDG6	87	4.0%	342	3.8%	
SDG7	768	35.0%	2 172	24.2%	
SDG8	138	6.3%	461	5.1%	
SDG9	584	26.6%	2 057	22.9%	
SDG10	33	1.5%	127	1.4%	
SDG11	379	17.3%	1 107	12.3%	
SDG12	372	16.9%	704	7.9%	
SDG13	602	27.4%	1 602	17.9%	
SDG14	124	5.6%	485	5.4%	
SDG15	154	7.0%	406	4.5%	
SDG16	515	23.5%	1 882	21.0%	
Total	2 194	100%	8 895	99.2%	

Source: CORDA and projects' description of action data.

The comparison of SDG coverage in Horizon Europe and Horizon 2020 programmes reveals a significant increase in the importance of the SDGs. At least one SDG was covered in 99.2% of projects analysed from Horizon Europe, which is 27 percentage points more than in Horizon 2020. All SDGs experienced improvement except SDG6 – Clean Water and Sanitation; SDG8 - Decent Work and Economic Growth; and SDG9 - Industry, Innovation and Infrastructure.

Thematic Priority	Total HE	Total H2020
SDG1	3.4%	2.0%
SDG2	3.4%	0.3%
SDG3	44.0%	26.6%
SDG4	15.6%	8.0%
SDG5	11.0%	1.0%
SDG6	3.8%	3.9%
SDG7	24.2%	12.1%
SDG8	5.1%	7.4%
SDG9	22.9%	24.5%
SDG10	1.4%	0.7%
SDG11	12.3%	10.6%
SDG12	7.9%	6.7%
SDG13	17.9%	17.3%
SDG14	5.4%	3.2%
SDG15	4.5%	3.5%
SDG16	21.0%	6.6%
Total	99.2%	72.2%

Source: CORDA and projects' description of action data.

The Table below shows the total EU allocated funding for each SDG by pillar, with the amount weighed by the coverage of a particular SDG by a project. The largest amount associated with achieving a goal in Pillar 2 – 2 912.9 EUR million, is devoted to SDG7 – Affordable and Clean Energy and is equal to nearly a fifth of all funds contributed by the EU. SDG 3 was consistently the most funded SDG across pillars and HE totals, except for Pillar 2. However, in Pillar 1, SDG3 still played a prominent role, receiving 17.8% of the EU contribution.

Thematic Priority		Pillar 1		Total		
		Number	Share	Number Share		
SDG1	41.7	0.3%	101.1	0.4%		
SDG2	213.7	1.5%	297.3	1.3%		
SDG3	2 474.2	17.8%	5 753.8	24.3%		
SDG4	132.4	1.0%	712.2	3.0%		
SDG5	144.1	1.0%	429.9	1.8%		
SDG6	190.2	1.4%	288.7	1.2%		
SDG7	2 912.9	20.9%	3 835.4	16.2%		
SDG8	155.5	1.1%	510.4	2.2%		
SDG9	1 204.2	8.7%	2 143.6	9.0%		
SDG10	27.2	0.2%	72.7	0.3%		
SDG11	821.0	5.9%	1 168.5	4.9%		
SDG12	938.2	6.7%	1 111.6	4.7%		
SDG13	1 240.7	8.9%	1 694.9	7.1%		
SDG14	393.2	2.8%	592.5	2.5%		
SDG15	367.4	2.6%	477.3	2.0%		
SDG16	829.8	6.0%	1 585.5	6.7%		
Total	13 888.8	99.8%	23 596.0	99.5%		

Table 91. EU contribution by SDG (in EUR million)

Source: CORDA and projects' description of action data (DoA).

The direct comparison of EU contributions in Horizon Europe and Horizon 2020 is not possible for the following reasons: (1) H2020 analysis was based on closed projects, (2) the early stage of the Horizon Europe programme, (3) H2020 analysis of EU contribution to the SDGs was based on the publications data, while such analysis in HE is based on the proposal text (DoA). However, the overall trend shows that the focus on sustainable development did not change significantly. SDG9 – Industry, Innovation and Infrastructure and SDG3 - Good Health and Well-being remained the most funding intensive.

Results at the level of Cluster 1, Cluster 2 and Cluster 3

The Table below provides a closer look at the Pillar 2 project distribution. The total number of projects analysed and used for further analysis excluded projects with missing information about SDG performance. At the time of this analysis, only one project was closed in Cluster 2, and only three were closed overall in Pillar 1.

HE Thematic Priority	Total Number of Projects	Number of projects with status = CLOSED	Total number of projects analysed	Total number of projects analysed in projects with status = CLOSED
Cluster 1	316	0	304	0
Cluster 2	151	1	151	1
Cluster 3	97	0	96	0
Total Pillar 1	2 217	3	2 195	3

Table 92. Overview of the projects' status

Source: CORDA database, June 2023 data release.

The breakdown of the three analysed Clusters reveals that in Cluster 1, 100% of the projects corresponded to SDG3 - Good Health and Well-being. In Clusters 2 and 3, the results were more mixed. SDG16 - Decent Work and Economic Growth comprised over 76% of the projects in Cluster 2, followed by SDG11 – Sustainable Cities and Communities with over 53% and SDG5 – Gender Equality, with over 36% of projects with an SDG theme. In Cluster 3, SDG9 – Decent Work and Economic Growth corresponded to over 88% of the projects, followed by SDG9 – Industry, Innovation and Infrastructure, which corresponded to over half of the projects (53.6%). Overall, Pillar 1's a relatively larger share of projects corresponded to SDG7 – Affordable and Clean Energy, SDG13- Climate Action and SDG3- Good Health and Well-being.

Thema Cluster 1		Cluster 2		Cluster 3		Total Pillar 1		Total HE		
tic Priority	Numb er	Share	Numb er	Share	Numb er	Share	Numb er	Share	Numb er	Shar e
SDG1	3	1.0%	32	21.2 %	7	7.3%	59	2.7%	301	3.4%
SDG2	0	0.0%	0	0.0%	0	0.0%	125	5.7%	302	3.4%
SDG3	304	100.0 %	12	7.9%	21	21.9 %	538	24.5 %	3 948	44.0 %
SDG4	10	3.3%	29	19.2 %	5	5.2%	106	4.8%	1 398	15.6 %
SDG5	1	0.3%	55	36.4 %	12	12.5 %	179	8.2%	988	11.0 %
SDG6	4	1.3%	1	0.7%	0	0.0%	87	4.0%	342	3.8%
SDG7	1	0.3%	1	0.7%	7	7.3%	768	35.0 %	2 172	24.2 %
SDG8	0	0.0%	39	25.8 %	1	1.0%	138	6.3%	461	5.1%
SDG9	5	1.6%	17	11.3 %	51	53.1 %	584	26.6 %	2 057	22.9 %
SDG10	0	0.0%	29	19.2 %	1	1.0%	33	1.5%	127	1.4%
SDG11	2	0.7%	81	53.6 %	19	19.8 %	379	17.3 %	1 107	12.3 %
SDG12	4	1.3%	6	4.0%	2	2.1%	372	16.9 %	704	7.9%
SDG13	9	3.0%	15	9.9%	12	12.5 %	602	27.4 %	1 602	17.9 %
SDG14	1	0.3%	2	1.3%	3	3.1%	124	5.6%	485	5.4%
SDG15	0	0.0%	0	0.0%	0	0.0%	154	7.0%	406	4.5%
SDG16	25	8.2%	116	76.8 %	85	88.5 %	515	23.5 %	1 882	21.0 %
Total	304	100.0 %	151	100.0 %	96	100.0 %	2 194	100.0 %	8 895	99.2 %

Table 93. Number of HE projects by SDG

Source: CORDA and projects' description of action data. June 2023 data release.

When comparing the Societal Challenges in H2020 and Clusters in HE, we can note that the SDG coverage in the Horizon Europe Projects has increased with more emphasis being placed on SDG 16 – Peace Justice and Strong Institutions and SDG 5 – Gender Equality.

Breaking it down by cluster, Cluster 1 is similar to Societal Challenge 1 as both heavily focused on SDG3. In Societal Challenge 1, more projects were emphasising SDG 4 – Quality Education, which changed from 7.2% to 3.3% coverage from H2020 to HE.

In Cluster 2, little over half of the projects focused on SDG11 – Sustainable Cities and Communities across both FPs. A significant difference can be observed in SDG16, where Cluster 2 had many more projects dedicated to (76.8%) than the corresponding Societal Challenge 6 (35.4%). A similarly large shift can also be noticed in SDG5 as the projects corresponding to SDG5 – Gender Equality in Cluster 2 (36.4%) increased from 3.3% in Societal Challenge 6.

In Cluster 3, in both H2020 and HE, projects corresponding to SDG9 – Industry Innovation and Infrastructure comprised about half of all projects analysed, remaining relatively consistent across the two Framework Programmes. Much like in Cluster 2, in Cluster 3, the SDG16 rose significantly as the share of projects rose from 52.4% in SC 7 to 88.5% in CL3. In this Cluster, SDG 5 also appears to have increased in prominence among the projects compared to SC7, demonstrating the growing interest in dedication towards Gender Equality.

Thematic Priority	Cluster 1 (HE)	Societal Challenge 1 (H2020)	Cluster 2 (HE)	Societal challenge 6 (H2020)	Cluster 3 (HE)	Societal challenge 7 (H2020)
SDG1	1.0%	2.3%	21.2%	13.4%	7.3%	5.3%
SDG2	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SDG3	100.0%	88.7%	7.9%	11.4%	21.9%	11.0%
SDG4	3.3%	7.2%	19.2%	35.4%	5.2%	12.2%
SDG5	0.3%	1.9%	36.4%	3.3%	12.5%	1.6%
SDG6	1.3%	0.0%	0.7%	2.4%	0.0%	6.5%
SDG7	0.3%	0.0%	0.7%	2.4%	7.3%	4.5%
SDG8	0.0%	3.2%	25.8%	35.8%	1.0%	12.6%
SDG9	1.6%	8.0%	11.3%	20.7%	53.1%	43.1%
SDG10	0.0%	0.0%	19.2%	6.5%	1.0%	0.4%
SDG11	0.7%	1.8%	53.6%	64.6%	19.8%	22.4%
SDG12	1.3%	0.7%	4.0%	4.1%	2.1%	2.8%
SDG13	3.0%	1.6%	9.9%	5.7%	12.5%	16.7%
SDG14	0.3%	0.5%	1.3%	2.0%	3.1%	0.4%
SDG15	0.0%	0.0%	0.0%	0.8%	0.0%	0.4%
SDG16	8.2%	5.5%	76.8%	35.4%	88.5%	52.4%
Total	100.0%	90.8%	100.0%	83.3%	100.0%	79.3%

Table 94. Comparison of the share HE and H2020 projects by SDG

Source: CORDA and projects' description of action data. June 2023 data release.

Overall, Pillar 2 trends are similar to Horizon Europe; SDG3, SDG7, and SDG9 received the largest share of EU contribution. When looking at the Clusters of interest, most funding in Cluster 1 went to SDG3, the most prominent SDG theme in the projects in this Cluster. In Cluster 2, as expected from a relatively larger share of projects, SDG16 and SDG11 received the largest shares of EU contribution - EUR 155.5 million and EUR 85.8 million, respectively. In Cluster 3, SDG16 and SDG9 received the largest share of EU contribution, corresponding to the share of projects with these SDG themes.
Themat	Cluster 1		Cluster 2		Cluster 3		Total Pillar 2		Total HE	
ic Priority	Numb er	Share	Numb er	Share	Numb er	Share	Numb er	Shar e	Numb er	Shar e
SDG1	3.6	0.2%	19.8	4.5%	5.8	1.4%	41.7	0.3%	101.1	0.4%
SDG2	0.0	0.0%	0.0	0.0%	0.0	0.0%	213.7	1.5%	297.3	1.3%
SDG3	1 976.3	85.8 %	7.6	1.7%	35.0	8.5%	2 474.2	17.8 %	5 753.8	24.3 %
SDG4	8.5	0.4%	39.7	9.1%	4.4	1.1%	132.4	1.0%	712.2	3.0%
SDG5	0.6	0.0%	39.9	9.1%	12.4	3.0%	144.1	1.0%	429.9	1.8%
SDG6	5.4	0.2%	1.0	0.2%	0.0	0.0%	190.2	1.4%	288.7	1.2%
SDG7	1.0	0.0%	1.3	0.3%	9.6	2.3%	2 912.9	20.9 %	3 835.4	16.2 %
SDG8	0.0	0.0%	30.5	7.0%	0.8	0.2%	155.5	1.1%	510.4	2.2%
SDG9	4.7	0.2%	15.4	3.5%	78.2	19.0 %	1 204.2	8.7%	2 143.6	9.0%
SDG10	0.0	0.0%	24.6	5.6%	0.7	0.2%	27.2	0.2%	72.7	0.3%
SDG11	3.2	0.1%	85.8	19.7 %	23.4	5.7%	821.0	5.9%	1 168.5	4.9%
SDG12	8.3	0.4%	6.0	1.4%	3.0	0.7%	938.2	6.7%	1 111.6	4.7%
SDG13	27.0	1.2%	9.7	2.2%	21.7	5.3%	1 240.7	8.9%	1 694.9	7.1%
SDG14	2.3	0.1%	3.4	0.8%	8.3	2.0%	393.2	2.8%	592.5	2.5%
SDG15	0.0	0.0%	0.0	0.0%	0.0	0.0%	367.4	2.6%	477.3	2.0%
SDG16	86.6	3.8%	155.8	35.7 %	155.5	37.7 %	829.8	6.0%	1 585.5	6.7%
Total	2 303.0	100.0 %	436.7	100.0 %	411.8	100.0 %	13 888.8	99.8 %	23 596.0	99.5 %

Table 95. EU contribution by SDG (in EUR million)

Source: CORDA and projects' description of action data. June 2023 data release.

Annex 4: Case studies

Introduction

The study completed **15 case studies** as part of the Resilient Europe study, feeding into the Final Report for the evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe. Completed case study reports can be found in this Annex 4.

Table 96. Resilient Europe under Horizon Europe: Case studies

No	Title of the case study				
CS1	From Innovative Medicines Initiative to Innovative Health Initiative – the early experience				
CS2	IMI2 and IHI: driving innovation in digital health				
CS3	The Contributions of EIT Health in the Fight Against Chronic and Multi-Morbid Conditions				
CS4	Contribution of EIT Health towards supporting the Venture Centre of Excellence (VCoE) and WorkInHealth Foundation				
CS5	Transitioning from EDCTP2 to Global Health EDCTP3 Joint Undertaking: transition measures and lessons learned from the predecessor				
CS6	Mission on Cancer: taking the EU's positioning in cancer research beyond what was done in the past while ensuring coherence and synergies with other EU programmes				
CS7	Research on democracy, in practice				
CS8	Cultural and creative industries				
CS9	Well-being and tackling inequalities				
CS10	Assessing the societal impacts of security research in addressing stakeholders' needs in the areas of Fighting Crime and Terrorism, Border Management, Resilient Infrastructure, and Disaster-Resilient Society				
CS11	Assessing the societal impacts of security research on cross-border cooperation between security practitioners and relevant authorities				
CS12	AI in cybersecurity: Building European competencies and synergies on AI and machine learning				
CS13	The new Transforming Health and Care Systems partnership – Learnings from previous partnerships and early experience				
CS14	ERA4Health: additionality and international positioning of the co-funded partnership				
CS15	European Partnership for the Assessment of Risks from Chemicals – PARC				
Source:	Source: Compiled by the study team.				

Case studies: coverage

The supporting study covered 15 case studies, with one specific to the mission covered under this study (i.e., 'Conquering cancer, mission possible'). The overarching goal of case studies in this Phase of the study was to have a strengthened focus on addressing evaluation questions under the relevance, coherence, efficiency, EU=added value and partnership-specific evaluation criteria. Additionally, completed case studies identified barriers and drivers to progress towards impact, also based on the past Framework Programmes where relevant.

The Table below presents all 15 case studies and highlights which evaluation questions and criteria each case study considered.

Programme Part	Case Study	Evaluation Questions to be covered
IMI2/IHI	CS1: From Innovative Medicines Initiative to Innovative Health Initiative – the early experience	RV6, CH4, CH4.1, EAV2
IMI2/IHI	CS2: IMI2 and IHI: driving innovation in digital health	RV6, CH4.1, EAV2
EIT Health	CS3: The Contributions of EIT Health in the Fight Against Chronic and Multi-Morbid Conditions	RV6, EFC5, EAV2
EIT Health	CS4: Contribution of EIT Health towards supporting the Venture Centre of Excellence (VCoE) and WorkInHealth Foundation	EFC5, PSC1, PSC1.1, EAV2, PSC6.1
EDCTP3	CS5: Transitioning from EDCTP2 to Global Health EDCTP3 Joint Undertaking: transition measures and lessons learned from the predecessor	RV6, PSC6.1, PSC6.1, EFC1.5
Mission on Cancer	CS6: Mission on Cancer: taking EU's positioning in cancer research beyond what was done in the past while ensuring coherence and synergies with other EU programmes	RV3, CH1, CH2, CH3
Cluster 2	CS7: Research on democracy, in practice	RV1, RV4, RV4.1, RV4.2, CH1, EFC1.3, EFC1.4, EFC1.5
Cluster 2	CS8: Cultural and creative industries	RV1, CH1, EFF2, EAV1, EAV1.1, EAV1.2
Cluster 2	CS9: Well-being and tackling inequalities	RV1, CH1, EFC1.8, EAV1, EAV1.1, EAV1.2
Cluster 3	CS10: Assessing the societal impacts of security research in addressing stakeholders' needs in the areas of Fighting Crime and Terrorism, Border Management, Resilient Infrastructure, and Disaster-Resilient Society	RV1, RV10, CH8, EFC12
Cluster 3	CS11: Assessing the societal impacts of security research on cross-border cooperation between security practitioners and relevant authorities	RV10, CH8, EFC7, EFC7.1
Cluster 3	CS12: Al in cybersecurity: Building European competencies and synergies on Al and machine learning	RV10, CH9, EFC16
Co-funded partnership (THCS)	CS13: The new Transforming Health and Care Systems partnership – Learnings from previous partnerships and early experience	RV6, CH4, EAV2
Co-funded partnership (ERA4Health)	CS14: ERA4Health: additionality and international positioning of the co-funded partnership	PSC1, PSC1.1, PSC1.2, PSC3, PSC3.1
Co-funded partnership (PARC)	CS15: European Partnership for the Assessment of Risks from Chemicals – PARC	PSC1, PSC1.1, PSC1.2, PSC4, PSC4.1, PSC4.2

Table 97. Distribution of case studies by programme part and evaluation criteria

Source: Compiled by the study team.

Case Study No 1: From Innovative Medicines Initiative to Innovative Health Initiative – the early experience

Executive Summary

The Innovative Health Initiative (IHI) was established in November 2021 as an institutionalised public-private partnership between the European Union and European life science industries. It follows the Innovative Medicines Initiative (IMI2), in which EFPIA, the European Federation of Pharmaceutical Industry Associations, was the sole private sector partner. IHI constitutes an expansion of the partnership to include a wider set of industry partners who contribute to medical innovation, complementing pharmaceutical research and development. The new partnership was created in recognition of developments in medical research, healthcare needs and healthcare delivery that require a different and increasingly cross-sectoral approach to research and development.

The new partnership is based on a new legal framework set out in Council Regulation 2021/2085 (the 'Single Basic Act'). The Single Basic Act sets out the programme's objectives and lays down the basic programme structure and rules. These include the new composition of the Governing Board as the main decision-maker and the introduction of a Science and Innovation Panel, which includes a broader set of stakeholders and functions in an advisory role. As of June 2023, the partnership has established the new governance arrangements, developed its strategic objectives, and launched its first calls for proposals.

Early experiences of stakeholders interviewed suggest that partners are generally optimistic about the partnership and provide positive feedback on the early experience of collaborating at the governance level. There is recognition that industry partners have different constituencies and can have different interests and objectives, but partners noted that discussions were constructive, and new partners felt that their voices were heard. As of June 2023, all governance arrangements of IHI have been established, and the first three calls of the programme were launched. There were a few operational hurdles to be navigated in this early phase, including a change in rules relating to the participation modality of entities established in Third Countries.

Introduction

The Innovative Health Initiative (IHI) was established in November 2021 as an institutionalised public-private partnership between the European Union (represented by the European Commission, EC) and European life science industries.¹⁵⁹ It follows the Innovative Medicines Initiative (IMI), which ran from 2007 to 2013 (IMI1) and 2014 to 2020 (IMI2), although these earlier programmes included the pharmaceutical industry as a private member only. Partners in IHI now include the industry associations MedTech Europe, COCIR and EuropaBio, in addition to EFPIA (also representing Vaccines Europe) and the EC.

The cross-sectoral approach of IHI reflects the fact that health innovation increasingly involves sectors other than pharmaceutical research and development, especially sectors such as medical technology, digital technology and biotechnology. Future breakthroughs are increasingly expected to include various combinations of technologies, such as setting up a

¹⁵⁹ Industry partners are European trade associations, including EFPIA (the European Federation of Pharmaceutical Industries and Associations), COCIR (the European Trade Association representing medical imaging, radiotherapy, health ICTs and electromedical industries), MedTech Europe (the European trade association representing the medical technology industries) and EuropaBio (representing the biotechnology sector).

new partnership. A new Council Regulation¹⁶⁰ was required and came into force on 30 November 2021 (referred to as the 'Single Basic Act'). The Single Basic Act sets up 9 institutionalised European partnerships under Horizon Europe and defines their common requirements/common provisions as well as specificities. In relation to IHI, it builds on the successes and experiences of IMI, although stakeholders emphasise that IHI represents a new partnership and a new approach to fostering innovation in the health field.

Purpose of this case study

The aim of the case study is to provide insight into how IHI was established to inform the Final Evaluation of IMI2 and the Interim Evaluation of IHI. For this purpose, the case study explores the early experience of implementing IHI between November 2021 and June 2023.

Specifically, the case study analyses:

- the legislative framework within which IHI operates and how it evolved from the framework for IMI2
- the governance arrangements in place to lead and oversee the new partnership
- the strategy developed and objectives set for IHI, and how they have been operationalised to date
- the early experience of stakeholders participating in IHI and contributing to its establishment.

The case study addresses several evaluation questions, specifically relating to the relevance, efficiency, and transparency and openness of IHI.

Scope of the case study

This case study examines the first 20 months of IHI. As the Single Basic Act came into force more than 6 months later than intended, the implementation of IHI also began later, and the period covered by this case study is shorter than expected in an Interim Evaluation. Specifically, there is limited experience in launching calls for proposals under IHI. To date, 3 calls have been launched, five grant agreements resulting from the 1st call have been signed by project participants, and 11 projects resulting from the 2nd and 3rd calls are in preparation. However, during the first 20 months, much work has been undertaken to build the partnership, establish its governance structures, and create processes and routines that put the Single Basic Act into action. Therefore, this case study focuses on the early experience of stakeholders setting up IHI.

Methodological approach

The case study uses desk research and stakeholder interviews. Sources included IHI programme materials and websites, the Single Basic Act, the Strategic Research and Innovation Agenda (SRIA), the first IHI work programmes, and the IHI Consolidated Annual Activity Reports.

The stakeholders interviewed included representatives of the member organisations of the IHI partnership, members of the States' Representatives Group, and the IHI Programme

¹⁶⁰ Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

Office. In total, ten interviews were held with twelve individuals. Interviews were conducted between May and June 2023 and lasted about 60 minutes on average. A topic guide was developed to structure the interviews. Interview data were recorded in writing in the form of a protocol. The protocol was shared with each interviewee for review and interviewees were able to comment and include corrections. The data collected in interviews were analysed thematically using the topics of interest of the case study. In what follows, all interviewees will be referred to as 'stakeholders', 'industry partners' refers to representatives of trade associations representing private partners and 'partners' refers to industry partners as well as the EC (i.e., private and public partners).

Rationale for the IHI partnership

The EC established a new, expanded partnership in response to changes in the nature and environment of research, development, and innovation in the field of healthcare. Two drivers were emphasised in interviews in particular: the changing nature of medical research, and the changing environment and needs for research and innovation.

1. Medical research is becoming increasingly cross-sectoral, and many innovations already involve more than one sector, such as medical devices, digital tools, diagnostic technologies, and biotechnology. These may be developed in combination with new medicines.

2. Developments in healthcare delivery and healthcare needs require an up-to-date crosssectoral approach to R&D. Healthcare is becoming increasingly complex, emphasising the importance of person-centred care and the need to improve the care continuum. Digitalisation provides enormous opportunities to improve the quality of care but has further increased the complexity of care delivery, underlining the need for interoperability and integration.

Expanding the partnership to include sectors that represent different types of technology responds to both trends. Stakeholders noted that the EC and industry partners recognised the changing context of IMI and took the initiative to expand the partnership. While it would have been possible to continue IMI as an 'IMI3', creating IHI was seen as an opportunity to bring new industry partners and new stakeholders into the programme and strengthen their role. Partners also noted that there was a desire to indicate 'a fresh start' by including a wider range of stakeholders.

Some stakeholders also highlighted a degree of continuity from IMI to IHI, both in terms of building on the successes of IMI and learning from its experiences. Stakeholders agreed that IMI1 and IMI2 were successful in creating a dynamic relationship between public and private partners built around trust and mutual aims. IMI also managed to bring together pharmaceutical companies that were usually in competition with each other and that were able to collaborate within the framework of this partnership. This required agreement on areas of collaboration that benefitted more than one company and motivated them to invest in these areas without relying on the prospect of immediate marketisation. This area of collaboration was defined as 'the precompetitive space' in which companies meet to work jointly towards shared objectives.

The new partnership also provided an opportunity to follow up on recommendations of the Interim Evaluation of IMI2. Its authors had considered the partnership as being too exclusively focused on the pharmaceutical industry, which they deemed insufficient in the face of future challenges. They recommended 'make a substantial adaptation to the collaborative and funding model to enable the active engagement of other industry sectors with the pharmaceutical industry to capitalise on their expertise in the development of new

healthcare interventions'.¹⁶¹ The setting up of IHI also responded to criticisms that the partnership was too industry-driven and insufficiently open to ideas from outside the partnership.

This led to the introduction of a new mechanism to elicit ideas for call topics from a wider audience in a 'bottom up' approach. Other lessons resulted from the inclusion of 'Associated Partners' in IMI2 projects, i.e., the possibility to include legal entities in project consortia that were not members of EFPIA. This concept was continued and expanded to all Joint Undertakings under Horizon Europe (now termed 'Contributing Partners'). In addition, changes in the corporate approach of the EC meant that at the beginning of IHI, industry partners whose members were based outside the EU/countries associated with Horizon Europe could no longer participate as beneficiaries in IHI projects, even when not requesting funding. As of IHI calls 4-5, launched in July 2023, such entities can participate as beneficiaries as long as they do not request funding and if their participation is considered essential for a given project (also see section 'Navigating operational hurdles at the start of the programme').

Legal framework

The IHI partnership is based on a legal framework set out in the Council Regulation (EU) 2021/2085, commonly referred to as the Single Basic Act. The Act sets up several Joint Undertakings (JUs) jointly, by which the EC forms partnerships with industries, research institutions or member states, with IHI being one of nine JUs. The Act builds on the wider legal framework of Horizon Europe. The Single Basic Act recognises the specificities of each JU (including specific objectives and governance aspects) while adopting common provisions applying to them.

The Single Basic Act sets out the objectives for IHI, identifies its partners and their contribution to the partnership (in-kind or financial), and defines its tasks, governance arrangements and financial rules.

Compared to IMI2, the Single Basic Act makes several new stipulations, including:

- expanding the partnership to include new partners, their role in proposing topics for calls for proposals and their representation in governing bodies;
- the possibility of adjusting the SRIA in light of scientific developments or emerging public health needs;
- the requirement that all types of stakeholders have the opportunity to propose ideas for future calls for proposals;
- provision that requires project consortia to ensure that products and services resulting from clinical studies performed in IHI funded projects are affordable, available and accessible to users outside the consortium at fair and reasonable conditions.

¹⁶¹ IMI2 Interim Evaluation, p.82.

In addition, the Single Basic Act sets out a series of new financial provisions, specifically:

- the possibility of additional activities that will be included in the calculation of the eligible in-kind contribution of industry partners while setting a ceiling of 40% at the programme level (i.e. industry partners' in-kind contribution covering additional activities cannot exceed 40% of total in-kind contributions);
- a minimum of 45% of in-kind contributions of eligible costs at the project level. This is the share of industry partners and contributing partners' contributions that must be met in every project (including costs for additional activities);
- a maximum threshold of 20% of in-kind contributions incurred in countries that are not in the EU and not associated with Horizon Europe. This threshold existed under IMI2 but was set at 30%.

Under IHI, in a single stage call process, all entities that fulfil the Horizon Europe eligibility criteria are eligible to receive funding.¹⁶² This includes all companies based in EU member states or Horizon Europe Associated Countries irrespective of their size. EFPIA companies have chosen not to apply for funding even when eligible to receive it in a single stage process. In a two-stage call process the topic text is prepared by a pre-identified consortium usually composed of companies and sometimes complemented by charitable or philanthropic organisations providing in-kind contributions. If an entity is part of the pre-identified industry consortium then they cannot receive IHI funding. In addition, all for-profit organisations with a turnover of EUR 500 million or more are also ineligible for IHI funding.

In addition, the partnership's operations are subject to EC corporate rules. Under the current EU multiannual financial framework (MFF) 2021-2027, the Commission has deployed a corporate Model Grant Agreement for all centrally managed EU programmes. This sets out core provisions common to the programmes, allowing synergies, alignment, and simplification. As a general principle, only entities eligible for funding can sign and participate in a grant as beneficiaries and/or affiliated entities. At the beginning of IHI this excluded some organisations based in Third Countries under Horizon Europe from becoming beneficiaries of the programme, even if they do not receive funding.¹⁶³ For them, an option would have been to participate in the project as Associated Partners, while remaining external to the grant agreement.¹⁶⁴ This does not provide the same rights and obligations are now able

¹⁶² There are two types of calls for proposals: In a single-stage call, a consortium consisting of industry and public partners comes together to submit an application at which stage it is required to demonstrate the availability of contributions of at least 45%. In a two-stage call, industry partners willing to participate in the call jointly commit funding before the call is launched. At the first stage, public consortia submit proposals to the call, which are evaluated and the most highly ranked consortium develops a full proposal together with industry partner at the second stage of the call.

¹⁶³ Organisations eligible for funding from Horizon Europe have to be established in the EU, in a country associated with Horizon Europe, or in a low- or middle-income country. Third Countries (i.e. those not meeting these criteria) include the Switzerland and the United States.

¹⁶⁴ The term 'Associated Partner' has different meanings under IMI and IHI. Under IMI, 'Associated Partner' referred to any legal entity that wished to contribute to the programme but was not a member of EFPIA. This role has evolved and is now termed 'Contributing Partner' under IHI. Under IHI, 'Associated Partner' refers to a legal entity that is part of a consortium but does not qualify as a beneficiary (i.e. is not based within the EU or a country associated with Horizon Europe) and therefore is not eligible to receive IHI funding.

to participate as beneficiaries as long as they do not request funding, if they are considered essential by the granting authority (e.g. the IHI Executive Director).

The Single Basic Act also sets out the administrative budget of IHI. This is set in accordance with EC-wide stipulations for programme administration. Compared to IMI2, the administrative budget for IHI has been reduced in line with EU financial rules. This means that the IHI Office will have to operate within a reduced budget, while the number of tasks deriving from the Single Basic Act have become more complex.

Governance structure

The governing bodies and their respective roles are set out in the Single Basic Act. Several changes have been made compared to IMI2. These reflect the new composition of the partnership, which involves a larger number of partner organisations, as well as lessons learned from IMI2.

Governing Board

The IHI Governing Board reflects the new composition of the IHI partnership. This is to ensure that all partners participate in the development of strategy, the setting of priorities for research, development and innovation, and the definition of topics for new calls of proposals. Under IMI2, companies of industries other than pharmaceutical companies could participate either as Associated Partners or as EFPIA Partners in Research in projects, but these sectors were not represented at governance level since only the pharmaceutical industry had made an upfront commitment to contribute to IMI2.

The Governing Board now has eight members, of which four represent the EC and four represent industry partners. The EC are represented by members of four EC Directorates-General, namely DG CNECT, DG GROW, DG SANTE and DG RTD. They oversee a wide set of policy areas within the EC. The EC and industry partners have equal voting rights, and the Governing Board members adopt decisions by consensus to the extent possible. If consensus is not possible, decisions are adopted when a 75% majority is reached. The vote of the EC is indivisible.

Industry partners now include MedTech Europe, COCIR and EuropaBio in addition to EFPIA and Vaccines Europe (which is associated with EFPIA). This means that there is a new need to coordinate between industry partners, as well as between a larger number of industry partners and the EC. This was seen by all stakeholders as adding complexity to the operations at governing level and as requiring additional coordination, education, and communication between industry partners, between industry partners and the EC, and between the partners and the IHI Office.

Industry partners have decided to coordinate positions internally. New partners noted that aligning their internal procedures with IHI governance processes has been a learning curve. This involves explaining the initiative to new audiences and communicating its aims and potential to member companies. As one partner stated the purpose of the public-private partnership is not always obvious to companies, especially if they are used to seeing each other as competitors and are new to this kind of collaboration. It was noted that EFPIA companies had undergone a similar learning experience during IMI1 and IMI2 and that EFPIA plays an important role in supporting new partners and their members while they develop their role in IHI and discover the potential of this partnership.

All partners noted that the early experience of contributing to the Governing Board has been positive. New industry partners may have had less experience in working together but they learned fast and were highly motivated. All in all, industry partners' general positions tended to be well aligned, although there may be differences in some priorities. New partners stated that they felt that their voice was always being heard and that discussions were active and productive.¹⁶⁵ Partners are committed to develop a joint understanding and common language to develop the programme together. Developing topics for calls of proposals was seen as a key strategic task for the Governing Board by all stakeholders interviewed, in addition to ensuring that the programme works towards the objectives set out for IHI.

Science and Innovation Panel

The Science and Innovation Panel (SIP) is a new scientific advisory body created under IHI, replacing the Scientific Committee of IMI2. The new body's composition and functions are laid down in the Single Basic Act. The SIP is composed of a wider group of panellists, in addition to scientific experts, representing stakeholders along the healthcare value chain. Members include representatives of healthcare professions, regulatory bodies, patients, and other end users of health innovations.¹⁶⁶ The Panel is joined by representatives of IHI partners (industry and EC) and the chair and vice-chair of the States' Representatives Group (SRG), representing the EU Member States/countries associated to Horizon Europe.

The aim of the SIP is to provide expert advice from a wide range of perspectives relevant to health innovation. The addition of representatives of IHI partners (industry and EC) aims to ensure that advice from the SIP will feed into discussions in the other governance bodies. The Single Basic Acts lists the tasks of the SIP, as providing advice on scientific priorities including the SRIA, the draft work programmes and the content of call topics. Stakeholders noted that the SIP is expected to be consulted earlier in the process of call topic development than the IMI2 Scientific Committee, to ensure that opportunities for synergies between industries and other (public and private) sectors are not missed. By June 2023, the SIP met six times since the inauguration of IHI and has met more frequently than the previous committee.

Several interviewees noted that there has been concern initially whether the members of the SIP would be able to speak for the sectors they represent. Individual panellists are expected to represent entire sectors (e.g. healthcare professions, patients) despite the obvious diversity of perspectives and experiences. However, it was felt that the number of members of the panel should remain limited, not to inflate the group and reduce its agility. Yet, while this was a concern, stakeholders noted that the SIP has operated well and members are able to make substantive contributions.

Other tasks set out in the Single Basic Act are to advise on the planning of additional activities of industry partners, to set up advisory groups if additional expertise is needed that is not present in the SIP, and to support IHI in creating synergies with other Horizon Europe activities. It was noted that no additional ad-hoc advisory groups to SIP have been formed yet, as this was not seen to be necessary.

¹⁶⁵ This is also relevant as industry partners differ in the size of their membership and their potential to participate in IHI projects. They also differ in their contributions to the IHI administrative budget.

¹⁶⁶ IMI2 involved Stakeholder Forum as a formal governance body. In practice, however, it did not work in this function and therefore was not established under IHI.

Partners noted that contributions from the SIP to discussions at the Governing Board are highly useful. However, some stakeholders noted that the role of the SIP was advisory only, while decision-making rested with the Governing Board. It was also noted that in the beginning, processes at the SIP were relatively slow as some SIP members needed to familiarise themselves with IHI and the role of the SIP. One stakeholder also noted that they felt that exchange with other relevant actors outside the SIP was restricted by strict confidentiality rules that apply to IHI (as a result of the HE rules and the SBA). Some industry partners felt that there could also be more interaction at strategic level between the members of the SIP and industry partners beyond those represented at the SIP.

States' Representatives Group

The States' Representatives Group (SRG) is the third governing body established by the Single Basic Act. The group consists of representatives of national ministries with research and innovation or health in their remit or their respective funding agencies. The group meets twice a year and has two main functions: 1. to ensure coordination with national research and development programmes to create synergies, avoid duplication and ensure compatibility with national legal/ethical frameworks, and 2. to champion IHI in their respective countries especially vis-à-vis national research communities, to provide advice and support to applicants and to connect with key national stakeholders in the field of healthcare.

Considering some of the novelties introduced by the Single Basic Act, the statutory role of the SRG has not changed much between IMI2 and IHI, although the portfolio of topics the SRG is consulted on has grown. Also, stakeholders noted that the nature of the topics for discussion has changed, reflecting the broadened cross-sectoral scope of IHI. Some stakeholders noted that emphasis has been given to the SRG as the interface between national and European research and innovation funding programmes. This new impetus was seen as a challenge given the large number of national and European programmes in the field of health and technology. It was noted that a strategy to ensure coordination between programmes, and possibly synergies, and the role of the SRG in this strategy has yet to be developed.

Developing the strategic direction

The objectives for IHI are set out in the Single Basic Act (Article 115). Stakeholders noted that there was a wide range of inputs into the development of the Single Basic Act and the strategy that followed it. The Single Basic Act defines general and specific objectives and sets out key impact pathways. General objectives are to be achieved by 2030 and include (in short):

1. to facilitate the translation of scientific knowledge into innovations by contributing to the creation of an EU-wide health research and innovation ecosystem

2. to respond to strategic unmet public health needs by fostering the development of safe, effective, people-centred and cost-effective innovations and

3. to drive cross-sectoral innovation for a globally competitive European health industry.¹⁶⁷

The Single Basic Act also sets out specific objectives to lay down the pathways as to how the general objectives can be achieved, for example, by better understanding the

¹⁶⁷ The full version of the IHI objectives can be found in the Annex of the main evaluation report.

determinants of health, integrating fragmented health research and innovation efforts, and by exploiting the full potential of digitalisation and data exchange.

To operationalise these objectives, the Governing Board adopted a Strategic Research and Innovation Agenda (SRIA), which defines the challenge and scope of each objective and sets out potential outputs and impacts. Draft versions of the SRIA were developed before IHI was launched, prepared jointly by the EC and IHI industry partners. The SRIA was also informed by a public consultation, conducted in 2019, to which about 100 stakeholders responded, including academic institutions, healthcare professionals and patient organisations.¹⁶⁸ The draft SRIA was published for comments before being adopted by the Governing Board.

While there is some continuity with regard to the general and specific objectives of IMI2 and IHI, the IHI SRIA has also evolved from its predecessor strategy in a number of aspects as it aligns with the purpose of the new partnership. Cross-sectoral collaboration is a key objective of the SRIA and several specific objectives speak directly to the joint contributions of different sectors.

The SRIA defines the specific objectives of IHI and sets out the criteria that will be considered by the SIP and Governing Board when selecting topic areas. These are:

1. the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it.

2. the high economic impact of the disease for patients and society.

3. the transformational nature of the potential results on innovation processes where projects are not focused on individual disease (e.g., health data analytics).

The SRIA no longer defines priority disease areas or aims to align with WHO priority medicines. Stakeholders noted that their aim was to keep the topic areas as open and flexible as possible to make it easier to integrate new topics and respond to new challenges. This was said to be in response to the experience of two infectious disease outbreaks (Ebola and Sars-Cov-2), to which IMI2 was able to react by making available significant investments; however, while these investments were aligned with the programme's strategic objectives these infectious diseases had not been part of the original WHO list. WHO priority medicines had been integrated in the IMI2 strategy and used as a Key Performance Indicator (KPI) to monitor programme implementation. However, it was noted that this was deemed unsuitable as a reference point for monitoring programme performance as it provided a moving target with WHO also changing priorities in response to regional and global events.

Several partners noted that there was a new emphasis on disease-agnostic approaches, especially but not exclusively in the fields of biomarker development and digital technologies. It was argued that such approaches would both capitalise on the opportunities arising from the cross-sectoral approach outlined in the SRIA and reflect developments in health research, development and innovation that enable such approaches.

The IHI SRIA aligns objectives that provide clear impact pathways and allow for the development of measurable KPIs. Stakeholders noted that specific efforts have been made to demonstrate the public value of the partnership as well as progress against objectives. KPIs are more strongly aligned with objectives under IHI than possible previously during IMI2

¹⁶⁸ https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda.

and designed to capture progress during the programme's lifespan. This is challenging given the precompetitive nature of research and development in this field, as even breakthrough innovations do not directly result in marketable products or services that would more immediately translate into health, social and economic impacts. Therefore, IHI KPIs are designed to capture the multi-stakeholder involvement across sectors, the ability of projects to interact with regulators, the generation of tools to use in clinical practice and the production of innovations enabling the integration and management of healthcare data, among others.¹⁶⁹

Developing the work programme

Developing the work programme, including calls for proposals, is a key function of the Governing Board. Call topics need to align with the strategic objectives of IHI set out in the SRIA and its guiding principles.

There is a wide spectrum of inputs into strategic discussions informing the implementation of the programme. The Governing Board involves the four EC departments that ensure that IHI decision-making is aligned with EC policy and funding programmes, as well as the four trade associations representing a wide range of industries across countries of Europe. The SIP and the SRG members can also suggest topics for future research. Under IMI2, Strategic Governance Groups used to discuss and advise on-call topics; however, these groups no longer exist under IHI.

The Single Basic Act has established a 'bottom-up' approach addressing earlier criticisms of IMI2 being insufficiently open to the views of stakeholders other than those involved in its governance (i.e., the EC, EFPIA at that time). Ideas for call topics can be submitted through a web portal on the IHI website.¹⁷⁰ Submitted ideas are screened by the IHI Office for completeness and relevance to IHI's objectives before being shared with the SIP. Ideas for topics are discussed by SIP, who advise on their relevance and suitability. The opinion of the SIP is then published on the IHI website and also shared with the Governing Board for their consideration. Stakeholders noted that incorporating external ideas in calls usually involved a process of 'maturing' topics through discussion and through working on the call documents. The IHI Office also plays a role in developing call texts. This was noted as being especially important for single-stage calls where the IHI office drafts the topic texts to prevent potential conflicts of interest of industry partners.

During IMI2, EFPIA launched a 'Think Big Initiative' that brought together the heads of R&D of the large pharmaceutical companies that are members of EFPIA to develop ideas for calls and set priorities for funding. At the time, the group identified four strategic pillars as areas of priority: immunology, innovations in clinical trials, antimicrobial resistance, and digital health. This helped EFPIA companies to consolidate their priorities and to convince company leaders to make financial commitments. A similar initiative has been started under IHI, aiming to define and consolidate strategic interests between all industry partners.

Calls for proposals can be organised as single-stage or two-stage calls. Single stage calls are usually used for topics where more than one approach could be possible and should be funded to tackle a specific objective. One key difference between these types of calls is the mode of participation of industry partners. In single-stage calls, consortia have to identify their own industry partners, i.e., companies that are able to contribute to its funding through in-

¹⁶⁹ https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/IHI_KPIs_2022.pdf.

¹⁷⁰ https://www.ihi.europa.eu/shape-our-future-research/propose-ideas. The web portal was introduced under IMI2 and further expanded under IHI.

kind contributions at the level of at least 45% of total project costs. Under a single stage call it is possible to have different companies joining different applicant consortia and thereby competing within one another under different proposals submitted to the same call. In two stage calls, companies come together and agree on an area or approach where they should work together to overcome a particular challenge and commit contributions (i.e. in-kind or financial contributions) to a topic, often as a group; this contribution is then matched by the EC. Consortia applying to these calls do not therefore include companies from industry partners, but consist of academic institutions, research institutes, public sector organisations and others. Following an independent evaluation process at stage one, only one proposal is taken forward to stage 2 and a joint proposal is co-developed with those companies that committed to the topic. Under IMI2, the majority of calls were organised in two stages, with the exception of a small number of calls, usually responding to health emergencies.

Some industry partners emphasised that they would like to see an accelerated process of developing call topics and select projects. They noted that having more single stage calls could help to accelerate this process. IHI has been encouraged to launch a larger number of single-stage calls. However, there are concerns that single stage projects result in a lower number of proposals given that applicants such as academic organisations or SMEs can find it difficult to identify industry members willing to provide the required 45% in-kind contributions. If the number of successful proposals is too low, there is a risk of the IHI budget not being used in full.

Early experiences of implementing IHI

Collaboration at the governance level and developing the strategic direction

Partners interviewed were generally optimistic about the partnership and provided positive feedback on the early experience of collaborating at governance level. Interviewees recognised that industry partners come from different backgrounds and may have different objectives, limitations and boundaries, as well as mechanisms for coordination. They also deal with different expectations from their constituencies. For new partners, participating in IHI brings a new set of tasks that comes with new demands and sometimes unexpected workloads. New partners also vary in size and capacity to participate. However, they all appreciated the potential of the partnership to benefit their member companies. Some expect to have only a few members eligible for participating in IHI, while for others participation is likely to grow substantially over time as member companies become more familiar with IHI.

It was noted that new partners were still in the process of learning how to collaborate with companies with whom they were normally in competition. While EFPIA members have now had over 15 years of experience, collaboration may be a new experience for members of other trade associations. Industries also differ in their approaches to innovation and times to market, in their current appreciation of working together on topics that are not immediately marketable and in defining in which areas of their work collaboration is possible (i.e. the precompetitive space). Some expect that IHI will be a 'game changer' for their sector as it would expose companies to new influences and prompt them to become more strategic about their role as innovators.

In general, stakeholders noted that discussions at the Governing Board were open and constructive, and new partners felt that their voice was heard and that their positions were taken into account. Partners noted that it was still relatively early in establishing IHI, given the late start of the partnership, and that many discussions had focused on resolving operational issues rather than strategy.

Developing the work programme and generating topics for calls for proposals

Adopting the annual work programme is a key responsibility of the Governing Board (as stated in the Single Basic Act). Call topics originated from a variety of sources, including through the 'bottom up' route via the new website portal and through 'top down' discussions at board level. However, stakeholders noted that it is the Board that takes the final decisions and is responsible for meeting the objectives set out for IHI.

Stakeholders were satisfied with the new opportunity to propose call topics through the web portal and other routes, such as through suggestions from the SIP. However, both the EC and the industry partners also emphasised the importance of call topics to reflect their priorities. This was seen as an essential condition for companies to become involved and for the EC to commit funding to IHI projects. From the perspective of industry partners, the 'top down' approach of decision-making remained highly important. They therefore welcomed the 'Think Big Initiative' launched by industry partners in 2022 and the idea of bringing together the companies' heads of R&D. Similarly, the EC wishes to ensure that IHI reflects its priorities on public health needs and policy objectives (such as contributing to specific plans and initiatives, e.g. the Europe's Beating Cancer Plan or the Green Deal). While partners stated that there could be tensions between partners about specific priorities, they were universally optimistic about their capacity to find solutions that suited all partners. All partners noted that call topics tended to mature over time and were the result of a longer process of honing ideas, with input from the SIP, the SRG and the IHI Office. At Governing Board level, priorities would be discussed and negotiated to bring together the priorities of all partners.

New partners agreed that it was not difficult for any partner to participate in strategic discussions, raise points and have their voice heard. However, one partner noted that it could be difficult to follow the process of topic development, describing an overload of information coupled with complex procedures. It was noted that there is great willingness and effort to hear all parties. While EFPIA had the most experience and contributed more funding at project and programme levels, new partners stated that this had no effect in terms of voice and contributions to discussions. One partner expressed the wish for the EC to provide more background on how its priorities are being formed and where they arise from.

A difference between IHI and IMI is that member companies of industry partners are more variable in size. This means that some companies will be eligible to receive project funding, and others will contribute financially or in kind; to some companies both will apply. Under IMI2, all industry partner companies contributed to the programme without requesting funding.

Navigating operational hurdles at the start of the programme

Horizon Europe rules stipulate that organisations in Third Countries not eligible for Horizon Europe funding cannot sign the grant agreement and therefore cannot participate in projects as beneficiaries. Such entities are given the option to participate with the status of 'Associated Partners'. This means that companies (and other organisations) based in Third Countries and wishing to provide in-kind contributions to a project rather than requesting funding are no longer allowed to sign the grant agreement and consequently do not have the same rights and obligations as a beneficiary.¹⁷¹ This also affects rules around intellectual property (IP)

¹⁷¹ An earlier provision excluding 'beneficiaries not receiving funding' from this rule was discontinued under Horizon Europe.

and liability that are of importance to all project participants. It was for this (and other) reasons that this provision was not acceptable to industry partners and respective companies.

The application of this new rule has had major implications as it led to some delay in implementing IHI as it took time to find a way to ensure that member companies from Third Countries providing important in kind contributions to projects could sign the grant agreement and assume the same obligations as other beneficiaries. As this new rule is anchored at the top level of the EC legal framework, changing it has not been an option, as this would have required legislative changes. As of June 2023, a pragmatic solution was found with the IHI Executive Director using their authority to decide on a case-by-case basis whether organisations with an essential role in project consortia should be allowed. This solution was agreed given the specific legal setup of IHI: according to the legal basis, the contributions of entities based in such Third Countries should be taken into account when calculating the contributions provided by the trade associations i.e. at least 45% of project costs. The Single Basic Act also allows up to 20% of in-kind contributions to operational activities (IKOP) to come from outside of EU. This means that non-EU entities bringing in their contributions are indispensable in IHI projects. This approach places the ultimate responsibility for decision-making on the Executive Director.

There is another operational hurdle associated with entities wishing to participate in IHI projects and provide in-kind contributions being based in Third Countries. This has to do with the maximum threshold set for in-kind contributions to IHI incurred in Third Countries that was reduced to 20% from 30% under IMI2. Stakeholders interviewed noted that this change in rule signified the intention of the Commission and the EU Member States to encourage industries to conduct their operations, specifically research and development, in the EU rather than in Third Countries. This move was not welcomed by all industry partners who considered they were bringing meaningful expertise and resources to EU public-private collaborations. In addition, there is now a larger number of countries classified as Third Countries, including Switzerland, home to significant pharmaceutical industries. This is likely to make programme management more complicated and, from an industry perspective, may create a hurdle for participation for some companies and non-profit contributions if they wish to participate from their sites based in third countries. At the same time, IHI is the only Joint Undertaking from all those established by the Single Basic Act that allows contributions coming from Third Countries. This exceptional approach for IHI was allowed to account for the fact that health threats and health research are global and solving some of them requires collaborating internationally.

Launching the first IHI calls for proposal

Stakeholders noted that it was important to commence launching calls for proposals as early as possible to generate the expected results and impacts. There are also important operational considerations such as budget execution. Industry partners and the EC noted that it was important to them to shorten the time between idea development and project start to align better with innovation cycles in industries. However, the process of producing well worded calls and selecting quality proposals is complex and there are many steps that cannot reasonably be accelerated without risking undermining the aim of selecting projects that lead to high quality outcomes.

During IMI2 the vast majority of calls were organised in two stages, i.e. industry partners came together to commit to a call topic and were joined by an academically led consortium selected by independent evaluators at stage one. Together they developed the project proposal at stage two. To date three IHI calls have been launched, two of which were single-stage and one a two-stage call. Five grant agreements have been signed so far, all resulting from the first (single-stage) call. Among stakeholders, views diverged as to whether

expanding the number of single-stage calls was beneficial to the programme. In interviews, some stakeholders suggested that single-stage calls may provide an advantage to some organisations that were able to use existing networks to establish a consortium, reducing rather than increasing competition among organisations. Some stakeholders also noted that single-stage calls had resulted in a lower number of proposals of good quality than expected, while at the same time they allowed for more openness of the topic and offered a wider choice of approaches to address the research and innovation challenges identified in call topics. Some interviewees saw the lower number of applications as an unwelcome effect of singlestage calls, as it may indicate difficulties of academic consortia in identifying suitable partners and raise the appropriate amount of contributions within the application period. Companies also needed to find enough funding at relatively short notice to meet the 45% threshold of inkind contributions from industry partners (and contributing partners). There has, therefore, been an agreement between the IHI partners and the IHI Office, confirmed by the Governing Board, to extend the time between the launch of a call and the deadline for proposal submission beyond the current three months. This decision, applicable to single-stage calls only, will be implemented from the next call onwards.

In contrast, others wished to promote single stage calls as it involved a shorter application period than a call consisting of two stages. Single-stage calls were also seen favourably by some who regarded them as a means to stimulate competition between companies for the best approach or best solution to be developed. It was also seen as a way of being able to fund more than one proposal, as long as these were within the budget set for this call. However, there were concerns that companies who had committed budgets internally would feel their efforts (and budgets) were wasted if they did not succeed in a call. Given the smaller number of proposals taken forward, some were concerned that budget allocated by the EC would not be used in full as there were fewer projects to co-fund.

It is yet too early to draw firm conclusions given the small number of calls and grant agreements signed. Analysing and evaluating the experience of the first rounds of calls will be an ongoing task for all stakeholders involved, including the Governing Board and the IHI Office.

Reflections on evaluation criteria

Relevance

The partnership is relevant to address the key goals of the European Union to promote innovative research and development, improve population health and strengthen the competitiveness of European industries. The experience of IMI2 has shown that the programme responds flexibly to emerging health needs including health emergencies such as Ebola outbreaks and the Covid-19 pandemic. The expansion of the partnership under IHI ensures that the programme will remain relevant and able to respond to new and unforeseen challenges in the future. It also institutionalises a cross-sectoral approach to research, development and innovation to ensure that the programme can achieve its objectives and fulfil its mission.

Efficiency

Stakeholders interviewed were generally satisfied with the collaboration between partners at governance level. The programme started later than expected due to the Single Basic Act coming into force over six months later than expected. Since then, all governance structures of IHI have been established and the new stipulations and financial rules set out in Council Regulation have been implemented. However, a few operational hurdles have emerged that

increased the workload and required significant operational attention, impacting on the operational efficiency of the programme at the early stage.

Transparency and openness

The partnership is open to new partners, as the transition from IMI2 to IHI demonstrates. New partners noted that they feel their voices are being heard and taken into account at governance level. A new route to generating topic ideas for new calls has been established under IHI, opening the process to a wide range of stakeholders, also those not related to IHI in any way. Topic ideas are screened by the IHI Office and discussed in the SIP and SRG with the Governing Board being the final decision-maker.

Key lessons learned and suggestions for improvement

It is possible to refresh and expand an institutionalised partnership to respond better to emerging and unforeseen challenges and to capitalise on opportunities arising from new technologies in an area of fast-paced innovation. However, in the case of IHI this required a substantial amount of work and energy to establish new governing bodies and to create new procedures, resulting from the new partnership as well as from new stipulations and rules set out in Council Regulation establishing IHI. Running IHI involves substantial workload for the IHI Office, as well as IHI partners.

IHI also demonstrated that it is possible to open the programme to a wider set of stakeholders. This includes Widening the group of stakeholders at governance level by creating the Science and Innovation Panel (SIP), which now includes healthcare professionals and representatives of regulators, health technology assessment (HTA) bodies and patients, in addition to researchers. It also established a mechanism for collecting ideas for call topics through a dedicated web portal on the IHI website.

The implementation of IHI has also been affected by changes in the EC corporate rules, set out in the EU multiannual financial framework. While these changes were not targeted at IHI specifically, they particularly affected the programme, as many global pharmaceutical companies involved (making in-kind contributions and thus being co-funders of IHI) are established in Third Countries. It is important that the rules and frameworks reflect, and support, the collaborative effort underpinning a public-private partnership to avoid 'teething problems'. This also applies to the administrative burden associated with the governance of the programme and its operations.

There is an expectation by some that IHI will launch a larger number of single-stage calls than were initiated under IMI2. In interviews, different reasons were given in support of this push for single-stage calls, including their suitability for topics where more than one approach should be funded, an expectation of beneficial competition between consortia and between companies, and an expectation that single-stage calls would shorten the period of proposal development compared to two-stage calls. It is too early to tell whether single-stage calls will serve all these purposes and there is a need to monitor their effects and analyse their advantages and potential disadvantages compared to alternatives, and explore mitigation strategies, if necessary.

Case Study No 2: IMI2 and IHI: driving innovation in digital health

Executive Summary

This case study analyses the contribution of the Innovative Medicines Initiative (IMI2) to the field of digital health and provides a perspective on the potential of its successor programme, the Innovative Health Initiative (IHI), to expand this focus. cThe analysis of programme data and information has shown that **IMI2 has made substantial contributions to the field of digital health**, by supporting a broad range of projects that contribute to the study and development of digital health technologies and their integration in practice. In addition, over two dozen IMI2 projects include a digital health component that contributes to the overall aim of the projects, without necessarily being their key component. Together these constitute a significant investment of IMI2's project funding in the field of digital health.

The case study also **analysed a cluster of four projects** using desktop analysis and interviews with project leaders. Projects included are IDEA-FAST, Mobilise-D, RADAR-CNS and RADAR-AD, selected for their shared aims and approaches to developing digital endpoints by testing and establishing the use of wearable devices. These projects have already **achieved several substantial outputs** including the establishment of data platforms to store and manage data collected in studies; the development of data analytics, algorithms and software to identify relevant data signals and validate their relevance and reliability; the validation of digital endpoints through clinical studies (although data analysis still has to be finalised in some cases); and contributions to ethical and legal issues, as well as informing the development of regulatory pathways. These **outputs are highly relevant** and will contribute to IMI2's vision of strengthening European industrial leadership, improving access to medical innovations and bettering population health and well-being.

Interviews with IHI stakeholders confirmed that digital health is a key area of IHI and well anchored in the programme's objectives and thematic priorities. The cross-sectoral nature of the IHI partnership, with technology companies being among its founding members, has obvious potential to **foster collaborations with technology companies** and others, and leverage the digital transformation for the benefit of patients. Stakeholders noted the importance of efforts to strengthen the sustainability of project findings and support their wider use and scaling in practice, which remains challenging as it requires substantial expertise, vision and commitment from many actors. IHI's **focus on digital health also sits well with other European policies, plans and programmes**, although stakeholders noted the increasing complexity of the policy landscape in this area which requires careful coordination and strategic planning.

Introduction

Purpose of this case study

This case study was commissioned to inform the Final Evaluation of IMI2 and the Interim Evaluation of IHI and is part of the Evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe. The aim of the case study is to analyse the contribution of the Innovative Medicines Initiative (IMI2) to the field of digital health and to provide a perspective of the potential of its successor programme, the Innovative Health Initiative (IHI). Digital health is a broad term encompassing a variety of terms, technologies and tools. The European Commission (EC) proposes the following broad definition that emphasises the multiple uses of and opportunities associated with digital health: 'Digital health and care refers to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and

management of health-related issues and to monitor and manage lifestyle-habits that impact health. Digital health and care is innovative and can improve access to care and the quality of that care, as well as to increase the overall efficiency of the health sector.¹⁷² A second definition proposed by the European Federation of Pharmaceutical Industries and Associations (EFPIA) highlights the multitude of terms used to describe digital health applications that include 'ehealth, m-health and telehealth' and capture 'everything from electronic patient records, remote monitoring, connected devices, digital therapeutics and more'.¹⁷³ The broad nature of both definitions is indicative of digital health still being an emerging field for research and development, with innovations continuously expanding its concepts and boundaries.

Scope of the case study

This case study examines the contribution of IMI2 to the field of digital health and provides a perspective on its potential to expand this focus under IHI. The analysis of IMI2 projects covers the full duration of the IMI2 from 2014 to 2021. IHI has only started its operations in November 2021, with only a few projects selected so far. However, the case study can draw on the early experience of key stakeholders of IHI and its strategy document to understand its prioritisation. Four projects have been selected for in-depth analysis. These have been chosen based on the advice of the IHI Office as they provide a coherent thematic cluster (focusing on developing digital endpoints through the use of 'wearable' devices), they have concluded or almost concluded their period of project funding and have already produced study findings and other projects results, including exchanges with medicines regulators. Projects selected include:

- IDEA-FAST;
- Mobilise-D;
- RADAR-CNS;
- RADAR-AD.

The case study concludes by relating the analysis to selected evaluation criteria, namely Relevance and Directionality.

Methodological approach

The case study uses three methods in particular: an analysis of programme data and related information; desktop research; and stakeholder interviews.

Programme data and information were analysed to examine the number and types of projects funded under IMI2 in the field of digital health. The analysis was conducted in three steps:

First, using the dataset provided by the IMI2 Dashboard, we used the existing labels ('tags') included in the dataset. These tags ('Digital Health', 'Big data and knowledge management' and 'Real-world data') were provided by the IHI Office and developed to allow the dataset to be searched for themes and to indicate project clusters (e.g. different disease areas). tSecond, we generated key words related to digital health using two sources: The opensource AI-supported research database 'OpenAlex'

¹⁷² EC (2023): eHealth: Digital health and care. Overview. https://health.ec.europa.eu/ehealth-digital-health-and-care/overview_en. 173 EFPIA (2023): Digital Health. https://www.efpia.eu/about-medicines/development-of-medicines/digital-health.

and keywords published in a scientific article reporting on a bibliometric analysis of studies published on digital health topics.¹⁷⁴

 Using this combined sample of projects (removing duplicates), we conducted a text analysis of the project summaries and project results as they were included in the IMI2 Dashboard. This thematic exploration resulted in a mapping of the types of digital health projects included in the sample.

Sources identified through desktop research included project information on IMI2/IHI websites (e.g. project factsheets) and dedicated project websites, published scientific papers, and the Strategic Research Agenda (SRA) of IMI2 and the Strategic Research and Innovation Agenda (SRIA) of IHI. RInterviewees included the project leaders, i.e. academic project coordinators and industry leads of the four selected digital health projects. In total, eight interviews were held with project leaders. Interviews were conducted between May and June 2023 and lasted about 60 minutes on average. The case study also draws on seven interviews with IHI stakeholders, including IHI partners and members of the States' Representatives Group, who have been interviewed about the early experience of IHI which included additional questions relating to digital health. A topic guide was developed to structure each interview. Interview data were recorded in form of a protocol. The protocol was shared with each interviewee for review and interviews were able to comment and record corrections. The data collected in interviews were analysed thematically using the topics of interest to the case study.

Analysis of IMI2 projects

In total, 123 projects were funded under IMI2. These projects were created in response to different call topics, some of which were specifically addressing a topic related to digital health while others focused on specific disease areas, to which digital technologies can make a contribution, although they were not necessarily the focus of the project.

As described above, the analysis of IMI2 project was conducted in several steps. In a first step, we used the tags provided in the IMI/IHI Dashboard, which is the central project database of the programme. Using the three tags that were indicative of digital health, this search resulted in 36 projects: 'Digital health' (resulting in 8 projects), 'Big data and knowledge management' (resulting in 18 projects) and 'real-world data' (resulting in 23 projects).¹⁷⁵ The resulting list of projects can be found in Table 99 in the Appendix.

In a second step, we used two sets of keywords to add to the analysis. This additional analysis was used to further explore the projects and in recognition of the fact that the Dashboard tags have evolved over time, with new tags (such as 'digital health') being introduced as a new field emerged. The first set of additional keywords is based on OpenAlex concepts¹⁷⁶, the second set is derived from an extensive bibliometric analysis of publications in the field 'digital health'. This search generated 23 additional search terms.

¹⁷⁴ Ahmadvand, A., Kavanagh, D. et al. (2019): Trends and visibility of 'Digital Health' as a keyword in articles by JMIR Publications in the New Millennium: Bibliographic-Bibliometric Analysis. Journal of Medical Internet Research 21 (12): e10477.

¹⁷⁵ More than one keyword can be used per project.

¹⁷⁶ OpenAlex is an artificial intelligence supported catalogue of the global research system, which includes scholarly papers, authors, journals and research institutions. The catalogue derives concepts by analysing the links between all items related to a concept (such as ,digital health'). Each concept has a parent and subsequent domain, as well as related concepts. https://explore.openalex.org/concepts/C2780433410

Using these additional search terms, we analysed the full set of IMI2 projects, identifying 28 projects in addition to those identified earlier. Search terms most frequently found were 'social media' (29 projects), 'health technology' (15), 'precision medicine' (10), 'wearable' (7), 'smartphone' (7), 'personalised medicine' (6), 'electronic health record' (5), 'digital health' (5) and 'mobile health' (2). One project each were identified using the keywords 'ehealth', 'mhealth', 'mobile apps/mobile applications', 'mobile phone' and 'telehealth'. While these keywords relate to different aspects of digital health, they show the scope and diversity of projects.

A full list of projects resulting from this analysis is found in Table 100 in the Appendix. Examining the projects suggests that many of these projects would not be classified as 'digital health' or 'big data' projects. Instead, digital technology is one component within a wider portfolio of activities. For example, the EBODAC project was established to study the feasibility and acceptability of vaccine trials under the conditions of an Ebola outbreak in West Africa. It used smartphone technology to send reminders to trial participants. While it did not contribute to the development of the technology, it generated insights in its usefulness and suitability for the purpose of trial implementation in this context and environment. The trials also used iris scanning to ensure that the correct patient is registered on recall. These examples show that digital health components already support a substantial number of projects and are developed in response to a large range of research questions, without necessarily being a 'digital health project' outright. These projects in turn help to expand the use of new technologies, and identify and overcome barriers to their uptake.

The Table below shows a summary of the total investment in this field under IMI2. Given the diversity of projects we have kept the distinction between the two methods of project selection, to indicate investments in the portfolio using the more narrow definition, as well as the wider definition.

Metho d	Total projec t costs	EU Contributio n	EFPIA Contributions		
			EFPIA Financial Contribution s	EFPIA In- kind contribution s	
Projects selected using IMI2 tags (23 projects)	717 206 038	360 202 598	41 063 425	311 334 425	
Projects selected using additional keywords (28 additional projects)	582 275 518	289 699 480	54 885 789	229 398 689	

Table 98. Investment in digital health projects under IMI2 (in EUR)

Source: IMI2 Databoard, analysed by Prognos.

The final step involves a text analysis identifying meaningful keywords within the project summaries and project results published in the project database (Dashboard). The 'cloud' of

the resulting keywords identified below illustrates the diversity and reach of concepts within the portfolio of digital health projects.¹⁷⁷

Figure 74. Illustration of frequency of keywords identified in project information



Source: IMI2 Databoard, analysed by Prognos.

Individual project analyses

The following section examines four selected projects. These have been selected as they form a cluster of projects that aim to develop digital endpoints by testing and establishing the use of wearable devices. Projects contribute to the study of different disease areas; however, these efforts all have in common that they address important challenges associated with established measurements of patients' health states and therefore have the potential to improve measurements by using digital technology. This can have substantial effects on the ability to study disease progression, demonstrate therapeutic effects on patients' health and disease, and ultimately improve patient care and population health^{178.}

IDEA-FAST

Project overview

The aim of IDEA-FAST is to develop and test digital endpoints for fatigue and sleep disturbances that provide a sensitive and reliable measure of the severity and impact of these symptoms in an at-home setting.¹⁷⁹ Fatigue and sleep disturbances are common symptoms of neurodegenerative and immune-mediated inflammatory diseases and are associated with poor quality of life. Currently, these symptoms are largely measured in the clinic by using standardised paper questionnaires. These measures are prone to recall bias and rely on

¹⁷⁷ Text analysis and cloud illustration were developed using specific analytical functions oft the ,R' packages (tm, wordcloud).

¹⁷⁸ Brem, A.-K., Kuruppu, S. et al. (2023): Digital endpoints in clinical trials of Alzheimer's disease and other neurogenerative diseases: challenges and opportunities. Frontiers in Neurology. https://www.frontiersin.org/articles/10.3389/fneur.2023.1210974/full.

¹⁷⁹ https://www.imi.europa.eu/projects-results/project-factsheets/idea-fast

patients' self-reported subjective assessments. The project used wearable technology to monitor patients' movements and sleep to collect data during patients' everyday activities.

Key results

The project has improved the clinical knowledge of fatigue to establish how fatigue can be measured (i.e. which endpoints to use), and selected and tested devices to monitor patients' activities. Using the recorded data, it developed strategies and algorithms to identify patterns and filter out data that is clinically meaningful (e.g. ECG data to detect sleep or movement). These data were validated against standard data collection approaches in several observational studies. Based on the data collected, the project developed analytical models to assess and predict levels of fatigue.

The project was able to demonstrate the usability of the devices (to aid the future selection of devices) and to establish the feasibility of the approach. Study results suggest that the objective physiological measures are correlated with fatigue and sleep patient-reported outcomes and demonstrate reasonable signal quality.¹⁸⁰

Clinical studies are still ongoing to establish the validity and reliability of the measures. The project also interacted with the European Medicines Agency (EMA) to ensure the resulting measures can be used in future clinical trials. Based on the findings to date, EMA provided Qualification Advice, advising the project team to run separate clinical trials to establish the use of these measures in studies testing pharmaceuticals.

Contribution to digital health

This project addresses a particular aspect of digital health: the **use of wearable devices** to generate patient data and the development of digital endpoint. Such biomarkers have the potential to produce **objective measures of a patient's state of health** that are accurate and meaningful to patients and professionals. Interviewees noted that for patients, using a portable digital device may be more practical and more acceptable than having to attend a hospital appointment to complete questionnaires. This could empower patients and provide more accurate information about the extent and impact of fatigue than previous methods of assessment.

In terms of disease-specific results, the clinical studies conducted contribute to the scientific knowledge of fatigue, which is a burdensome symptom of many neurodegenerative and immune-mediated inflammatory diseases. A future aim is to establish **biomarkers that are disease agnostic** and can be used across several disease areas. Interviewees noted that this would constitute a major development in clinical trials and associated regulatory processes and could increase the efficiency of such processes substantially.

In addition to the data collected during the project period, the project aims to develop software to analyse data recorded by wearable devices. Both the **data collected and the data infrastructure** developed can be used to promote research in this area, and there are plans in place to make the data available to researchers outside the project. Stakeholders noted that the IMI2 project allowed companies to work together in an area of research in which they do not compete but which has the potential to benefit them in future. Instead, it is expected that the development of digital endpoints and common standards flanked by agreed

¹⁸⁰ Antikainen, E., Njoum, H. et al. (2022): Assessing fatigue and sleep in chronic diseases using physiological signals from wearables: A pilot study. Frontiers in Physiology, DOI 10.3389/fphys.2022.968185.

regulatory processes will benefit any company active in this field. Interviewees stated that some pharmaceutical companies already invest in this area to be able to use digital biomarkers as endpoints in clinical trials, to demonstrate the effectiveness of novel pharmaceuticals and to show additional benefits of drugs specific to fatigue. This **common interest** is echoed by the fact that the IDEA-FAST consortium collaborates with other IMI2-funded projects, such as RADAR-AD, RADAR-CNS and Mobilise-D, together generating opportunities for mutual learning and exchange.

However, as this is a new frontier in pharmaceutical development, regulatory approval is largely lacking and only one digital endpoint has been approved in the EU to date (none by the FDA in the US). This is why the exchange of the project consortium with EMA is important in showing the way for future developments in this field. If a letter of support is published based on the qualification advice, this information can benefit companies other than those directly involved in the project. Project leaders noted that it is hoped that regulatory guidance and acceptance would lead to the development and more widespread use of digital endpoints and clinical trials in Europe in the future. However, interviewees cautioned that the utility of these endpoints crucially depended on the scientific results of the project and whether studies can prove that endpoints are valid and reliable.

Mobilise-D

Project overview

The aim of Mobilise-D is to demonstrate that digital endpoints derived from measurements of mobility using wearable devices can provide meaningful information on conditions associated with mobility loss.¹⁸¹ These digital endpoints can be used in clinical studies to provide information about the effectiveness of novel pharmaceuticals. They also have the potential to be used in clinical practice, for example, allowing patients and clinicians to monitor disease progression and the effects of treatment.

Mobility is an important marker of health and slow gait is associated with a greater risk of disease, falls and cognitive decline. Mobilise-D developed digital endpoints by testing and comparing several devices monitoring people's gait. The project validated the use of these devices for the purpose of data collection and monitoring by comparing the data to those generated by gold standard methods (technical study). It then conducted a series of clinical (observational) studies to demonstrate that these endpoints are clinically valid by testing these endpoints in patients with chronic obstructive pulmonary disease (COPD), Parkinson's Disease, multiple sclerosis, or recovering from hip fracture. The study used centre of mass devices (worn on a belt or on the back), as wrist worn devices were not suitable for use in some patient groups (e.g. in patients with Parkinson's Disease with tremor). The team also carried out substantial patient engagement activities to ensure the acceptability and feasibility of the approach.

Key results

The technical study testing the devices showed that the data collected are sufficiently accurate and sensitive to change clinical practice and that the approach has the potential to be used to monitor the effects of drugs used to improve mobility in these disease areas.

¹⁸¹ https://www.imi.europa.eu/projects-results/project-factsheets/mobilise-d

Data from the clinical studies are currently being analysed. The clinical study captured everyday mobility of about 2400 patients enrolled in the study over a seven-day period each. The aim is to validate digital endpoints by comparing against established measures of mobility (in the clinic or lab). The low drop-out rate in the studies suggests that the approach was acceptable to patients.

Contribution to digital health

This project aims to establish innovative digital endpoints to shift monitoring mobility from measuring a person's ability to walk in a hospital or laboratory setting to measuring how people walk in their daily lives. Monitoring a person's actual activities rather than their ability to move in a clinical setting is hugely meaningful to patients and their quality of life. The project builds on an exciting body of research that was judged by project leaders as being the most advanced in the field with the highest potential to translate into innovation that makes a difference to patients' lives.

While the project was focused on specific diseases to establish the use of wearable technologies and validate specific endpoints, the project also aims to develop these endpoints so that they can be used for different diseases. By testing and comparing different types of wearable monitoring devices, the project investigated the characteristics required for devices to be used when measuring mobility and developed standards and protocols to ensure devices used in future meet the requirements specified for this purpose. Both components of the project have contributed to moving this field closer to developing an approach that is both disease agnostic and device agnostic when measuring mobility. This means that endpoints could be used to monitor mobility associated with different types of disease but also use different types of wearable technology for this purpose.

Establishing these endpoints involved an intense exchange with the EMA. EMA provided three rounds of advice and published two letters of support, relevant for this study and in view of taking the next steps in the regulatory process.¹⁸² Specifically, EMA advised to use the technologies and test the new endpoints in an investigational drug trial in future, alongside traditional approaches to data collection and established endpoints. Such a trial is beyond the lifespan of the project; however, project leaders noted that EFPIA companies are already considering how they can take this approach forward in a drug development process.

Project leaders suggested that there were several advantages of doing this project in Europe and that there were clear benefits for the competitiveness of European industries and academia. First, the project added to the scientific expertise and knowledge of participating academic institutions on how to develop digital endpoints and conduct the necessary trials to establish their validity. Second, it contributed to creating a regulatory environment that is supportive of future innovations in the field, as EMA is becoming more experienced in using digital endpoints in different disease areas in its regulatory processes. Third, companies developing and manufacturing devices benefit from this regulatory environment and from the exchange of experience between the regulator, the research consortium and other companies. As a result, project leaders expect that the project does not only help to establish

¹⁸² EMA (2021): Letter of support for Mobilise-D digital mobility outcomes as monitoring biomarkers.

https://www.ema.europa.eu/en/documents/other/letter-support-mobilise-d-digital-mobility-outcomes-monitoring-biomarkersfollow_en.pdf. EMA (2020): Letter of support for Mobilise-D digital mobility outcomes as monitoring biomarkers. https://www.ema.europa.eu/en/documents/other/letter-support-mobilise-d-digital-mobility-outcomes-monitoringbiomarkers_en.pdf.

the use of digital technologies in clinical studies and clinical practice but also help stimulate technological innovation.

RADAR-CNS

Project overview

The RADAR-CNS (Remote Assessment of Disease and Relapse – Central Nervous System) project aims to develop new ways of monitoring major depressive disorder (MDD), epilepsy, and multiple sclerosis using wearable devices.¹⁸³ Patients with these disorders often experience periods where their symptoms are manageable, followed by periods of deterioration and acute illness. Technology now has the potential to continuously assess patients' daily activities and provide a more complete picture of their condition and disease progression.

The project tests whether smartphones and other (mainly consumer-grade) wearable devices can be deployed as a means of tracking health states in these three conditions. It addressed several questions for each condition: To what extent is data collection through wearables feasible? How can signals gained in this process inform about a patient's health state? How can these data be used to predict relapse?

The goal was to develop a monitoring strategy that helps predict periods of deterioration, so that patients are better able to manage their symptoms and to prevent relapse, which would improve their quality of life. For this purpose, the project team conducted several studies to investigate the use of remote measurement technologies in patients with MDD, epilepsy and multiple sclerosis. The project undertook substantial engagement activities with patients and their carers, to understand their concerns and requirements and establish the feasibility of the approach. The project built a data platform and infrastructure that can be used across numerous conditions and scenarios (RADAR-base) and is available as an open-source technology. The platform can receive the data collected from devices, sort, organise, analyse and visualise them. RADAR-base supports seven wearable devices and includes two apps, one for passive data and one for active data collection.

Key results

The project resulted in a host of insights related to the specific diseases. For epilepsy, study results showed that remote monitoring for patients with epilepsy is feasible and produces data of sufficient quality.¹⁸⁴ For patients with depression, more complex treatment and clinical characteristics resulted in reduced long-term engagement with the technology.¹⁸⁵ Findings also showed that alterations in heart rate during all day and night are associated with depression severity.¹⁸⁶

Study findings suggest that wearables can be used to assess ambulatory impairments in people with multiple sclerosis.¹⁸⁷ The project also gained substantial insights into the

¹⁸³ https://www.imi.europa.eu/projects-results/project-factsheets/radar-cns

¹⁸⁴ Böttcher, S, Vieluf, S et al. (2022): Data quality evaluation in wearable monitoring. Scientific Reports 12: 21412.

¹⁸⁵ de Angel, V., Adeleye, F. et al. (2023): The feasibility of implementing remote measurement technologies in psychological treatment for depression: mixed methods study on engagement. JMIR Mental Health 10: e42866.

¹⁸⁶ Siddi, S., Bailon, R. et al. (2023): The usability of daytime and night-time heart rate dynamics as digital biomarkers of depression severity. Psychological Medicine 53 (8): 3249-3260.

¹⁸⁷ Sun, S, Folarin AA (2022): The utility of wearable devices in assessing ambulatory impairments of people with multiple sclerosis in free-living conditions. Computer Methods and Programs in Biomedicine 227: 107204.

acceptability of this method of data collection to patients and therefore the feasibility of the approach. In addition, the RADAR-Base platform was used to investigate the effect of Covid-19 related policy responses, such as the effects of lockdown policies on people's behaviours (e.g. mobility, social interaction) and on adults with MDD.¹⁸⁸

Contribution to digital health

This project was designed as a discovery project and its study aims were largely exploratory. It produced an enormous amount of data and insights in all three disease areas. Project leaders noted that these types of data did not exist before and they are still explored and continue to be analysed after the end of the project period. Deepening the understanding of diseases and disease progression was judged as being highly valuable for industry partners and academic researchers alike. For the pharmaceutical companies involved these insights could help to target treatment more effectively.

The project also made contributions to developing insights into the technologies used for monitoring patients. Devices selected were 'consumer-grade', i.e., devices that are already marketed and widely used by people. It was reasoned that patients and clinicians were more likely to be familiar with these devices and their use would be acceptable. Project leaders interviewed stated that this was preferable to a single commercial solution as this would have limited data collection to a specific device and limited types of data. The study team found that this approach had advantages as well as disadvantages. An advantage was that devices were indeed already widely used (e.g., Fitbits), and patients liked that they looked ordinary and did not carry stigma. However, the approach was limited by the fact that the study team did not always have access to the raw data and was required to use the data provided by the companies owning the technology.

The data platform, RADAR-base, is compatible with different types of devices and can be used to investigate various disease areas. It is currently used by 20 different research projects, among them IMI2 projects RADAR-AD, AIMS-2-TRIALS and BigData@Heart. So far it has generated 17 use cases, i.e., it is applied to examine different types of research questions. The platform is open source and will continue to be available for use for research purposes. This will reduce the costs of this type of research in future projects.

Project leaders noted that the project has generated many important insights but has not yet produced a 'breakthrough' finding. However, the studies involved were the starting point for a process that could lead to the validation of digital biomarkers and their commercialisation. While this goes beyond the lifespan of the project, the project has laid the groundwork for investigation and research in other disease areas and related endpoints. Project leaders would like to see pharmaceutical companies investing in these areas, however, as this project is geared towards improving patient care (i.e., not specifically clinical trials for drug development) there is no immediate link to pharmaceutical research and development. The project team is currently investigating other approaches to taking the project findings further and developing a business case for commercial development.

Study findings generated by RADAR-CNS were presented to the Foundation of the National Institutes of Health, and advice was sought and received from both the EMA and the FDA.

¹⁸⁸ Sun, S, Folarin, AA et al. (2020): Using smartphones and wearable devices to monitor behavioral changes during COVID-19. Journal of Medical Internet Research 22 (9): e199992. Lavalle, R, Condominas, E. et al. (2023): The impact of COVID-19 lockdown on adults with major depressive disorder from Catalonia: a decentralised longitudinal study. International Journal of Environmental Research and Public Health 20: 5161.

Both agencies advised that further clinical studies (in the form of RCTs) will be required to validate the digital endpoints developed by the project.

RADAR-AD

Project overview

RADAR-AD aims to develop our understanding of how digital devices can be used to measure functioning in patients with Alzheimer's Disease (AD) and to develop valid digital endpoints.¹⁸⁹ For this purpose, the project developed a digital platform that brings together data collected through digital devices that allow tracking subtle changes in cognitive and functional ability of people with AD.

The project had several main strands:

- Identification of digital devices that can measure relevant endpoints and testing eight of them in a clinical study, comparing their performance and acceptability to patients, and comparing them to existing gold standard measures (e.g., pen and paper tests).
- Exploring a large number of research questions in three clinical studies to understand better the different disease pathways and to investigate how sensors can measure progression at different stages of disease (especially the early stages), using different types of monitoring devices such as wearables, sensors fitted into their homes, and the use of a model home fitted with sensors.
- Developing data analytics to be able to compare the performance of different combinations of devices and analyse the data collected by the studies.

The project builds on the existing platform of RADAR-CNS (RADAR-base) and adapts it for data collected from patients with AD. As the project is not yet finished, there is still a substantial amount of analysis to be done.

The project also provided significant insights into how different technologies can be combined. Data analysis confirms that there are promising measures capable of distinguishing healthy people from patients with early stage (pre-clinical) Alzheimer's (i.e., patients do not have symptoms but can be identified in terms of neurological changes). Project leaders noted that these findings to date are confirmatory and will be useful in developing treatment at the early stages of disease.

Contribution to digital health

The specific contribution of RADAR-AD lies in its development of digital endpoints by using different types of sensors and measuring different aspects of AD in the real world. This can be used to develop diagnostics, tools for screening, clinical trials associated with drug development, and to help monitor disease progression.

The project did not aim to measure longitudinal decline in individual patients, but it collected data that can inform future studies in this area. It collected data from patients with pre-clinical

¹⁸⁹ https://www.imi.europa.eu/projects-results/project-factsheets/radar-ad

AD, mild cognitive impairment and mild to moderate AD. It also applied different technologies that measured different predictive endpoints.

In terms of regulation and transfer to health systems, an important future question is which evidence is needed to be able to roll out in practice and clinical trials. Engagement with regulators is part of the project and project leaders met with the EMA to seek qualification advice on its research and use of digital devices for future studies.

There are plans to ensure that the data collected by the project will be available to others. This is a requirement of IMI2. Data access will be restricted to research purposes. Plans for ensuring access need to take the costs of data storage as well as ethical and legal considerations into account.

Key findings from the individual project analyses

The section above reports the analyses of selected IMI2 projects. Four projects focused on testing the use of portable devices ('wearables') to collect real-life data during patients' everyday activities. These four projects differ in scope, focus and disease areas. However, they have shared aims and approaches, including:

- They aim to improve the knowledge of diseases, their progression and symptoms.
- They test the use of wearables to collect data from patients during their daily activities and conduct extensive patient engagement activities to understand better the feasibility and acceptability of the approach.
- They establish data platform to store the large amounts of data collected and make them available to other users, often in combination with the algorithms and software to support data analyses.
- They developed data analytics, algorithms, and software to identify relevant data signals and established and validated their clinical relevance and reliability.
- They derived and validated digital endpoints that can be used in clinical studies (e.g. for drug development) and for disease monitoring in clinical practice.
- They clarified numerous ethical and legal issues, informed pathways for regulatory approval and published different types of standards that can be used by future teams.

Associated with these aims and approaches are several contributions to the field of digital health. Each of these projects have developed large databases that bring together large amounts of data collected in the studies conducted during the projects. The data held are disease specific and can be used for a multitude of (emerging) purposes, establishing different 'use cases. A milestone was the development of RADAR-base that provides on open-source platform to leverage data from wearables and mobile technologies and enables the scalable integration of various data sources to collect sensor data in real-time, store and manage the data and make them available to researchers.

Most projects aim to make these databases available to other researchers, so that they can be used for future (commercial and non-commercial) purposes. However, in some cases there are questions as to how to fund the maintenance in future and how to manage access that are yet to be resolved. In addition to these databases, projects developed data analytics, algorithms and software that can be used for future purposes.

Projects typically examined the use of wearables for monitoring endpoints related to several diseases, although this does not apply to all projects and, if there were several diseases involved, this does not mean that endpoints would necessarily be used for all diseases. There will also be great value in developing endpoints for specific diseases. However, most project leaders stated the intention for endpoints to be used beyond the specific disease area explored during the project, with the long-term aim being to develop endpoints that are 'disease agnostic', i.e., could be applied to different types of disease areas and still provide meaningful and valid measures of disease progression and/or treatment effects. Projects involved different types of validation, including validation of the technical aspects and characteristics of the data collection method, i.e., the technical device and its application, and the validation of the clinical validity, i.e., precision, reliability and sensitivity to change, of digital endpoints.

There were two types of uses aspired to by the project: Digital endpoints could be used in clinical studies to measure changes in patient's health status as part of the process of drug development. For this purpose, endpoints need to be recognised and accepted by the pharmaceutical regulator, the European Medicines Agency (EMA). Projects have made important strides towards regulatory approval by exploring and establishing the regulatory pathway for digital endpoints and related methods used in data collection and data analysis. A second field of application of digital endpoints is their use in clinical practice to monitor patients' disease progression as well as their well-being and, in some cases, to develop predictive models that help patients, e.g., to adjust their medication to prevent deterioration. However, the route to establish digital endpoints in clinical practice seems less clear than the route to their use in clinical studies. For one, this requires that digital endpoints be developed in conjunction with a product and service that could be brought to market. However, no obvious route or driver exists to develop these products and services. There are also regulatory hurdles to be overcome, in addition to the challenge of establishing such an innovative approach in established clinical practice. Projects have already carried out substantial patient engagement activities to establish the acceptability of wearables to patients and often their relatives and carers. The use and usefulness of any of these devices crucially depend on the acceptability, feasibility, and usability of digital assessments. Research suggests many barriers to implementation need to be overcome.¹⁹⁰ This knowledge will be vital for future use of wearables' digital endpoints. However, on its own, this will not be sufficient to change clinical practice. IMI2, therefore, initiated several projects that take this work further and test the use of digital technologies in practice (e.g., Trials@Home, BEAMER, Gravitate Health, PharmaLedger),

The future of digital health projects under IHI

The previous section demonstrates that digital health is already a well-established field of research, development, and innovation under IMI2, with a large number of projects already using different types of digital technology to develop novel solutions for existing public health challenges. Indeed, stakeholders noted that IMI2 was 'ahead of the curve' with regard to supporting and promoting digital health innovations at the time.

¹⁹⁰ Brem A.-K., Kuruppu, S. et al. (2023).

For IHI, stakeholders stated that digital health is a key area and has already been identified as a thematic pillar for the future strategic development of IHI. The aim of this pillar is to leverage the digital transformation and use the opportunities arising from collaborations with technology companies and others. This aim will be considerably strengthened through the cross-sectoral nature of the IHI partnership, with technology companies being among its founding members.

Digital health is also well anchored in the SRIA, both in the specific objective on digitalisation and in objectives that touch on various aspects of digitalisation, such as the objectives to integrate fragmented health research (which will require interoperability) and to improve people-centred healthcare solutions (which often involve a digital health component). The importance of digital health is already reflected in the first IHI calls (Box 1) and will inform upcoming calls.

Examples of digital health call topics under IHI

Call 1:

Topic 1: An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities

Topic 2: Next-generation imaging and image-guided diagnosis and therapy for cancer

Topic 4: Access and integration of heterogenous health data for improved healthcare in disease areas of high unmet public health need

Call 3:

Topic 1: Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Topic 2: Patient-generated evidence to improve outcomes, support decision-making, and accelerate innovation

Topic 5: Digital health technologies for the prevention and personalised management of mental disorders and their long-term health consequences

Partners agreed that IHI should make a strategic contribution to the field rather than promote individual project ideas only. Building on the experience and expertise gained under IMI2, this includes work that would help develop technology standards and digital endpoints that can be used in regulatory processes. It was noted that IMI2 projects already contribute to developing the data infrastructure by establishing structures that are more permanent and go beyond the boundaries of individual projects (e.g. EHDEN's federated data network contributing to the creation of the European Health Data Space and to the DARWIN project of the EMA).

An interesting characteristic of digital health applications is their potential to work across different disease areas. In principle, there is enormous potential to scale such technologies and related approaches. However, implementing and scaling these approaches in practice requires substantial expertise, vision and commitment from many actors including regulators, companies, legislators and payers of healthcare services (e.g. public payers, health insurers). Stakeholders noted that IHI is the ideal 'playground' for developing digital solutions as it brings together different types of organisations that can contribute different technologies,

tools, capabilities and expertise. The multi-stakeholder approach is also important to develop trust and dissolve some of the suspicion that exists around the use of patient data. Such data platforms have enormous potential to improve patient care, but there are also barriers, risks and unknowns that IHI projects can help to address and navigate.

Partners emphasised the importance of ensuring that the project's results are sustained beyond the funding period. There are efforts to strengthen the sustainability of project findings, and it was noted that these will become more systematic under IHI. For example, project applications have to demonstrate that they have a plan for sustaining the results after the end of the project funding period. However, ensuring sustainability is a challenge for digital health in general, given the fast-paced development of these solutions and the difficulty of developing any project into a viable, sustainable business model. One stakeholder noted that integrating novel technology into clinical practice has remained challenging, with many actors involved in deciding on the use of new technology. Overcoming this challenge tends to be a long-term effort that requires considerable resources and the involvement of healthcare professionals and patients to overcome barriers to implementation.

Regulating new technologies under medical device legislation has also been identified as a challenge, although one that has been tackled in many IMI2 projects. It was noted that the development of new technologies tends to be much more dynamic than the regulatory process, adding to already existing bottlenecks in regulation. However, it has also been noted that approaches to involving regulators in projects under IMI2 have successfully developed regulatory capacity in this field. A strong and competent regulatory approach, it was argued, is beneficial for companies, as it provides reassurance to patients and professionals and strengthens the sector in the long-term.

IHI's focus on digital health also sits well with other European policies, plans and programmes, including the EHDS, Europe's Beating Cancer Plan and the development of the Digital Single Market. In its Communication on the role of digitalisation in the future of health and care systems, the EC highlighted the importance of digital technologies for ensuring the sustainability of European health and care systems and for empowering citizens by improving their access to high-quality health services.¹⁹¹ However, it was also noted that there is a degree of proliferation with regard to EU policies in this space and that it is important to plan strategically and ensure coordination to create synergies while avoiding unnecessary **overlap.**

Reflections on evaluation criteria

Relevance

This analysis demonstrates the frontrunning position of IMI2 and IHI in the field of digital health underlining the continuous relevance of the programme. IMI2 projects are already making significant contributions to the field both in relation to the range of topics, tools and technologies being addressed and the depths of their contribution to specific areas of digital health (e.g., the development of digital endpoints). Under IMI2, the number of projects funded in this field was significant, covering a wide range of topics, disease areas, and types and uses of technologies. Under IHI, the potential for development has been strengthened by expanding the partnership to include the medical and digital technology sectors. The

¹⁹¹ EC (2018): Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society. Brussels, European Commission.

examination of the project cluster involving 'wearable' technology to develop digital endpoints suggests that these IMI2 projects have made an important contribution in terms of expertise, methods, tools and data generated that will inform future developments in the field. Through well-planned interactions with regulatory bodies, they have also made significant strides towards informing the regulatory pathway for future uses in clinical trials and patient care.

Directionality

The IMI2 projects analysed in this study demonstrate the significant contributions projects have made to the development of methods, tools, and expertise in this domain, as well as to exploring and establishing the use of such technologies in clinical studies and patient care. These outputs have directly contributed to the objectives of IMI2 and its vision to improve the competitive position of European innovation and research, improve access to medical innovation for patients and strengthen population health and well-being. Recent IHI calls are well aligned with IHI objectives set out in the SRIA, which directly refer to the role of digitalisation. Other objectives related to priorities will require a significant role of digital tools and technologies to be achieved. Topics selected for the first calls for proposals also clearly align with these objectives, promising significant contributions to IHI objectives.

Key lessons learned

IMI2 has made substantial contributions to the field of digital health by supporting a broad range of projects that contribute to the research and development of digital health technologies and their integration into practice. In addition, many IMI2 projects include a digital health component that contributes to the overall aim of the projects without necessarily being the key ingredient for the project's purpose.

The analysis of the project cluster involving 'wearable' technology to develop digital endpoints shows that IMI2 projects have made important contributions that are relevant concerning creating the impacts that IMI2 was set out to achieve, i.e., improve the competitive position of European innovation and research, improve access to medical innovations and positively impact on health and well-being.

Digital health is a key area under IHI, which is expressed in several of its objectives. Supporting digital health projects is important to the partnership's impact pathway. IHI's potential to achieve the outcomes and impacts set out for it is strengthened by the cross-sectoral nature of the new partnership, with associations comprising several sectors of industry relevant to digital health (e.g., digital technology, diagnostics, medical devices). The importance of digital health is already reflected in the first calls for proposals initiated under IHI.

Partners interviewed emphasised the importance of IHI making a strategic contribution to the field rather than investing in individual project ideas only. The impact of this approach is demonstrated by project clusters developing digital endpoints under IMI2 and the contribution to developing the data infrastructure that is informing the creation of the European Health Data Space. Interactions with the EMA that inform the development of the regulatory pathway for novel digital health applications also illustrate the importance of a strategic approach to developing the field.

Establishing digital health applications in practice comes with many challenges. Scaling these approaches requires substantial commitment, expertise and vision from many actors, including regulators, companies, legislators and payers of health and care services. While the multi-stakeholder approach is well suited to test-run novel applications and establish their

feasibility and acceptability, scaling and integrating them in existing health systems will remain a challenge for many innovations. It is hoped under IHI that the new partnership setup will help navigate these challenges once projects end their lifespan.

IHI is expected to contribute to many European policies, plans and programmes. IHI's digital health projects align well with the EC's digitalisation strategy and the role it sees for digital technologies in future health and care systems. Given the increasingly busy landscape of European (and national) policies impacting this field, these efforts will require strategic planning and careful consideration to create synergies and avoid unnecessary overlap.

Acronym	Project title
ADAPT-	Accelerated Development of Appropriate Patient Therapies: a Sustainable,
SMART	Multi-stakeholder Approach from Research to Treatment-outcomes
BEAMER	BEhavioral and Adherence Model for improving quality, health outcomes and cost-Effectiveness of healthcaRe
BigData Heart	Big Data 4 Better Hearts
BIGPICTURE	Central Repository for Digital Pathology
COMBACTE- CDI	Combatting Bacterial Resistance in Europe - Clostridium Difficile Infections
ConcePTION	Building an ecosystem for better monitoring and communicating of medication safety in pregnancy and breastfeeding: validated and regulatory endorsed workflows for fast, optimised evidence generation
COVID-RED	COVID-19 infections - Remote Early Detection
DO-IT	Big Data for Better Outcomes, Policy Innovation and Healthcare System Transformation
DRAGON	The RapiD and SecuRe AI enhAnced DiaGnosis, Precision Medicine and Patient EmpOwerment Centered Decision Support System for Coronavirus PaNdemics
DRIVE	Development of Robust and Innovative Vaccine Effectiveness
EHDEN	European Health Data and Evidence Network
EPND	European platform for neurodegenerative disorders
eTRANSAFE	Enhancing TRANslational SAFEty Assessment through Integrative Knowledge Management
FAIRplus	FAIRplus
GetReal Initiative	The GetReal Initiative
Gravitate- Health	Gravitate–Health: Empowering and Equipping Europeans with health information for Active Personal Health Management and Adherence to Treatment
H2O	H2O Health Outcomes Observatory
HARMONY	Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in HematologY
HARMONY PLUS	Healthcare alliance for resourceful medicines offensive against neoplasms in haematology – plus
IDEA-FAST	Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities in daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases
Inno4Vac	Innovations to accelerate vaccine development and manufacture
MELLODDY	MachinE Learning Ledger Orchestration for Drug DiscoverY
MOBILISE-D	Connecting digital mobility assessment to clinical outcomes for regulatory and clinical endorsement
NGN-PET	Modelling Neuron-Glia Networks into a drug discovery platform for Pain Efficacious Treatments
OPTIMA	Optimal treatment for patients with solid tumours in Europe through Artificial Intelligence

Table 99. List of projects selected using IMI2 Dashboard tags

Acronym	Project title
PharmaLedger	PharmaLedger
PIONEER	Prostate Cancer DlagnOsis and TreatmeNt Enhancement through the Power of Big Data in EuRope
PREFER	Patient Preferences in benefit-risk assessments during the drug life cycle
PREMIER	Prioritisation and Risk Evaluation of Medicines in the EnviRonment
RADAR-AD	Remote Assessment of Disease and Relapse – Alzheimer's Disease
RADAR-CNS	Remote Assessment of Disease and Relapse in Central Nervous System Disorders
ROADMAP	Real world Outcomes across the AD spectrum for better care: Multimodal data Access Platform
SOPHIA	Stratification of Obesity Phenotypes to Optimize Future Therapy
Trials@Home	Trials@Home: Center of Excellence – Remote Decentralised Clinical Trials
VITAL	Vaccines and Infectious Diseases in the Ageing PopuLation
WEB-RADR 2	WEB-RADR 2

Source: Compiled by the study team.

Acronym	Project title	Keywords identified
AIMS-2-TRIALS	Autism Innovative Medicine Studies – 2 – Trials	wearable, personalised medicine, precision medicine
BEAt-DKD	Biomarker Enterprise to Attack DKD	health technology, personalised medicine, precision medicine
BIOMAP	Biomarkers in Atopic Dermatitis and Psoriasis	precision medicine
COMBINE	Collaboration for Prevention and Treatment of MDR Bacterial Infections	social media
EBODAC	Communication strategy and tools for optimizing the impact of Ebola vaccination deployment	mobile health, mobile phone, smartphone
EFOEUPATI	Ensuring the future of EUPATI beyond 2020	health technology, personalised medicine, social media
FACILITATE	FrAmework for ClInicaL trlal participants daTA reutilization for a fully Transparent and Ethical ecosystem	social media, smartphone, wearable
HIPPOCRATES	Health Initiatives in Psoriasis and PsOriatic arthritis ConsoRTium European States	precision medicine
Hypo-RESOLVE	Hypoglycaemia - REdefining SOLutions for better liVEs	smartphone
IMMUcan	Integrated IMMUnoprofiling of large adaptive CANcer patients cohorts	social media
IMPRiND	Inhibiting Misfolded protein PRopagation in Neurodegenerative Diseases	social media
INNODIA HARVEST	Translational approaches to disease modifying therapy of type 1 diabetes - HARVESTing the fruits of INNODIA	wearable technology, wearable
ImmUniverse	Better control and treatment of immune-mediated diseases by exploring the universe of microenvironment imposed tissue signatures and their correlates in liquid biopsies	precision medicine, social media
Immune-Image	Immune-Image: Specific Imaging of Immune Cell Dynamics Using Novel Tracer Strategies	social media

Table 100. Projects identified using additional keywords
Acronym	Project title	Keywords identified
MACUSTAR	Develop and validate appropriate and acceptable outcome measures in intermediate age-related macular degeneration for future interventional clinical trials	health technology
NEURONET	Efficiently Networking European Neurodegeneration Research	social media
PRISM	Psychiatric Ratings using Intermediate Stratified Markers	smartphone
PROTECT-trial	Proton versus Photon Therapy for Esophageal Cancer - a Trimodality Strategy	health technology
PrIMAVeRa	Predicting the Impact of Monoclonal Antibodies & Vaccines on Antimicrobial Resistance	social media
RAPID-COVID	Robust Automation and Point of Care IDentification of COVID	social media
RESCEU	REspiratory Syncytial virus Consortium in EUrope	health technology
RHAPSODY	Assessing risk and progression of prediabetes and type 2 diabetes to enable disease modification	precision medicine
RTCure	Rheuma Tolerance for Cure	precision medicine
ReSOLUTE	Research empowerment on solute carriers (ReSOLUTE)	social media
SCREEN4CARE	Shortening the path to rare disease diagnosis by using newborn genetic screening and digital technologies	electronic health records, social media
SISAQOL-IMI	Establishing international standards in the analysis of patient-reported outcomes and health-related quality of life data in cancer clinical trials	health technology, social media
VALUE-Dx	The value of diagnostics to combat antimicrobial resistance by optimising antibiotic use	social media
iConsensus	Integrated control and sensing platform for biopharmaceutical cultivation process high- throughput development and production	health technology

Source: Compiled by the study team.

Table 101. List of keywords identified in the R (text) analysis

Key words

Data FAIRification, Preclinical safety, Off-target pharmacology data, SEND format, Integrative data infrastructure, Computational methods, Translational safety assessment, Drug development process, Analytical technology, Real-time analysis, Process Analytical tools, Design Space, iConsensus, Data FAIRification, Preclinical safety, Off-target pharmacology data, SEND format, Integrative data infrastructure, Computational methods. Translational safety assessment, Drug development process, Analytical technology, Real-time analysis, Process Analytical tools, Design Space, iConsensus, Cultivation processes, Advanced MBR, Commercial manufacturing processes, Data-driven models, Pharmacovigilance systems, Drug safety assessment, Sustainable drug safety knowledge, Data provision, Clinical data vocabularies, Data sharing, Knowledge sustainability, Analytical tools, Quality control, Translational analysis, Multi-parametric search, Biomarkers, Query analysis, In silico models, Research reproducibility, Biobank for vaccine responses, Educational materials, Healthcare support, API integration, Data normalisation, Regulatory systems, System vaccinology, Predictive drug safety research, Biological components analysis.

Process/product development, Robustness, Innovation, Impact on society, Virtual Control Group, 3Rs principles, Model verification guidelines, Ethical use of animals, Pharmacovigilance, COVID-19 pandemic, Vaccine responses, Immunological mechanisms, Diagnosis of Coronaviruses, Disease burden in ageing adults, Hotspots of specific ID, Primary care during COVID-19, Medical data prediction. Multi-dimensional Prognostic Index, Healthcare workers' perceptions, Communication skills in vaccination, European regions, Educational framework, VITAL project, Clinical trials, Vaccine uptake, Health condition of ageing adults, NAAT diagnostic tests, Epidemiological studies, Interoperability strategy, Knowledge management, Semantic services, Study Report Data mapping rules, Pharmacological information, Sustainable drug safety platform. Disease burden evaluation, Risk profiling, Ageing adults, COVID-19 vaccination programs, Web application, Preclinical drug development, Text-mining pipeline, Ethical use of animals in research, Analytical tools for manufacturing, Knowledge Hub.

Source: Compiled by the study team.

Case Study No 3: The Contributions of EIT Health in the Fight Against Chronic and Multi-Morbid Conditions

Executive Summary

This case study reviews the contributions of EIT Health, a Knowledge and Innovation Community (KIC) within the European Institute of Innovation & Technology (EIT), in the fight against four chronic and multi-morbid conditions between 2016 and 2022. The study takes the KIC's main objective, creating positive societal impact through its healthcare interventions, as a starting point and adapts it based on its Business Plan 2021-2022 conception by addressing societally relevant diseases such as chronic and multi-morbid conditions.

The data analysis and the stakeholders interviewed demonstrated that EIT Health's interventions in the last seven years have been relevant and necessary in the European healthcare market and that these have also reported steady growth since the creation of the KIC. Similarly, the evidence showcases EIT Health as an indispensable player within the European healthcare market due to three factors: its targeted interventions at a critical stage in the development of innovations, its ability to create and foster partnerships and networks, and its support to innovation projects that otherwise could not have been realised.

The study also identifies some of the internal and external barriers that impact the release of relevant healthcare innovations into the market. Among these are the slow-paced nature of the European healthcare market, the heterogeneity of the European regulatory environment, and the complicated administration of market release processes, such as validation and reimbursement, all of which EIT Health seeks to address and streamline.

However, at the same time, other factors associated with EIT Health's interventions act as barriers to developing new innovations. The administrative burden tied to EIT Health's financial support often requires dedicated personnel, which may not be readily available. The funding and reporting calendar may be incompatible with the needs, realities and operations of a healthcare start-up, and projects may need to include industrial partners associated with EIT Health regardless of their expertise in the field or understanding of the project, which may limit opportunities to work with trusted partners, thereby impacting the capacity to bring innovations to the market. Interviewees expressed that in these terms, despite the benefits EIT Health may bring to the Table, EIT Health support does not always compare to support obtained from other sources.

EIT Health could take several actions to reduce the administrative burden for participating organisations, provide greater flexibility in their budgeting and reporting calendars to better fit the needs of participating organisations, and provide better accompaniment to beneficiaries in their integration into the healthcare market.

Similarly, the study found that there exists great potential to harness EIT Health's strengths with other programmes within Horizon Europe. However, due to external factors, such as a lack of knowledge of each programme's scope and limitations, this potential is not used to the extent it could be. The risk of double reporting that is exacerbated by a lack of harmonisation among other parts of the programme also contributes to challenges in seeking synergies with other parts of Horizon Europe. However, the study also found that, for innovation projects, national and regional funding sources were sufficient to realise their projects and that there is a need to strengthen the KIC's communication and dissemination activities within its own partners.

Overall, the study demonstrates that EIT Health has been relevant and successful in the delivery of technologies in the fight against chronic conditions, albeit in a rather limited fashion, since its effectiveness is highly reliant on the product or innovation supported.

Introduction

Purpose of the case study

Considering that EIT Health has become a relevant actor in the European healthcare market and that, through its activities, it has the objective to improve the European healthcare system; the present case study focuses on addressing EIT Health's interventions in the fight against chronic and multi-morbid diseases through its entrepreneurship, and innovation and research activities, particularly, how impactful, and successful such interventions have been to counter these conditions. This is the understanding that chronic conditions represent a crucial area of healthcare that will become more fundamental as the population ages.

Scope of the case study

Considering that EIT Health was established in 2015 and had its first full operational year in 2016, the study focuses on activities conducted between 2016 and 2022. The study will focus on answering questions about EIT Health's relevance, coherence, effectiveness, and EU

Added Value by analysing the impacts of its support activities involved in the fight against specific and societally relevant diseases, namely, cancer, diabetes, Alzheimer's disease, and circulatory and cerebrovascular conditions. Such activities will include EIT Health's entrepreneurship and innovation portfolio interventions. It is important to notice that while EIT Health has other relevant intervention pathways that could play into this objective, its education and management activities' contributions are rather indirect compared to the targeted support that its entrepreneurship and innovation activities provide to European healthcare start-ups. Therefore, this case study will focus exclusively on the direct effects observed from its entrepreneurship and innovation activities.

Similarly, it is important to note that the study is rooted in EIT Health's explicit objectives until 2022, given that, since 2023, it has re-assessed its objectives and priority areas and regrouped them into 'Flagship' areas¹⁹². While this re-assessment still addresses chronic conditions, it does so more indirectly with measurements related to the quality of life. In this respect, the study will focus primarily on EIT Health's explicit objectives to address chronic conditions, as found in its 2021-2022 Business Plan¹⁹³.

Methodological approach

To assess EIT Health's impact in the fight against chronic and multi-morbid diseases, the study identified four of the leading conditions associated with a relatively high mortality rate in the EU and compared them with the conditions and diseases supported by EIT Health through its support activities. The conditions were identified by comparing different data sources on leading causes of death, such as reports from Eurostat¹⁹⁴ and the Organization for Economic Co-Operation and Development (OECD)¹⁹⁵, then cross-comparing these datasets with EIT Health Grant Assessment and Dealroom data. In the case of the latter, the study focused on those datasets relevant to its purposes, such as the type and number of innovation projects supported, the average investment raised by companies targeting chronic conditions, and the allocation of budget shares into condition-specific innovation projects.

Considering that COVID and other infectious diseases took a predominant role in the European healthcare sector as part of the aftermath of the COVID-19 pandemic, and considering that infectious diseases, due to their nature, tend to target the general population, rather than people at most risk, the study team excluded such conditions from the study to favour chronic and multi-morbid diseases and narrowed the selection down to four conditions: cancer, diabetes, neurodegenerative diseases, and circulatory and cerebrovascular conditions. In the case of the latter, considering that circulatory diseases and cerebrovascular accidents (the two leading causes of death in Europe, next to cancer, according to the OECD¹⁹⁶) can be caused by a diverse set of conditions, the study considered those EIT Health's interventions specifically targeted at preventing or diagnosing these wider categories, thus including all activities involved in this objective. In the case of diabetes, it is important to notice that, while this disease does not represent one of the leading causes of

- 193 EIT Health, "Business Plan 2021-2022: Summary of Planned 2021-2022 Activities and Projects" (EIT Health, 2021), 4.
- 194 Eurostat, "Major Causes of Death in the EU in 2020," March 2023, https://ec.europa.eu/eurostat/statistics-

¹⁹² EIT Health, "Business Plan 2023-2025: Summary of Planned 2023-2025 Activities and Projects" (EIT Health, 2023), 5–7, https://eithealth.eu/wp-content/uploads/2023/07/EIT-Health_Business-Plan_2023-2025.pdf.

explained/index.php?title=Causes_of_death_statistics. [Accessed on 15.06.2023]

¹⁹⁵ OECD and European Union, Health at a Glance: Europe 2022: State of Health in the EU Cycle, Health at a Glance: Europe (OECD, 2022), https://doi.org/10.1787/507433b0-en.

¹⁹⁶ OECD, Health at a Glance 2021: OECD Indicators, Health at a Glance (OECD, 2021), https://doi.org/10.1787/ae3016b9-en.

death in Europe, it is included in the study given its high level of comorbidity with the other conditions and its potential to become an aggravating factor to such.

The methodological approach to assess the four evaluation criteria (relevance, coherence, effectiveness, and EU Added Value) was composed by the following methods:

- Desk research: Conducted on the documents relevant to this case study, such as EIT Health's 2021-2022 and 2023-2025 Business Plans, previous evaluations conducted on EIT Health, such as the 7-Year Review of 2nd Wave KICs: EIT Health¹⁹⁷, and existing reports on the KIC's activities;
- Analysis of administrative and monitoring data: A topic classification was conducted on Dealroom and grant assessment data, particularly on the typology of innovation projects/business supported, the share of investment distributed to projects/companies dealing with chronic conditions, and the share of innovation projects supported by the KIC;
- Interview programme: after conducting desk research, a random sample of eight innovation projects supported by EIT Health (two per condition) was selected, whose leaders were invited to participate in the interview, and out of which seven interviews were successfully conducted. In addition to this, the study also conducted two interviews with EIT Health staff directly overseeing research and innovation projects. Further details regarding the interview schedule can be found under Appendix 1.

To assess **relevance**, the following criteria were evaluated:

- The extent to which the activities are deemed relevant to market and policy needs;
- Appropriateness of targeted chronic conditions by EIT Health when compared to societal challenges;
- Rationale and theory of change behind the selection of relevant chronic conditions;
- Existence of relevant consultation processes to ensure the adequacy of interventions
- Barriers, opportunities, and gaps filled by EIT Health's interventions.

Additionally, the following criteria were used to evaluate effectiveness:

- Cumulative investment raised by start-ups per type of condition;
- Number and share of innovation projects supported targeting chronic and multimorbid conditions;
- Share of innovation budget targeted at chronic conditions;
- The number of companies supported per type of chronic conditions;
- Investment attracted by companies targeting each type of chronic condition;
- Satisfaction of supported companies/projects with EIT Health's interventions.

¹⁹⁷ Deloitte. 7-Year Review of 2nd Wave of KICs: EIT Health. Final Report. March 2022. https://eit.europa.eu/library/7-year-review-2nd-wave-kics-eit-health-final-report

Similarly, the study assessed the extent to which EIT Health's interventions in the fight against these conditions provide **EU Added Value** compared to other funding sources at national, regional and EU levels.

Context and background

EIT Health is a Knowledge and Innovation Community (KIC) within the European Institute of Innovation and Technology (EIT) structure, a European Union body created to find and foster solutions to global challenges. The EIT is integral to the European Union's Framework Programme for Research and Innovation.

KICs are fundamental within the EIT structure since they enable co-operation between businesses, research centres, and higher education institutions into partnerships and projects that allow the development of new innovations, the acceleration of innovative ideas, and the creation of new agents of change. Like many KICs, EIT Health integrates research and technology, education, and business creation and support to achieve innovations in the healthcare market, an approach generally known as the 'Knowledge Triangle'. In this respect, the knowledge triangle integrates educators, researchers, entrepreneurs, innovators, investors and experts through various interventions to create new services and products that provide added value to Europe's population.

On this subject, the European population is currently experiencing a demographic shift. While there is a downward trend in population growth (heading to a population decline), the existing European population seems to be experiencing significant ageing. As of 2021, people aged 65 and above represented 20.8% of the European population, a percentage that is expected to increase to around 30% by 2050.¹⁹⁸ This population shift represents an appearance of several challenges for future European societies since an older population is often linked with increased fiscal sustainability risk, given that older citizens require better access to healthcare and healthcare infrastructure.¹⁹⁹

Given the challenges an ageing population poses, healthcare professionals and policymakers have been aware of the stakes required to make the healthcare sector more resilient to these challenges. In this respect, it is clear that a shift to a more preventive healthcare model represents a more sensible strategy for the long-term survival of both healthcare and the economy.²⁰⁰ However, such a shift on a larger scale still represents a tangible challenge for many European countries²⁰¹.

Within this wider context and following its own strategic goals to ensure societal challenge through its interventions, EIT Health has updated and reviewed its portfolio to contribute positively and help realise this shift faster and more efficiently. In its strategic documents, EIT Heath has included the support for chronic and multi-morbid conditions in its strategic objectives, aiming to involve 12,800 people directly in the pursuit of solutions to these

¹⁹⁸ European Commission, "The Impact of Demographic Change in a Changing Environment," January 2023, 11, https://commission.europa.eu/system/files/2023-01/Demography_report_2022_0.pdf.

¹⁹⁹ European Commission, 12.

²⁰⁰ Fuhmei Wang and Jung-Der Wang, "Investing Preventive Care and Economic Development in Ageing Societies: Empirical Evidences from OECD Countries," Health Economics Review 11, no. 1 (December 2021): 18, https://doi.org/10.1186/s13561-021-00321-3.

²⁰¹ European Commission, 2022. Knowledge for Policy: Shifting Health Challenges. https://knowledge4policy.ec.europa.eu/shiftinghealth-challenges_en [Accesed on 19.07.2023]

diseases and benefit 80,000 people by 2022.²⁰² Additionally, the KIC aims to impact the health of at least 150,000 European citizens and/or patients three years after the completion of each innovation project in any track.²⁰³

Outcomes/results

Chronic and multi-morbid conditions

Based on the EIT Health start-up database, out of the 1 147 companies that EIT Health has supported throughout its lifespan, 356 (31%) specifically targeted cancer, neurodegenerative diseases, cardiovascular and cerebrovascular conditions or diabetes. Out of these, companies related to the fight against cancer (12.1%) and cardiovascular and cerebrovascular conditions (11.5%) were the most commonly supported by EIT Health's entrepreneurship activities.

²⁰² EIT Health, "Business Plan 2021-2022: Summary of Planned 2021-2022 Activities and Projects," 4.

²⁰³ EIT Health, "Business Plan 2023-2025: Summary of Planned 2023-2025 Activities and Projects." [Accessed on 17.07.2023]

Table 102. Number of companies and share of budget dedicated to the fight against cancer, diabetes, neurodegenerative and cardiovascular conditions

	Cancer	Neurodegenerative diseases	Cardiovascular and cerebrovascular conditions	Diabetes	Total
Number of companies	139	32	132	53	356
% share out of the total number of companies (n=1 147)	12.1	2.8	11.5	4.6	31.0
Investments attracted (EUR million)	810.4	78.3	639.4	292.0	1 820.0
Average investment attracted per company (EUR million)	5.8	2.4	4.8	5.5	5.1

Source: EIT Health Start-up database. https://startups.eithealth.eu/dashboard.

Similarly, looking at the investment raised by companies, cancer and cardiovascular diseases remained the two most supported diseases. However, when looking at the average investment per company, diabetes and cancer slightly take the lead over cardiovascular diseases. An important aspect to notice is the relatively low number of companies related to neurodegenerative diseases supported by EIT Health and the relatively low investment these companies attracted. A potential reason for this is the relatively higher difficulties reported by interviewees working on projects related to this disease regarding technical expertise and regulatory requirements, which showed that this field is particularly difficult to take the leap from academia into business creation.



Figure 75. Cumulative investments based on total investment during the last funding round, 2018-2022 (EUR million)

Source: EIT Health Dealroom data 2016-2023. Years 2016-2017 were omitted as figures were less than 0.2 million.

Looking at the total cumulative investments attracted by companies supported by EIT Health, we can observe that, besides year-to-year fluctuations, the investment raised by companies targeting chronic conditions has a continuous upward trend. This is particularly true for cancer, diabetes and cardiovascular conditions-related businesses, whose investments at least doubled between 2021 and 2022. A similar trend, albeit much less pronounced, can be observed with businesses targeting neurodegenerative conditions.

Year	Total number of innovation projects	Cancer (n &% out of total number of innovation projects)	Neurodegenerative diseases (n &% out of total number of innovation projects)	Cardiovascular and cerebrovascular conditions (n &% out of total number of innovation projects)	Diabetes (n &% out of total number of innovation projects)	Total (n &% out of total number of innovation projects)
2016	23	4 (17%)	3 (13%)	5 (22%)	6 (26%)	18 (78%)
2017	31	5 (16%)	4 (13%)	6 (19%)	6 (19%)	21 (68%)
2018	43	5 (12%)	5 (12%)	12 (28%)	10 (23%)	32 (74%)
2019	66	5 (8%)	3 (5%)	14 (21%)	6 (9%)	28 (42%)
2020	91	12 (13%)	2 (2%)	17 (19%)	9 (10%)	40 (44%)
2021	35	2 (6%)	1 (3%)	7 (20%)	4 (11%)	14 (40%)
2022	16	1 (6%)	1 (6%)	5 (31%)	2 (13%)	9 (56%)
Total	305	34 (11%)	19 (6%)	66 (22%)	43 (14%)	162 (53%)

Table 103. Number and share of innovation projects supported by EIT Health per type of chronic condition

Source: EIT Health Grant Assessment data 2016-2022.

Looking at the innovation projects, out of the 305 projects supported between 2016 and 2022, 162 (53%) have targeted chronic conditions. Out of these, diabetes (14%) and cardiovascular conditions (22%) have received the most support, followed by cancer (11%) and neurodegenerative diseases (6%). A noteworthy fluctuation can be observed: while chronic conditions represented ca. 70% of the innovation projects supported until 2018, the share decreased to around 50% in the subsequent years. While this can be partially explained by an overall decrease in the number of innovation projects supported, there has still been a sharp decrease in supporting projects targeting cancer, particularly between 2021 and 2022.

However, looking at budget data, we can note that, in general, out of the EUR 216.7 million budgeted for innovation activities in 2016-2022, 60.7% have been dedicated to targeting either cancer, neurodegenerative diseases or conditions, cardiovascular and cerebrovascular conditions and diabetes. This suggests that the focus of EIT Health's interventions has been rather targeted and limited to highly promising innovations, where a relatively higher proportion of the budget can be allocated and yield better results. This was further confirmed by interview evidence: around 2/3 of the total grants distributed between 2016 and 2022 concentrated in 5 areas: Infectious diseases, oncology, neurology (mainly strokes), metabolic disorders (mainly diabetes), and disease-agnostic (mainly Clinical Decision Support Systems [CDSS]). In this respect, most of the budget allocated for infectious diseases was dedicated to an extraordinary COVID-related call, while those targeting CDSS could often be used to diagnose several different diseases.





Source: EIT Health Grant Assessment data 2016-2022.

Considering these points, the data suggests that, while the share of the budget targeting specific conditions has reduced over the years, the overall efforts of EIT Health contributing to the fight against chronic conditions have remained a high priority.

Reflections on evaluation criteria

Relevance

Study findings reveal that EIT Health's efforts in the fight against chronic and multi-morbid conditions are **relevant to the societal challenges addressed under Horizon Europe**, especially those aimed at Pillar 3 and those included in Horizon Europe's Cancer Mission.

Interviews with EIT Health staff and leaders of projects under Horizon Europe's Innovation portfolio demonstrate that the KIC is constantly involved in the process of revising its own strategic goals and finding areas where its interventions have the most potential to create meaningful impact and that these interventions are adequate in the overall fight against chronic diseases. Here, interview evidence revealed the reasoning behind this approach: given that around 20% of the population uses around 80% of the available healthcare resources (a percentage set to increase with an ageing population), **providing targeted support**, especially for secondary prevention, **proved more effective** than a 'top of the pyramid' approach, which requires a lot of resources and expertise and has relatively less potential to create meaningful impact. At the same time, citizens and patients seek solutions for multi-morbid and chronic conditions. Over 25% of EIT Health-supported start-ups and scale-ups indicated that citizens and patients seeking solutions for multi-morbid and chronic conditions.

As evidence of the adequacy of EIT Health's activities, **most interviewed project leaders considered that they fill a gap in the European healthcare market by supporting** both start-ups and promising innovation projects at a stage that investors often overlook. They cited several reasons behind this, such as the nature of the healthcare sector, the relative underdevelopment of healthcare innovation in Europe compared to other developed nations, and the difficulties in translating breakthrough research into marketable healthcare innovations.

Interviewees deemed the transition from academia to the market as a particularly important gap addressed by EIT Health's interventions, especially given that, due to the relatively high risk that healthcare innovations pose, investors prefer to fund innovations that are either at a very advanced stage of development or are being developed under bigger companies or consortia that are better fit to bear the risks. Therefore, due to this lack of willingness to fund and help develop promising innovation ideas, EIT Health's connectivity between academia and business creates an ideal scenario for promising research projects that want to break it in the European healthcare market. This represented a relevant approach to innovations fighting chronic and multi-morbid conditions, especially those that require a relatively high investment to come into reality, such as cancer and neurodegenerative diseases.

However, evidence from interviews also suggests that the adequacy of these interventions wanes progressively as innovations mature in their development process and can also vary depending on the field it is applied. For example, innovation leaders on neurodegenerative

²⁰⁴ Deloitte. 7-Year Review of 2nd Wave of KICs: EIT Health. Final Report. March 2022. https://eit.europa.eu/library/7-year-review-2nd-wave-kics-eit-health-final-report

diseases expressed a need to include more guidance specific to foster innovation within their field, particularly, to navigate the more complex regulatory environment applied to their specific healthcare field. Similarly, project leaders in the field of cancer considered that EIT Health, by supporting the development of a product involved in the diagnosis of the disease, indirectly provided a wider benefit in the fight against cancer. However, they also encountered similar obstacles within the European regulatory environment.

To identify its areas of intervention, EIT Health follows a forward-thinking logic to identify which areas of healthcare it has the chance to achieve better impact through its support activities. On the one hand, it seeks areas where innovation is needed, which, considering the demand in the healthcare sector, tends to favour chronic conditions over other better-researched areas, such as infectious diseases. On the other hand, it seeks innovations and projects whose potential to be introduced to the market are the most promising. As a result, in the last five years, EIT Health has directed its efforts towards favouring innovation projects in a select number of conditions almost identical to this study's: oncology, neurology (mainly strokes), metabolic disorders, and infectious diseases. However, its support towards infectious diseases should be regarded considering the COVID-19 pandemic.

However, it is important to notice one aspect of EIT Health's support activities: their focus on innovations that are disease agnostic or that work for Clinical Decision Support Systems (CDSS) since they contribute towards improving the diagnostic capacities of healthcare providers, and thus, to the early prevention of other chronic and multi-morbid conditions. While indirect, this last aspect is especially important to the fight against chronic and multi-morbid conditions since it enables earlier and more effective detection and a better understanding of under-researched conditions and comorbidities. Interviews with project leaders confirmed the efficacy of this approach since those projects that were more relevant to support CDSS proved to have a significantly higher potential for impact than those related to later stages of a disease, such as treatment and therapy.

Coherence

Study findings show that EIT Health's interventions are **highly coherent with other European Union funding schemes** and moderately coherent with national and regional investment funds, particularly when assisting in the overall fight against chronic and multi-morbid conditions.

The coherence of EIT Health lies in its high capacity to generate synergies with other European Union funding schemes, such as the EIC, EIF, and the Partnership for Personalised Medicine, all of which EIT Health currently has partnerships. However, while these synergies are possible to achieve, interviews with EIT Health staff have demonstrated that there is a **need to ease the communication** between the different programmes under the Pillars of Horizon Europe, to raise awareness on how each funding programme works, what limits between them exist, and how they can foster, create, and enhance co-operation among them to create better synergies. Similarly, interviewees identified other areas hindering synergies, such as the **risk of creating double reporting** for both participants and EU staff, as crucial to prevent the appearance of more synergies among EU funding schemes.

In contrast, while participating organisations and projects did not have the support of other EU funding schemes during their participation with EIT Health, the nature of their projects and organisations allowed for a **high level of coherence** between other related projects and theirs, which resulted in continued support to other projects related to the fight against the specific chronic disease they address. This proved particularly useful for the development of innovations in specific fields where targeted research could yield positive results with

relatively low investments. Examples of such were found in the fields of radiotherapy, early detection of metabolic diseases, such as diabetes, and cardiovascular health. In such instances, the leaders of the relevant innovation projects mentioned how EIT Health's support created pathways that could be complemented with national or EU funding at later stages and how this additional funding was useful for the further development of innovations in their field of research.

However, while projects directed by project leaders were highly coherent with other existing EU funding sources, a menial number of interviewed participants and leaders of innovation projects knew about the other intervention pathways available through EIT Health. While, in some cases, this lack of knowledge was related to the organisation not fitting the requirements to participate in other interventions (like being too big to be considered a start-up), in some other cases, there was little accompanying provided to transition to other potential interventions that could result in the creation of start-ups or spin-offs. Similarly, interviewees showed little knowledge about other projects or ventures supported by EIT Health that could be relevant or useful within their medical field. While, in some cases, project leaders were indeed invited to further projects related to the fight against the disease they addressed, knowledge of other complementary projects was limited to these instances. This showed room for improvement in how EIT Health communicates and networks relevant actors in one medical field in the fight against chronic and multi-morbid conditions.

Effectiveness

Evidence from the study has shown that **EIT Health is effective in tackling chronic and multi-morbid conditions** through its targeted support for promising innovations in the healthcare market, particularly in the fields of cancer, diabetes, neurodegenerative and circulatory diseases. As noted by a previous evaluation, EIT Health has constantly followed and responded to emerging societal challenges and paid attention to the areas of unmet needs, including chronic diseases, with 35% of EIT Health-supported start-ups and scale-ups reporting that their activities have been either extremely or very impactful in treating and managing chronic diseases²⁰⁵.

Interviews with innovation project leaders demonstrated that the support provided by EIT Health is effective, not only in the realisation of individual projects but also in **fostering positive contributions to the overall fight against specific chronic conditions**. An example of this was observed in projects related to diabetes, where the targeted interventions of EIT Health, while minimal in terms of financial investment, proved to have a significant effect in the overall fight against the disease given that the field and scope of their application proved to create a high positive impact. This was evidenced by the D4Kids²⁰⁶ and D4Teens²⁰⁷ projects, which develop artificial pancreas for children and teenagers with Type 1 diabetes, respectively, seeking to provide children and teenagers with the benefits of the Diabeloop artificial pancreas²⁰⁸. As noted in interviews, this approach will provide considerable long-term impact as the project's results will support patients throughout their lifetime. Another project raised in interviews, DeTecT2D, will develop a precise means to detect pre-diabetes

²⁰⁵ Deloitte. 7-Year Review of 2nd Wave of KICs: EIT Health. Final Report. March 2022. https://eit.europa.eu/library/7-year-review-2nd-wave-kics-eit-health-final-report

²⁰⁶ See also: EIT Health: D4Kids. https://eithealth.eu/product-service/d4kids/

²⁰⁷ See also: EIT Health: D4Teens. https://eithealth.eu/product-service/d4teens/

²⁰⁸ See also: EIT Health. EIT Health-supported Diabeloop raises €70 million. https://eithealth.eu/news-article/eit-health-supporteddiabeloop-raises-e70m/

and undiagnosed cases of type 2 diabetes, thereby contributing to both preventing and treating the condition²⁰⁹.

The stage in which innovation projects were supported, together with EIT Health's hypertargeted approach to their interventions, were mentioned as the main enabling factors that allowed to advance the creation of successful healthcare innovations in their respective medical fields. However, some obstacles were also identified, such as the nature of the healthcare market and the regulatory heterogeneity of the European healthcare sector.

In this respect, validation, reimbursement, and certification processes, all integral parts of the market release process, were considered specifically challenging for most interview respondents, who clearly identified these as the main obstacles in the market release process of their innovations. Here, EIT Health has been aware of the difficulties and needs of European innovation projects in these regards and has tried to provide the necessary support to address them. Examples of this are its efforts to harmonise validation processes throughout the EU, promote the adoption of 'fast-track' procedures to reimbursement, and ease European start-ups' access to notified certifying bodies. However, the evidence showed that the effectiveness of such support was highly reliant on several external factors, such as the field where the technology is (set to be) applied, the countries where validation, reimbursement, and certification processes were conducted, the adequacy of industrial partners, and the complexity of the disease the innovation is aiming to address.

Yet, interview respondents also identified several areas of opportunity within EIT Health's support that could have played against the success of their innovation projects, such as a **copious administrative burden** tied to its financial support, which often required personnel specifically dedicated to it; the **incompatibility of the funding (and reporting) calendar** to the needs, realities, and operations of a healthcare start-up, or the **need to include industrial partners associated with EIT Health** regardless of their expertise in the field or understanding of the project. This last aspect proved particularly challenging to some respondents, who expressed that the requirement to partner up only with EIT Health associates hindered their ability to work with trusted and reliable partners, ultimately influencing their ability to bring their innovative products into the market.

In this respect, when comparing EIT Health's support to other funding sources, both national and at the EU level, respondents agreed on the fact that the support provided by EIT Health often could not compare with the support obtained through these other sources, especially in the terms mentioned above, but also regarding the clarity in the communication line of command. This significantly hindered the value added by the KIC to their activities since many respondents considered the administrative costs of the participation in EIT Health's Innovation portfolio incompatible with the benefits it yielded.

Despite this, EIT Heath's support was deemed overall effective in realising the individual project's goals at an appropriate time, even when the level of satisfaction of project leaders varied between these instances.

EU Added Value

In terms of added value, the evidence showed that EIT Health's main sources of added value come from its **ability to create partnerships and foster collaboration** among several, often disconnected, areas within the healthcare sector. This provided good added value to

²⁰⁹ See also: EIT Health: DeTecT2D. https://eithealth.eu/product-service/detect2d/

innovation projects tackling chronic diseases, particularly those that did not come with solid guidance to translate academic projects into marketable solutions.

A good example of such added value was the projects related to diabetes. Here, interview respondents indicated that EIT Health's capacity to create collaboration networks was particularly important for realising their innovation projects and other related ones in the same field. According to respondents, **the combination of targeted support and network access was especially valuable** since it enabled collaboration between experts on similar topics. This experience was shared with respondents working on projects tackling other diseases, such as neurodegenerative and cardiovascular ones.

Conclusions

EIT Health's interventions in the last seven years have been relevant and necessary in the European healthcare market, and these have also reported steady growth since the creation of the KIC. Similarly, the evidence showcases EIT Health as an indispensable player within the European healthcare market due to three factors: its targeted interventions at a critical stage in the development of innovations, its ability to create and foster partnerships and networks, and its support to innovation projects that otherwise could not have been realised. Overall, the study demonstrates that EIT Health has been relevant and successful in the delivery of technologies in the fight against chronic conditions, albeit in a rather limited fashion, since its effectiveness is highly reliant on the product or innovation supported.

Lessons learned and suggestions for improvement:

- EIT Health's entrepreneurship and innovation & research activities are relevant and adequate in supporting the development of innovations that address chronic and multi-morbid conditions, particularly within the fields of oncology, cardiology, neurology, and metabolic diseases (all the fields chosen by this case study);
- The rationale behind EIT Health's focus on chronic and multi-morbid conditions is relevant and effective in the support of chronic diseases. The KICs focus on supporting projects dealing with specific chronic conditions, but especially those dealing with CDSS, which show a particularly high potential to generate meaningful impact in the fight against specific diseases, such as cancer and diabetes;
- While the effectiveness of EIT Health's support varies according to several external factors, such as the medical field where the innovation is developed, there are several actions that the KIC could take to improve the effectiveness and attractiveness of their support, such as 1) reducing the administrative burden for participating organisations (as the administration often requires dedicated personnel) or 3) providing better accompanying to beneficiaries in their integration to the healthcare market (especially as relates to bringing in industrial partners as often there is a need to include industrial partners associated with EIT Health regardless of their expertise in the field or understanding of the project);
- A clear need to streamline administrative processes was identified. Particularly, to reduce the frequency of reporting periods, to improve the digital system responsible for reporting, and to create a clear line of communication between beneficiary organisations and EIT Health staff;
- EIT Health's activities work in synergy with other national and European funding
 programmes to assist in the overall fight against diabetes, cancer,
 neurodegenerative and cardiovascular diseases, albeit rather indirectly. To improve
 this synergic functioning, interviewees identified a clear need to map out the
 competencies and scope of other funding programmes, as well as to harmonise
 reporting rules across programmes within Horizon Europe;

- A negligible number of supported organisations were aware of the other intervention pathways supported by EIT Health. This demonstrated a need to improve the efficiency of the communication regarding navigating other potential interventions and narrow the gap between academic and business-creation activities;
- Similarly, the leaders of innovation projects were unaware of other promising innovation projects currently and/or previously supported by EIT Health within their fields of expertise. Providing better communication about EIT-supported novelties in their medical field could be an area of opportunity to facilitate the creation of networks for future work.

Appendix 1: Interview questionnaire

A different interview questionnaire was conducted both for project leaders and EIT Health staff, whose questions are detailed in the Table.

Table 104. Interview Questions

General Questions				
Could you give a detailed explanation of your project/intervention, its scope, main activities, objectives, and main approach for their implementation?				
What have been the main enabling factors and obstacles throughout the implementation of your project/support? Why and how have those factors affected implementation?				
Specific Questions				
	Innovation Project Leaders	EIT Health Staff		
Effectiveness/Relevance	How has EIT Health's supported your project? Has it been effective and adequate to its needs? Why/Why not?	Which aspects of EIT Health's support would you rank as most valuable in the fight against chronic conditions?		
	Do you think EIT Health's support failed to address specific aspects of your project? If so, which ones?	How does EIT Health identify societal challenges and how they change over time in the fight against chronic conditions?		
	Are there specific aspects of EIT Health's support that you think need some improvement? If so, which ones?	What processes does EIT Health have to ensure its strategic documents and its support activities are up to date and fit to cater to market and policy needs?		
	Was EIT Health's support clear in its scope, extent, requirements, and expectations concerning your project?	Can you envision any setbacks or obstacles to realise your support on the side of the supported organisations?		
	Has communication between EIT Health and your organisation been effective in transmitting updates, concerns, and other types of feedback?	Has communication between EIT Health and the different project teams/organisations been effective in transmitting updates, concerns, and other types of feedback?		
	Would you cooperate with EIT Health in future projects related to your current one? If so, why?	How do you think EIT Health's support impacts the efforts to fight against (chronic disease)?		
	How do you think EIT Health's support impacts the efforts to fight against cancer/alzheimer's/cardiovascular	What is the rationale for targeting chronic and multi-morbid conditions specifically?		

diseases/diabetes and other neurological

	diseases? Do you consider this support adequate to contribute towards this goal?	
		What role does EIT Health aim to play in the fight against chronic and multi-morbid conditions?
		Are there any chronic conditions regarded as more urgent than others by EIT Health? If so, which ones?
		Could you give a detailed account of EIT Health's support to address the fight of chronic and multi-morbid diseases?
		What are the main challenges you observe while providing support specifically in the fight against chronic and multi-morbid diseases?
Coherence	Does your project count with other national/regional/EU-level funding sources? If so, which ones?	Are there any national/regional/EU-level funding schemes envisioned to be complimentary to EIT Health's support? If so, which ones?
	How easy/difficult has it been for your project to navigate EIT Health's support/interventions other than this one?	
Added Value	To what extent has EIT Health's funding been effective to carry out your project? Why?	What do you consider are the main advantages of counting with EIT Health's support in comparison to other EU funding programmes (both national and regional)?
	What is the added value EIT Health provides compared to other funding programmes?	How has the feedback been between EIT Health and its supported organisations?
	Does it compare to other national sources of funding? To European ones? What makes it different from those?	How crucial would you consider EIT Health's support is in the development of innovations that contribute to the fight of (chronic condition)?
	Would you consider EIT Health's support necessary for realising projects similar to yours? In which ways?	
Directionality		How would you assess EIT Health's progress in the fight against chronic and multi-morbid diseases?
Transparency & Openness:	How open do you regard EIT Health's support to new participants?	Which processess/guidelines does EIT Health follow to involve new partners in its R&I activities targetting chronic and multi- morbid diseases?
	How open would you rate consultation processes with EIT Health and other stakeholders involved in your project? Would you consider all relevant stakeholders are openly and properly consulted at every state of EIT Health's support?	How open are, in average, research results produced by partner organisations? How does EIT Health promote Open Science practices with their partners?

How open would you consider your research results to be to the public? Have other research results relevant to your project been accessible to you? Would you consider your intervention has an impact on patients' and citizens' engagement in EIT Health processes? If so, how?

How does EIT Health ensure the participation of competent and relevant authors in the fight against chronic diseases?

Source: Compiled by the study team.

Case Study No 4: Contribution of EIT Health towards supporting the Venture Centre of Excellence (VCoE) and WorkInHealth Foundation

Executive Summary

Additionality

This case study is dedicated to analysing the operational logic and effectiveness of the Venture Centre of Excellence (VCoE) and WorkInHealth Foundation. Specifically, it asks questions on how each organisation attracts funding to generate returns on investment, how they contribute to the longevity, self-sufficiency and sustainability of EIT Health, and what the conditions are for each programme to initiate and operate within EIT Health.

The VCoE is studied in its ability to successfully operate its concrete methods, which include increasing its investment capabilities by mobilising diverse resources through the SDUF Health Compartment. This flexible financial vehicle is supported by the European Commission as an anchor investor and is operated by the EIF. VCoE also operates a custom-built AI engine that facilitates scouting, sourcing, and syndication of co-investment scenarios by program members based on customised, confidential parameters. They are increasingly focused, motivated networking and community-building between different investor groups of focus: EIT Health-linked Corporate / Academic / Tech Transfer / Industrial / Insurance partners and EIF-linked selected Venture Capital firms. These firms include first-time, emerging, and established Life Sciences-dedicated fund managers across Europe.

From its 2021 inception onward, the VCoE has been quite successful in meeting its financial goals, even meeting its initial goal of achieving the ability to leverage EUR 2 billion in investment capabilities by January 2023. On top of two meetings of the VCoE member community (allowing new members to be introduced, insights to be shared by both EIT Health and EIF, and concretely anchoring trust and exchange at the heart of the group), VCoE met many stated Key Performance Indicators (KPIs) over the course of 2021 and 2022. In addition, ten new members, corporations, and VCs were onboarded and trained using the Skopai AI system throughout 2022, adding to the existing pool of private funding to be connected to investment opportunities.

The EIT Health WorkInHealth programme is an effort to address the glaring and widening talent and skill gaps in the European healthcare sector. In order to increase the sector's appeal to fresh talent and promote its transformation, the initiative aims to draw in, keep, and train talent in the field of healthcare innovation. The WorkInHealth Foundation intends to focus on four key areas of activity: Promotion of the healthcare industry to a diverse pool of talent; Matching of talent and employers using cutting-edge technology; Futureproofing by employing intelligence and analytics to anticipate the need for skills; Building a bridge between academia and industry through training. EIT Health is looking for collaborators to join a European Coalition that pursues these objectives. The WorkInHealth Online Career

Fair is one of the events organised by EIT Health to showcase open positions in health startups and companies, creating a connection between offer and demand.

The goals of WorkInHealth primarily focus on improving the skills and talent of healthcare workers in Europe. Besides its four focus areas, it also organises events to connect health start-ups and companies with potential employees, which it has found success in. However, the organisation has struggled to attain financial independence. WorkInHealth staff interviewed during the duration of the case study mentioned several possible factors in this area. For example, the organisation struggles to source external funding to drive the physical networking spaces that it uses to match health talent and healthcare firms. Given that this network is their ultimate goal, interviewees communicated a struggle to identify places where their actions result in direct benefits to citizens or patients in reports to EIT Health, which is exacerbated by the lack of appropriate KPIs at EIT Health to measure their success. Additionally, WorkInHealth experienced some growing pains in their ability to adapt to differences in national healthcare systems, though interviewees indicated that these problems are becoming less prevalent as the organisation progresses. Despite these challenges, WorkInHealth believes that it can become financially independent in the long run by developing new technology and building trust with stakeholders - though interviewees were unsure if this could be achieved in the initial timeline.

Introduction

Purpose of the case study

This case study investigates the operational logic and externalities contributed to the EIT Health ecosystem by the Venture Centre of Excellence (VCoE) and the WorkInHealth Foundation. The study asks questions such as how each organisation contributes to the longevity and sustainability of EIT Health and who the related stakeholders are, as well as what the conditions are that allow for these programs to initiate and operate within EIT Health.

Scope of the case study

The case study begins with the inception of VCoE in 2020²¹⁰ and the WorkInHealth Foundation in 2020. The case study covers the to-date lifespan of both programmes as related to the broader EIT Health ecosystem, analysing the operational logic and externalities contributed to the EIT Health ecosystem by VCoE and the WorkInHealth Foundation. Additionally, this case study aims to understand how both organisations aim to establish Europe as a leader in fostering innovation, asking how each organisation contributes to the longevity and sustainability of EIT Health, who the relevant stakeholders are, and what the conditions are that allow for these programs to initiate and operate within EIT Health. **Given the VCoE collaboration in financing the HERA Initiatives that bolstered the EU's response to the COVID-19 pandemic in just their first two years, the organisation quickly found success in the capital allocation and management advisory space**.

Specifically, the case study attempts to answer the following evaluation questions: **PSC1**: How much private and/or public R&I contributions has been mobilised on EU priorities thanks to partnerships? **PSC1.1**: What is the partnerships' budget leverage factor, in mobilising additional resources, on top of contribution from partners? **EAV2**: What is the value resulting from partnerships in this area that is additional to the (i.e., EIT Health) out at regional or

²¹⁰ The VCoE inception was in 2019 but only commenced operations in Q1 2020.

national level? **PSC6:** What are the foreseen measures and conditions set for the orderly phasing-out of the Partnership from the Framework Programme funding? **PSC6.1:** Are these measures appropriate with regards to a possible phasing-out (or renewal) of the partnership?

Methodological approach

This case study employs several methods to acutely realise the dimensions of each programme. First, the study team used desk research as a method to gather and analyse existing EIT Health data and information that has already been collected and published without the need for primary data collection, allowing them to conduct analyses on the two programmes. This can be a cost-effective and time-efficient way to gain a comprehensive understanding of a research topic, especially when the available information is reliable and relevant to the research question. Furthermore, the use of desk research helped identify gaps in existing knowledge of VCoE and WorkInHealth as well as highlight areas that require further investigation with additional methods.

Next, the study team engaged with the monitoring and administrative data associated with both programmes, building on desk research to design suitable questions to understand both operational logics. The case study uses these techniques to determine the specific effects on research and innovation each programme produces, as well as the internal funding mechanisms within the larger EIT Health framework. This information was drawn from the EIT Health Grant Assessment data, which includes a set of comprehensive EIT- and KIC-suggested KPIs that measure success across time, as well as several sub-KPI's which feed into general parent KPIs. Specific VCoE data was made available and isolated within this dataset.

Finally, EIT Health, VCoE, and WorkInHealth experts, employees, and advisors were interviewed to gain insights into the internal operational logic of the two programmes, assessing the performance of how each provides tools for research and innovation to SMEs and healthcare workers. The team structured the interviews as follows:

- Define the research question: In this case, the research question asks what factors are contributing to the outcomes of the VCoE and WorkInHealth;
- Identify participants: Identify a diverse group of experts, employees, and advisors to EIT Health and the two programmes who have relevant knowledge and experience with each programme;
- Develop an interview guide for participants: Researchers developed an interview guide with open-ended questions that allow participants to share their experiences and insights about the two programmes in the case study. The guide also includes prompts for follow-up questions to encourage deeper exploration of topics;
- Conduct interviews: Conduct in-depth interviews with participants using the interview guide;
- Analyse data: Transcribe and analyse interview data to identify common themes and patterns related to the success of the VCoE and WorkInHealth;
- Report findings: Researchers summarise and report findings in a clear and concise manner that addresses the research question and objectives.

Context and background to the initiatives

EIT Health is a partnership organisation that aims to enable people in Europe to live longer, healthier lives. Their work goes beyond conventional approaches to disease management and disease prevention. They are eager to welcome new partners that can help them strengthen and extend their network. EIT Health is addressing the impact technology is having on both healthcare employees and end user patients through innovative training that up-skills the health workforce and improves patient care. They have identified six of the most urgent healthcare challenges facing society and are dedicated to finding solutions to strengthen healthcare systems, promote better health of citizens, and contribute to a sustainable health economy in Europe. In terms of citizen and patient training, EIT Health ultimately aims to improve the health and well-being of European patients and citizens, following a patient-centred approach where individuals' specific health needs and health outcomes are the driving force behind all healthcare decisions and quality measurements.

EIT Health Entrepreneurship activities encompass a diverse array of programmes aimed at enabling and managing early venture businesses and strengthening existing firms through operationalising investment penetration and better positionality for new and existing ventures within European markets. These activities are primarily found under EIT Health's accelerator, which offers different programmes to start-ups, scale-ups, and innovative companies at all stages in their lifespan. This is the area of the VCoE, offering a public-private co-investment programme within the accelerator that focuses on providing companies with EIT Health's support ahead of their Series A, B, or pre-IPO fundraising rounds.

WorkInHealth

The WorkInHealth Foundation is an initiative launched by EIT Health in 2021 to address the evident and growing skills and talent gaps within the healthcare industry across Europe.²¹¹ The foundation plans to work across four main activity areas: attraction – promoting the healthcare sector to a diverse pool of talent; matching – using the latest technology to match talent and employers; future proofing – using intelligence and analytics to get ahead of the skills need.²¹²

By identifying urgently needed skills gaps, attracting and assessing talent, and developing customised training programmes, WorkInHealth aims to address the unprecedented talent crunch in the healthcare industry.²¹³ Healthcare offers a meaningful career with competitive remuneration, excellent working conditions, and a chance to be at the forefront of cutting-edge innovation.²¹⁴ **It is committed to improving access to quality healthcare, promoting healthy lifestyles, and addressing innovative and skill gaps.** In doing so, the foundation deals with divergences between qualities of health across Europe through four main channels²¹⁵:

- Attraction promoting the healthcare sector to a diverse pool of talent;
- Matching using the latest technology to match talent and employers;

²¹¹ Home page - WorkInHealth Foundation. https://WorkInHealth-foundation.org/.

²¹² WorkInHealth Foundation - EIT Health. https://eithealth.eu/what-we-do/WorkInHealth-foundation/.

²¹³ Home page - WorkInHealth. https://WorkInHealth.eu/

²¹⁴ Healthcare Operations: The Benefits of Effective Healthcare - G2. https://learn.g2.com/healthcare-operations

²¹⁵ Driving impact in healthcare through operational readiness. https://www2.deloitte.com/us/en/pages/life-sciences-and-healthcare/articles/driving-impact-through-operational-readiness.html

- Future-proofing using intelligence and analytics to get ahead of the skills needed;
- Training helping to bridge the gap between academia and industry.

With over 100 000 healthcare workers upskilled and 2 million recruited, the WorkInHealth Foundation represents a significant block of novel work in European healthcare.²¹⁶

Venture Centre of Excellence

The Venture Centre of Excellence (VCoE) is a public-private co-investment program operated by EIT Health and the European Investment Fund (EIF) to empower finance for European health small and medium-sized enterprises (SMEs). The VCoE connects life science investors with high investment capacities such as venture capital funding. The goal of VCoE is to provide access to finance and strategic connections for European health SMEs. By connecting life science investors with high investment capacities, VCoE aims to empower finance for these SMEs and help them grow and succeed in their respective fields.

Since its inception in October 2019, the Venture Centre of Excellence has connected approximately 130 organisations within their co-investment universe; the Centre links science investors with high investment capacities such as venture capital funding, corporate or industrial firms, Technology Transfer Offices, insurers and more – with highly qualified Pan-European SMEs using an exclusive Artificial Intelligence platform that brings all members together. It is worth noting that while the VCoE went through its inception phase in 2019, the first formal partnership was established in Q1 2020. Companies that are successful in the selection process and wish to confirm their participation in the VCoE will pay a service and mentorship fee of EUR 8 000. The Centre also works with industry partners to support research and development and to identify opportunities for collaboration, as well as allows SMEs in the program to join the EIT Alumni network comprised of nearly 3500 companies.

Outcomes

WorkInHealth

As discussed in the earlier sections, WorkInHealth is an EIT Health programme dedicated to connecting life sciences stakeholders and addressing the general talent crunch in the European healthcare industry. There are two sides to WorkInHealth outcomes: the commercial venture, which matches talent and health-oriented large firms and start-ups, and the foundation, which acts as a semi-independent body and whose goals are to expand the funding and network for the organisation.

Commercial Venture

The commercial venture structure of WorkInHealth exists to directly address previous calls from academics and national healthcare policymakers to deal with existing gaps in healthcare hiring markets and help upscale existing healthcare markets. In effect, the programme "smooths out" any discrepancies in talent and need across European health markets, several areas which became apparent to EIT Health following the COVID-19 pandemic.²¹⁷ Following

²¹⁶ Home page - WorkInHealth. https://WorkInHealth.eu/

²¹⁷ Eurohealth, "Health system resilience post-COVID: Moving towards more European cooperation, 2022.

https://eurohealthobservatory.who.int/news-room/news/item/05-04-2022-health-system-resilience-post-covid-moving-towardsmore-european-cooperation

a lengthy call programme, WorkInHealth first began operations in 2021, hosting its first career fair in 2022. According to interviewees, this event was the first of its kind hosted by EIT Health, having been suggested several times by alumni before. By employing their existing connections with stakeholders and EIT Health's network of universities and young researchers, WorkInHealth aimed to fill this niche. Interviewees reported that the only problems faced during this event were driven by the total number of online participants greatly outnumbering their expectations (the career fair had a greater number of students and firms than they had initially expected), causing some technical difficulties. Since then, WorkInHealth has hosted another career fair to similar measured success. WorkInHealth internally measures their performance using a combination of the general EIT Health KPIs that it shares with other EIT Health programmes, but internally records performance by employing unique metrics for each kind of event (e.g., career fairs use an analytics online tool to see several metrics such as CVs exchanged, discussions had and followed up with, as well as a combination of surveys and short interviews before and three to four months after the career fair). For these kinds of events, in particular, it is this follow-up interview that was reported as most crucial to interviewed WorkInHealth staff, as it allows them to record the employment status and outcome of their interactions at the career fair.

Interviewees indicated that one positive externality of these career fairs was the increased discourse on and between stakeholder groups in healthcare markets. According to them, existing hiring practices for European healthcare workers generally are a binary relationship between the firm and the prospective employee. However, despite WorkInHealth interviewees conceding that even more can be done in this area, their career fairs encourage several different groups (e.g., patients' groups, citizens' groups, national public health organisations, and international healthcare organisations) to participate directly or indirectly with their programme. While this area is an improvement on the status quo for European healthcare labour markets through building new channels to encourage external practitioner and patient engagement, interviewees acknowledged that WorkInHealth struggles to demonstrate the clear benefits to patients and citizens that other EIT Health programmes do.

Furthermore, while WorkInHealth staff reported success at their career fairs, they also indicated difficulties in progressing in their ability to deliver more than those events. There were several reasons for this, namely struggles stemming from initially underestimating discrepancies in healthcare governance and access to funding. It is these two barriers that, according to interviewees, are the catalysts behind the observation that WorkInHealth has not made much progress towards coordinating other events or programmes. Notably, WorkInHealth has not coordinated any training programmes at present, instead using their career fairs to promote the organisation and offer support throughout the relationship between the firm and employee. Another area that interviewees showed interest in expanding was WorkInHealth's ability to identify talent and market spaces farther in advance. This space is also where they cooperate most with other EIT KICs, reporting collaboration with EIT Digital, Food, and Manufacturing in order to successfully identify talent in other fields that might map onto existing needs in European healthcare labour markets. Internally, WorkInHealth employs tools such as the Health Labour Market Analysis Guidebook designed by the World Health Organisation (WHO) as a model to estimate future medium-term (3-5 years) labour market outlooks.

Looking forward, both researchers and interviewees agreed that this is a specific niche with great market potential, possibly offering an avenue towards financial independence. Currently, WorkInHealth has a goal of building its own novel Artificial Intelligence (AI) measurement tool to estimate healthcare labour market outcomes in the longer term (5-10 years), rather than just reacting to existing market trends. Such an instrument does not yet exist at the European level except for the European sections in the *Health Labour Market*

Analysis Guidebook, the exact tool that WorkInHealth currently employs and has identified weaknesses in (such as a lack of specificity to European markets and limitations on scale), thereby seeking to improve upon. WorkInHealth interviewees were confident that, if they were able to successfully develop such an instrument, its utility would expand well beyond their own internal talent identification; it would be of interest to national governments, private healthcare firms, research institutions, and industry groups who could employ it upon joining WorkInHealth, thereby offering WorkInHealth, a wider network of market stakeholders. Furthermore, WorkInHealth staff indicated that their elevated perspective above national hiring markets (e.g., not centred on one specific European national healthcare industry) and between healthcare providers and staff places them in an opportune position to develop a new Al tool. Developing such a tool thereby could ameliorate the two primary challenges of differences in governance and funding by building a unitary metric for European healthcare labour markets and adding a new revenue stream independent of EIT funds. At the moment, however, interviewees indicated difficulties in developing this tool at the current state of funding, leading to the creation of the WorkInHealth Foundation, designed to attract investors and healthcare partners to balance EIT funding and eventually pursue financial independence.

WorkInHealth Foundation

The WorkInHealth Foundation was created as a semi-separate entity to the commercial venture as a way to market themselves to EIT Health and as a new potential revenue stream towards financial independence. Currently, the foundation is structured in a way where it oversees all relevant revenue streams and drives financial growth for WorkInHealth, which, at the moment, is through an established price point for private companies to join their career events (thereby giving firms access to greater visibility for those companies found at their events and student network). In the next year, WorkInHealth also aspires to establish a limited group of large private supporters by offering a one-time kick-off subscription, where a company would be able to join all future WorkInHealth events with a one-time fee. Finally, as mentioned earlier, interviewed WorkInHealth staff were most excited about the prospects of an Al-driven identification tool used to estimate and map future growth and challenges in European healthcare labour markets. So far, these attempts to attract investors have been relatively unsuccessful. According to 2022 Grant Assessment data, they have twice failed to acquire external funding despite hiring external consultants to help fundraise (most recently at the end of 2022). The WorkInHealth website does designate four donors and ambassadors (Cap Digital, CEBR, BioMedAlliance, AlforHealth). However, only information on AlforHealth was available in the Grant Assessment data because that company hosted a booth at a WorkInHealth event. With that being said, the programme has found revenue from its internal marketplace. WorkInHealth has seen periods of surplus revenue; funds that interviewees report are immediately invested back into the education programme.

Challenges

Funding represents the greatest challenge to WorkInHealth, with interviewed staff reporting themselves struggling to find new investors on a limited budget. They are hopeful in the innovative capacities of the programme, particularly in relation to the potential AI-driven labour market instrument but are sceptical on their ability to finance this innovation at the current level of EIT funding. Furthermore, due to the nature of their programme as linking health experts and firms, interviewees reported finding it difficult to demonstrate their direct benefit to citizens and patients to EIT Health. This dynamic feeds into another barrier faced by WorkInHealth, which is the reported feeling that some of the EIT Health KPIs are not effectively designed for WorkInHealth. For example, there is no current way to measure the ecosystem for the people who indirectly benefit from the WorkInHealth programme, such as patients who benefit from greater efficiencies in their healthcare

markets. Interviewees reported that these funding issues are likely to limit their ability to become financially independent within the anticipated timeframe but are confident in the eventual independence of the programme (especially if they are able to access other EU funds). The final challenge is related to differences in governance, which affected the WorkInHealth programme upon its inception (though it has since affected the programme less). Differences in the way national administrative bodies funded and managed their healthcare industries led WorkInHealth to have to learn to navigate each national bureaucracy quickly, as cross-border labour mobility was one of the primary interventions described in their launch event.²¹⁸ Interviewees indicated that this challenge was further amplified by EIT Health gradually gains the trust and knowledge of national healthcare markets, expanding its corpus of stakeholders through connections with health officials, healthcare firms, and interested talent.

Overall, the WorkInHealth Programme model maps onto the large objectives of EIT Health by connecting all key players in healthcare markets, strengthening the European healthcare economy, and promoting talent issues as crucial to European healthcare markets. Interviewees reported that the programme struggles with balancing their current level of EIT funding with marketing their programme. However, they are hopeful that the efficiency gains found through developing innovative technology – such as an AI-driven predictive model for labour markets – and through increases in human capital vis-à-vis governance will reduce their reliance on EIT funding in the future.

Venture Centre of Excellence

Additionality

The VCoE has been quite successful in its efforts to promote and manage investment into early-stage innovative European healthcare markets, filling a role that Europe had a dearth of compared to the rest of the world. Through 2022, the VCoE supported 23 different start-ups and Scale-ups, 19 classified by the VCoE as dedicated to Business Creation and four to Entrepreneurship outputs. These partnerships took place primarily in France and Western Europe, with one firm located in Israel (**Error! Reference source not found.**). The d iscrepancy toward France can likely be explained by the fact that the VCoE was launched by EIT Health France, with its legal office still located in the country.



Figure 77. Start-ups and scale-ups supported by registered country

Source: EIT Health Grant Assessment Data 2021-2022.

²¹⁸ EIT Health. WorkInHealth Launch Event, 2021. https://eithealth.eu/event/eit-health-WorkInHealth-launch/

From 2021 to the present, the VCoE has also seen significant increases in annual revenue, nearly tripling from 2021 to 2022 alone. Their projections continue this trend positively, projecting EUR 1.9 million in revenue by 2025 (**Error! Reference source not found.**).



Figure 78. VCoE annual revenue (EUR)

Source: EIT Health Grant Assessment Data 2021-2022.* 2022 is an estimate taken from the total revenue with 2/3 subtracted to be paid to other partners. VCoE also received other revenues that may not be accounted for, such as workshop, management, and vetting fees, as well as milestone payments for the launch of the Neurotech prize.** 2023 onward are VCoE projections for future annual revenue.

Given the attention from both the EU and industry stakeholders alike, combined with its startup-friendly methods, it is unsurprising that the VCoE has become an attractive partner for European health start-ups. VCoE has been very active in screening start-ups for investment readiness. Out of the start-ups screened, this number was placed into the Dealflow management tool, and this number was invested in. This is seen with increases in the number of start-ups screened for investment readiness per year, demonstrating both the visibility of the VCoE and the screening capabilities of the organisation (**Error! Reference s ource not found.**).



Figure 79. Number of start-ups screened for investment readiness

After the initial screening phase, start-ups are then consulted by VCoE staff and are placed into the Dealflow Management tool. Dealflow is a Customer Relationship Management (CRM) tool designed by Attio that helps the VCoE measure and compile pipelines (workflows for specific start-ups), manage relationships between start-ups and investors, and track portfolios of future and existing partnerships. Not only increasing in gross annual revenue, the number of start-ups that have been screened and placed into the Dealflow management tool has also increased on a year-by-year basis (**Error! Reference source not found.**).



Figure 80. Number of start-ups that have been screened and can be placed into the Dealflow management tool

Source: EIT Health Grant Assessment Data 2021-2022. As mentioned earlier, while the VCoE was approved and funded by 2019, it was only formally launched in Q1 2020.

Start-ups and scale-ups supported by the VCoE are also successful at attracting additional investment outside of that directly facilitated by the VCoE. In 2021-2022 alone, these firms

Source: EIT Health Grant Assessment Data 2021-2022.

attracted EUR 77.8 million of additional investment, averaging EUR 12.9 million per qualified start-up. When compared to the average annual and cumulative investments attracted by companies backed by EIT Health from 2016-2020, this Figure is significantly higher. Across all EIT Health start-up/scale-up programmes, the average investment was (in millions) EUR 0.26 in 2016, EUR 0.29 in 2017, EUR 0.30 in 2018, EUR 0.42 in 2019 and EUR 0.61 in 2020.²¹⁹



Figure 81. VCoE Investment attracted by start-ups/scale-ups (EUR million)

It is worth noticing that the number of start-ups and scale-ups has significantly increased across time (consistent with the revenue findings), although there was a decrease in the number of start-ups supported (at the time of data publication) from 2021 to 2022. There are several potential reasons for this, one of which was the shifts in selection criteria for the VCoE, which, as mentioned by several interviewees, has shifted from early-stage start-ups to an increasing number of firms coming from the (EIT-preferred) mid-stage start-ups. One good practice example of these, the Emma Triage Private Company, designed software during the COVID-19 pandemic that was intended to decrease emergency room wait times using a patient triage app. Not only did this investment help fulfil patient needs by decreasing wait times, but also investor needs by reducing the cost of care (a one-hour increase in wait times results in a 30% increase in cost of care).²²⁰

Source: EIT Health Grant Assessment Data 2021-2022.

²¹⁹ European Commission. Evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe, p. 390.

²²⁰ Emma Emergency Clinical Support. https://www.emmatriage.com



Figure 82. Number of start-ups and scale-ups supported

Source: EIT Health Grant Assessment Data 2021-2022.

Furthermore, it is crucial to highlight how potential shifts in VCoE application methodology (e.g., making changes that impact the percentage of accepted firms) might have impacted the data discussed above. In this area, the VcoE has changed slightly – shifting from a 30% acceptance rate (the number of applicants to the VcoE vs the number of available places) to 35% between 2021 and 2022. However, given the overall increase in attention given to the VcoE and the resulting surge in applicants, successfully fulfilled partnerships, and overall profitability, this increase was expected by interviewed VcoE staff who referenced the increase in quality applicants and the early stage in the VcoE lifespan. In fact, of the three start-ups in 2022, all were from new countries (two in the Netherlands and one in Israel). The number of start-up markets is also increasing from general innovative health to more specific disciplines. For example, in 2021, the VcoE declared a partnership with IT-MEDicine Kft, a firm developing a gynaecological medical device designed to measure foetal EEG and ECG waveforms during both pregnancy and labour. Such a device had not been brought to market yet by any firm or start-up but has since been included in the Central Europe "deeptech landscape" prepared by Aper Ventures, highlighting large market movers in specific innovative industries.



Figure 83. Number of applicants in EIT Health programmes (number requested) vs available places (number requested) expressed as a percentage

Source: EIT Health Grant Assessment Data 2021-2022.

European added value

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Error! Reference source not found.80). The VcoE is an increasingly fashionable resource f or European health innovators, demonstrating the added value that such a partnership can contribute to such start-ups and scale-ups when compared to existing institutions at the regional or national level. However, we also found it worth investigating the added value that the VcoE provides to EIT when compared to these institutions. Since its inception, the VcoE has existed as an enterprise established jointly between EIT Health and the European Investment Fund (EIF). Therefore, as was indicated by VcoE staff in the interview programme, intercontinental collaboration has always been at the centre of the project. When selecting and handling start-ups and scale-ups on a day-to-day basis, the EIF tends to represent private Venture Capital funds (VCs) while EIT Health represents start-ups, corporations, and industrial actors.

Interviewees demonstrated how the added value benefits to this dynamic are twofold: First, start-ups trust that their interests will be met when discussing and negotiating the terms to future investment. The same is true on the contrary with VCs and other investors concerned with delegating some of their leverage to the VcoE. Second, both parties can also be assured that due diligence has been conducted on behalf of the other party. Rather than just being a consortium of investors (which already exist at both public and private levels, the VcoE establishes and guarantees a binding agreement between investors and corporate and industrial players. Start-ups, in particular, see significant benefits from this dynamic relative to that facilitated by existing agencies and organisations. While it might first appear difficult to operate as a fund obliged to EU goals compared to private funds not beholden to such objectives, interviewees indicated that the granularity and attention required to build these objectives into start-up programmes was the exact dedicated attitude that was attractive to start-ups. On the other hand, the European Commission's backing of EIT and the VcoE acts as a signal to the health market, producing significant positive externalities that benefit VC funds. For example, given the rigorous and transparent methods for selecting start-ups, there is greater trust in this selection process than individual VCs. Furthermore, because of their wide reach and access to the EIT Network, the VcoE is able to foster and develop longlasting relationships with other European VCs and industry representatives, thereby consistently adding new potential stakeholders. In the interview programme, interviewees highlighted these areas as crucial to bolstering the VcoE added value.

Given the clear and unique benefits that the VcoE provides to start-ups and VCs, it is unsurprising that they have quickly built a consortium of firms and VCs that have demonstrated profitability to a significant extent. It is their commitment to building and facilitating start-to-finish relationships between VCs and firms (e.g., by using public support and tools such as regulations, risk underwriting, and reimbursements) to create markets that are favourable to the crucial 'first mover' start-up. By ensuring the alignment of the public strategy needs with private partners through ensuring the involvement of every player at every stage, the VcoE sets itself apart from other public funds. Their close working relationship with the EIF as well as the European Investment Bank (EIB), WorkInHealth, and the broader EIT Health Innovation and Accelerator catalogue of programmes all allow them access to a network of innovative agents and markets that can be paired up with their large association of potential investors.

Finally, participants in the interview programme made clear that VcoE's goals are not limited to short-term public goals, either (e.g., the immediate need of a specific medicine). In fact, their expansion beyond such objectives is another degree of positive separation between themselves and existing public funds and private markets. Rather, the VcoE also helps

facilitate the short-term goals of private firms (helping with recruitment, DEI, etc.), the longterm goals of private firms (future R&I market outlooks), as well as long-term public goals such as favourability towards sustainable innovation or facilitating innovation in lagging industries. While the final point might initially appear as VcoE being exposed to greater risk than consortia of private funds, several interviewees indicated that this position is where VcoE creates most of its nominal value. Because EIT Health is an implementing partner, this space is an opportunity to operationalise EIT Goals on behalf of the EU.

While the ability of VcoE to access and achieve such a diverse set of goals drives their added value relative to existing organisations, it also exposes them to the changing circumstances impacting each interest group. In particular, VcoE interviewees indicated that the one challenge they continue to face is managing EIT Health's initiative benchmarks and goals. While representatives of VCoE considered that the goals were manageable to a certain degree (e.g. the flagship initiatives), some challenges were identified in relation to EIT's measured KPIs. While the KPIs capture a diverse range of dimensions, including indicators related to start-up and scale-up creation and finance, however, VCoE staff expressed that the KPIs did not fully reflect their abilities in advisory management and in providing access to a wide-reaching network of private investors. This was perceived as potentially creating situations where, in order to achieve certain KPIs, especially short-term KPIs, it would be more appropriate to provide companies with a static pool of funding rather than their full array of dynamic capabilities, including providing a market access point for start-ups at which VCoE is successful. However, other KPIs such as the financial leveraging factor, to which VCoE successfully contributes, do capture the work conducted by VCoE.

Phasing out preparedness

Demonstrated by the VCoE assisting the original EIT Health programmes with their own financial sustainability, the VCoE is very effective in supporting EIT Health's goal of being financially independent. As long as the VCoE is continually provided with long-term market access, the interviewees felt that the programme was likely to continue seeing significant revenue at the margins (e.g., a small percentage but large net revenues). This consistency is maintained by the ability of VCoE to outperform other funds and market-makers given their unique public-private position and expert knowledge of innovative health market ecosystems. Furthermore, interviewees claimed that the VCoE is one of the only European institutional investment structures not limited by academic requirements with a limited risk to investors (because of the available public funding), therefore it best encourages partnerships to secure the 'birth moment' of innovation.

The focus on the genesis of innovation is particularly attractive to European investors given that, by most measures, innovation in Europe itself is high but the successful transition into corporate bodies remains low. This is indicated by European researchers sitting near the top of the highest share of the top 1% highly cited scientific publications, remaining nearly unchanged from 2000 to 2014, while in 2017 the number of European unicorns (private companies with a market valuation above \$1 billion) was half that of China, and under one-quarter that of the United States.221 As others have pointed out, being first-to-market ('disruptive innovation') is one of the key indicators of future start-up success, which is an area where Europe has fallen behind the United States and East Asia²²². Funding these firms

²²¹ World Economic Forum. "The state of research and innovation in Europe in 7 charts," 2018.

https://www.weforum.org/agenda/2018/02/the-state-of-research-and-innovation-in-europe-in-7-charts/

²²² Bughin et al. "Reviving Innovation in Europe," McKinsey Discussion Paper, 2019. https://www.mckinsey.com/featuredinsights/innovation-and-growth/reviving-innovation-in-europe

has proven difficult to European investors despite demonstrated profitability elsewhere in the world. In the immediate aftermath of the 2007 Global Recession, VC funds in the United States raised just EUR 8.6 billion compared to EUR 2.6 billion in Europe. By 2016, European funds had raised EUR 6.0 billion, while funds in the United States raised five times more funding than their European counterparts at EUR 38.0 billion. This institutional gap that exists in Europe is the exact niche that VCoE has found success in, and its demonstrated capacities as a financial leveraging factor, market access point, and 'first mover' catalyst all encourage a future phasing-out (or renewal) of the partnership at a future point.

Reflections on evaluation criteria

WorkInHealth

The *WorkInHealth* programme was limited in its quantitative data made available in the Grant Assessment to researchers, therefore this study is primarily informed using interviews with *WorkInHealth* staff. Interviews provided researchers valuable insights and perspectives from the individuals being interviewed, but they may not provide a complete or representative picture of the entire programme or offer future outlooks for EIT. The information gathered from interviews is subject to the biases and perspectives of the interviewees and may not accurately reflect the experiences or opinions of all stakeholders. Additionally, interviews provided minimal quantitative data or objective measures of success, which can be important for evaluating the effectiveness of a program. To overcome these limitations, it may be useful to supplement interviews with other data sources in the future, such as surveys, statistical analysis, or document review, especially with regard to past completed and/or incomplete KPIs.

Venture Centre of Excellence

Relevance

The Venture Centre of Excellence was created to support the key need for partnerships and co-investments between stakeholders in life science integration. As it continued to grow, it has shifted from supporting primarily early-stage start-ups to mixed-stage firms, more closely mirroring those supported widely by EIT Health. While some identified start-ups are drawn from independent searches, many are drawn from the EIT Health ecosystem and its members, and some are alumni or products of the EIT Health bootcamp and its early-stage programmes. Given this link, it is unsurprising that interviewees indicate that the number of organic references for new start-ups grows alongside the broader EIT Health network.

Coherence

As a principle, the VCoE asks how and seeks to align public strategic needs with private partners. This could take the shape of using public support to create markets employing public tools (regulations, risk underwriting, or reimbursements). Often, this is recognising that there always needs to be a 'first mover' start-up in a potential market – this is where the implementing partner (VCoE) comes in to identify and facilitate the integration of the start-up. By ensuring the alignment of the public – private goals, it is crucial to maintain **the importance of keeping each important player involved**. Interviewees particularly emphasised this point, that merely public funds are not enough to stand apart, as engagement at each level of involvement is a crucial investment in and of itself.

The VCoE maintains standardisation by employing a scorecard metric to ensure that each case features the important structural dimensions of a company. This metric takes many

different approaches, in particular the different routes to a long-term vision or perspective in assessing each company's risk and opportunities. The VCoE connects Vision and overall analysis to market needs, and by identifying market trends in a start-up's market. This is primarily through employing individual experts and coaching the CEO of the company. It is worth noting that most relevant start-ups today have *some* pre-existing relationship to EIT Health (either through referral or through the EIT ecosystem), so it is rare that a full analysis of the firm is necessary.

Efficiency

Broadly speaking, VCoE interviewees spoke on the EIT's overarching goals for the VCoE as untroublesome (e.g. flagship initiatives). VCoE has proven efficient in its ability to form relationships with high-potential start-ups and guide them to profitability. Because each VCoE participant is designed through bespoke methods and relationships with start-ups, the startto-finish process is transparent and controlled. The VCoE also improves efficiency by cooperating with some other VC funds. However, given the market signals of the VCoE being backed by EU investment, often collaboration with other VCs not as important. Ultimately, as interviewees pointed out, funds from the European Commission and the 20 VCoE members, corporates, and VC funds are all blended to a larger VCOE pool. Furthermore, each of these stakeholders are trained to use Skopai AI, a platform providing investment firms with a broad and substantive database on all start-ups, scale-ups, and innovative companies across the world. In particular, Skopai delivers investment firms summary and detailed metrics on the technology, market, financial, and team maturity levels of each startup. Not only does this tool aid the VCoE through developing the knowledge base of each investing partner, but it promotes efficiency by ensuring the consistency of information across the VCoE portfolio. In a 2022 appraisal, Jean-Marc Bourrez, Director of EIT Health France and Co-Managing Director of InvestHealth, advocated for Skopai by stating: "We have been working closely with Skopai for years. Their research, tools, and expertise have enabled the realisation of ambitious European projects such as the European Investment Fund's Venture Centre of Excellence program."

Effectiveness

Today, with 23-member investor entities (both corporations and VCs) onboard the VCoE, over EUR 77.8 million have been raised by 23 beneficiary start-ups. Furthermore, the number of potential markets, funds, and firms have expanded alongside the EIT Health network, allowing for greater potential growth in new and diverse areas. Nonetheless, interviewees still referred to several challenges that remain facing them. First, there are still barriers to aligning the VCoE and EIT Health pillars. Having a dispersed office presence network offers strong benefits to start-up relations, but running sourcing activities across this decentralised system provides challenges since the needs of most start-ups tend to be very specific. Given that start-ups strongly prefer the decentralised method to feel a stronger sense of engagement with the VCoE, interviewees indicate that this barrier has been difficult to dislodge. Only through continuing to improve coordinated trainings to partners as well as staff across Europe has the VCoE been able to see significant change, efforts that continue to this day.

Second, there are certain challenges with EIT Health increasingly being seen by the European Commission as an asset, namely with efficiency issues stemming from increases in perceived top-down control over the necessarily volatile and speculative start-up and SME market. Therefore, as the VCoE goals align with the EC, it sometimes becomes difficult for VCoE staff to make clear to start-ups the importance of connecting their firm to broader EU goals. However, in terms of profitability, interviewees referenced that 'this is the other side of the coin' of the importance of granularity and attention provided to health start-ups and is also

the space where the VCoE creates most of its nominal value. Since EIT Health remains an implementing partner, this risk and profitability is an opportunity to adjoin the goals of EIT Health on behalf of the EU.

EU Added Value

The VCoE has been successful in contributing additional value to that which is already provided by existing organisations supported by the EC. A substantial amount of this value comes from collaboration with the EIF (which represents VCs while EIT Health represents start-ups, corporations, and industrial actors). Therefore, rather than just acting as a unitary consortium of investors, the VCoE establishes a binding agreement between investors and corporate players that facilitates greater trust between stakeholders. The EU investment into the VCoE also produces externalities that allow the VCoE to outperform private consortia of VCs, especially insofar as signalling public trust in specific focus areas. Interviewees offered the HERA Initiatives as an example of this, where the VCoE facilitated a new market space that was aligned with EC programmes and objectives in the future, in this case improving European capabilities to respond to health emergencies.

Conclusions

The findings of this case study support the claims that the Venture Centre of Excellence (VCoE) and WorkInHealth Foundation have generated returns on investment and that they have contributed to the longevity, self-sufficiency and sustainability of EIT Health. The VCoE in particular has directly aided in facilitating the financial self-sustainability of EIT Health by earning around EUR 1.3 million in revenue for their services in 2021-2022. It is expected that the VCoE annual revenue will increase to EUR 1.9 million in 2025. These outcomes have led to greater attention being paid to the VCoE within the healthcare industry as a viable progenitor for start-ups and SMEs, positive attention that interviewees indicated has compounded onto the EIT Health ecosystem. Resultingly, the VCoE has seen significant increases in the number of companies applying for funding, the total number of companies funded across time, and the total amount of funding made available.

While less developed than the VCoE, the WorkinHealth Programme has had moderate success in their more limited goals. For example, WorkinHealth was the first EIT Health Programme to host a career fair between health firms, students, and prospective employees in 2022, something that EIT Health alumni had suggested for years. However, the programme has struggled to expand further beyond hosting career fairs, a situation that interviewees indicated has improved as WorkinHealth has continued adapting to the differences in national healthcare systems and labour markets. Nonetheless, there is cause for cautious optimism in the future, as WorkInHealth hopes to soon build a novel Artificial Intelligence instrument to predict healthcare labour market outcomes in the medium term (five to ten years). Such a tool could provide direct revenues through subscriptions and industry attention for WorkInHealth and EIT Health.

Key lessons learned and suggestions for improvement

WorkInHealth

WorkInHealth is an initiative that aims to enhance the abilities and expertise of healthcare professionals in Europe. In addition to its four main areas of focus, it also hosts events to link health start-ups and companies with potential employees, which has been successful. However, the organisation has had difficulty achieving financial independence. Staff members interviewed for the case study mentioned several possible reasons for this. For

instance, the organisation has difficulty obtaining external funding to support the physical networking spaces it uses to connect health talent with healthcare firms. Furthermore, WorkInHealth encountered some difficulties adapting to differences in national healthcare systems, although interviewees indicated that these issues are becoming less prevalent as the organisation progresses.

Interviewees were uncertain about the feasibility of achieving their initial goals within the proposed timeline, but do foresee an instrumental path forward, in particular through the development of new financial technology and building lasting trust with stakeholders. It is the former where WorkInHealth will derive its greatest potential successes from, as developing technology such as their aspirational AI-driven labour market model could provide WorkInHealth with a stable revenue stream, increased attention to their career events, and ultimately enhance the network of industry-focused healthcare firms and researchers.

Venture Centre of Excellence

The VCoE has found quick success in the European health start-up market, nearly doubling the number of annual applicants screened and between 2021 and 2022 and increasing the number of start-ups and scale-ups by 19 between 2021-2022. While the Venture Centre of Excellence can widely be considered a success when measured by its own and EIT's goals, there are still challenges areas suitable for improvements. The first is for the VCoE to continue to improve its staff education and training to standardise key pieces of how the organisation operates, particularly regarding how they operate at each stage of the start-up lifespan. This improves the organisation's ability to operate with consistency across Europe despite their decentralised structure.

Furthermore, it is worth discussing how replicable the VCoE approach might be within other EIT KICs or elsewhere in the Framework Programme. It is possible that the above concerns might be best addressed by similar firms engaging with specialised regions or themes, allowing for greater centralisation while maintaining the same degree of attention and knowledge of a specific area. In the short-term, such a change risks interfering with the VCoE growth direction as they uncover and facilitate markets, but it is worth considering in the medium to long-term.

While the VCoE has made itself attractive to start-ups and investors, at the same time there is room to grow and market the VCoE further, as evidenced by the rather low subscription rate to the programme. VCoE should therefore still seek to create further synergies and visibility for the programme.

The second lesson learned can be gathered from how VCoE staff view the EIT objectives set for the VCoE. The VCoE staff also indicated that the current EIT Health KPIs do not capture the dynamic capacities of the organisation as a successful creator of healthcare markets and provider of market access points for start-ups. However, at the same time, this does not harm the minimum profitability of the VCoE, although it may be worth considering further aligning the KPIs with the functions that VCoE performs. Nonetheless, looking forward, the VCoE is making substantial contributions to the financial sustainability of EIT Health, as indicated by the long-term profitability projections laid forth by the organisation. As long as EIT continues to enable long-term market access for the VCoE, the EIT Health can earn significant net revenue at the margins, thereby continuing to encourage partnerships in securing the crucial 'birth moment' of innovation.
While the effectiveness of the VCoE is reliant on the ever-volatile healthcare start-up and SME markets, interviewees indicated a shift from focusing on early-stage start-ups as they had at the VCoE inception to a more diverse portfolio of start-ups across different stages. Given the demonstrated profitability of the current VCoE selection criteria, we suggest that this shift should be welcomed by EIT Health as the VCoE mitigates risk while maintaining long-term financial sustainability and facilitating capital mobility between stakeholders. Second, EIT Health ought to consider the measurement criteria of VCoE, in particular the feedback of interviewees that the current metrics fail to capture the full breadth of the VCoE as more than just a static source of funding, but instead a dynamic relationship between stakeholders that both creates and facilitates healthcare markets. In doing so, the VCoE will be able to better supply firms and market players with support and feedback that is less easily measured by standard investment metrics, actions that they have seen to be ultimately successful in the medium-term financial outcomes of startups.

Appendix 1: Interview questionnaire

Effectiveness/Relevance

Coherence

General Questions

Could you give a detailed explanation of your relationship to EIT Health? (its scope, main activities, objectives, and main approach for their implementation)?

Describe, if possible, your role at your organisation and how it relates to EIT Health?

VCOE-Specific Questions

How has EIT Health supported VCoE? Has it been effective and adequate to its needs? Why/Why not?

Are there specific aspects of EIT Health's support that you think need some improvement? If so, which ones?

Has communication between EIT Health and VCoE been effective in transmitting updates, concerns, and other types of feedback?

Would you cooperate with EIT Health in future projects unrelated to VCoE? If so, why?

Did EIT Health offer you a strong network of experts during and after your participation?

In your eyes, how successful are SMEs pre-versus-post VCoE investment?

Are there any hindrances that VCoE has faced in supporting European health SMEs? How were they addressed?

How does the VCoE identify the needs and challenges faced by European health SMEs? Do you see it as successful? How is this success measured at VCoE?

How easy was it to understand how VCoE could progress through EIT Health's different initiatives? E.g., did you find EIT Health's benchmarks and goals for VCoE managable?

- To what extent has EIT Health's funding been effective at VCoE? Why? Added Value/Visibility
 - What is the added value EIT Health provides compared to other funding programmes?

How does VCoE compare to other national sources of funding? To European ones? What makes it different from those?

Does the VCoE collaborate with other EIT Health programmes?

Can you offer a "success story" of an SME that found success through the VCoE?

		How could the VCoE education programme and network result in visibility for EIT and the broader European Partnership?			
	Directionality	Which other VC funds does VCoE collaborate with? What tangible benefit does VCoE see from this collaboration?			
	8	Do you feel that the VCoE application process is sufficiently transparent to potential applicants?			
	ness	How open do you regard VCoE's financial support to participants?			
	Transpe Open	How open would you consider VCoE-supported research results to be to the public?			
	ality	If possible, do you see VCoE's collaboration with the European Investment Fund as important? Why?			
	Additiona	In your experience, can/do the financial relationships developed through VCoE investments result in additional advantages, such as future partnerships?			
	asing out	How effective is VCoE in supporting EIT Health's goal of being financially independent? Why?			
	Phi				
	Phi	WorkInHealth-Specific Questions			
	Ph	WorkInHealth-Specific Questions How has EIT Health supported WorkInHealth? Has it been effective and adequate to its needs? Why/Why not?			
	vance Ph _i	WorkInHealth-Specific Questions How has EIT Health supported WorkInHealth? Has it been effective and adequate to its needs? Why/Why not? Are there specific aspects of EIT Health's support that you think need some improvement? If so, which ones?			
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	tiveness/Relevance Ph.	WorkInHealth-Specific Questions How has EIT Health supported WorkInHealth? Has it been effective and adequate to its needs? Why/Why not? Are there specific aspects of EIT Health's support that you think need some improvement? If so, which ones? Has communication between EIT Health and WorkInHealth been effective in transmitting updates, concerns, and other types of feedback? Would you cooperate with EIT Health in future projects unrelated to WorkInHealth? If so, why?			
	Effectiveness/Relevance Ph.	WorkInHealth-Specific Questions How has EIT Health supported WorkInHealth? Has it been effective and adequate to its needs? Why/Why not? Are there specific aspects of EIT Health's support that you think need some improvement? If so, which ones? Has communication between EIT Health and WorkInHealth been effective in transmitting updates, concerns, and other types of feedback? Would you cooperate with EIT Health in future projects unrelated to WorkInHealth? If so, why? Can you describe WorkInHealth's mission and goals in supporting European healthcare professionals?			
	Effectiveness/Relevance Ph	WorkInHealth-Specific Questions How has EIT Health supported WorkInHealth? Has it been effective and adequate to its needs? Why/Why not? Are there specific aspects of EIT Health's support that you think need some improvement? If so, which ones? Has communication between EIT Health and WorkInHealth been effective in transmitting updates, concerns, and other types of feedback? Would you cooperate with EIT Health in future projects unrelated to WorkInHealth? If so, why? Can you describe WorkInHealth's mission and goals in supporting European healthcare professionals? How were they addressed?			
	Coherence Effectiveness/Relevance Ph	WorkInHealth-Specific Questions How has EIT Health supported WorkInHealth? Has it been effective and adequate to its needs? Why/Why not? Are there specific aspects of EIT Health's support that you think need some improvement? If so, which ones? Has communication between EIT Health and WorkInHealth been effective in transmitting updates, concerns, and other types of feedback? Would you cooperate with EIT Health in future projects unrelated to WorkInHealth? If so, why? Can you describe WorkInHealth's mission and goals in supporting European healthcare professionals? Can you describe any challenges or obstacles that WorkInHealth has faced in supporting European healthcare professionals? How were they addressed? How does WorkInHealth measure the impact of its initiatives and programmes on European healthcare professionals?			
	dded Coherence Effectiveness/Relevance Ph ie/Visib 	WorkInHealth-Specific Questions How has EIT Health supported WorkInHealth? Has it been effective and adequate to its needs? Why/Why not? Are there specific aspects of EIT Health's support that you think need some improvement? If so, which ones? Has communication between EIT Health and WorkInHealth been effective in transmitting updates, concerns, and other types of feedback? Would you cooperate with EIT Health in future projects unrelated to WorkInHealth? If so, why? Can you describe WorkInHealth's mission and goals in supporting European healthcare professionals? Can you describe any challenges or obstacles that WorkInHealth has faced in supporting European healthcare professionals? How were they addressed? How does WorkInHealth measure the impact of its initiatives and programmes on European healthcare professionals? What is the added value EIT Health provides to European healthcare compared to other funding programmes?			
	Added Coherence Effectiveness/Relevance Ph Value/Visib	WorkInHealth-Specific Questions How has EIT Health supported WorkInHealth? Has it been effective and adequate to its needs? Why/Why not? Are there specific aspects of EIT Health's support that you think need some improvement? If so, which ones? Has communication between EIT Health and WorkInHealth been effective in transmitting updates, concerns, and other types of feedback? Would you cooperate with EIT Health in future projects unrelated to WorkInHealth? If so, why? Can you describe WorkInHealth's mission and goals in supporting European healthcare professionals? Can you describe any challenges or obstacles that WorkInHealth has faced in supporting European healthcare professionals? How were they addressed? How does WorkInHealth measure the impact of its initiatives and programmes on European healthcare professionals? What is the added value EIT Health provides to European healthcare compared to other funding programmes? Does WorkInHealth collaborate with other EIT Health programmes?			

	How does the WorkInHealth and network result in visibility for EIT Health and the broader European Partnership?
	Do you consider WorkInHealth to be solving issues that cannot be solved at the national/regional level? Were such efforts unsuccessful in the past?
	Can you give an example of a successful initiative that WorkInHealth has implemented to support European healthcare professionals?
Directionality	Does the WorkInHealth programme clearly map onto the vision of EIT Health?
sseuue	In your opinion, does WorkInHealth have sufficient channels to encourage external engagement (e.g., practitioner and patient engagement)?
∕& Ope	Do you feel that the monitoring, selection, and retraining process is sufficiently transparent to participants in the WorkInHealth education system and network?
arency	Does WorkInHealth encourage feedback and/or modifications to the model for measuring talent gaps in European medicine?
Transp	Does WorkInHealth successfully identify talent in other fields, and if so, how do they identify them?
onality	How does WorkInHealth collaborate with other organisations and stakeholders in the healthcare industry to support European healthcare markets?
Additic	Do you consider the WorkInHealth network as successful as the education programme? E.g., does WorkInHealth develop lasting R+I networks beyond the education programme?
ing out	As it stands, does WorkInHealth have measures in place to be on track to fulfill it's organisational goals and eventually oversee a complete transition to financial independence from EIT Health?
Phas	Do you consider the measures that WorkInHealth have for financial independence from EIT Health appropriate to that end?

Source: Compiled by the study team.

Case Study No 5: Transitioning from EDCTP2 to Global Health EDCTP3 Joint Undertaking: transition measures and lessons learned from the predecessor

Executive Summary

This case study reviews the transition from the second phase of the European & Developing Countries Clinical Trials Partnership (EDCTP2) to its third phase, namely the Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU). The scope of the case study has been defined and confirmed by the EC Policy Officers in February 2023. The focus of this case study is on the key measures adopted for transitioning from EDCTP2 to the Global Health EDCTP3 JU and lessons learned from the predecessor. This involves the efforts undertaken to sustain the successes and incorporate the lessons learned as well as the effective communication to external stakeholders about the activities of both phases of the programme, among others. The case study covers the time period between November 2021, when the JU was established, and when EDCTP2 moved into the phase of managing current projects to successful completion until 2026, when the mandate of EDCTP2 is set to expire. This time period was selected for the review because both phases of the programme are set to operate at the same time during it. Considering that EDCTP2 and EDCTP3 operate as

different legal structures (i.e., while EDCTP2 was established as a public-public partnership, EDCTP3 was set up as a Joint Undertaking), the Global Health EDCTP3 JU should not be understood as a direct extension of EDCTP2 but rather a new legal structure that builds on the successes and lessons learned from its predecessors.

Two overarching priorities guided the transition from EDCTP2 to the Global Health EDCTP3 during this period according to the key interviewed stakeholders from the Secretariat of the EDCTP Association, Members of the Global Health EDCTP3 JU Scientific Group and Stakeholder Group, and the Secretariat of EDCTP2. Firstly, there was an emphasis on the successful closure of ongoing projects by EDCTP2. Secondly, there was a focus on the establishment of the Global Health EDCTP3 JU as a new legal autonomous entity. Given that the legal bases establishing EDCTP2 and the Global Health EDCTP3 JU are different, these processes are not directly linked to one another. Overall, the findings of the case study demonstrate that the transition from EDCTP2 to the Global Health EDCTP3 JU has been smooth between November 2021 and early September 2023, however, a number of changes and challenges have limited the progress made towards these two priorities. These changes and challenges were primarily linked to adjustments that were necessary in light of different legal bases for the establishment of EDCTP2 and the Global Health EDCTP3 JU.

While there was a high level of thematic continuity between EDCTP2 and the Global Health EDCTP3 JU, five key changes mostly falling in the areas of technical and administrative operation of the EDCTP programme occurred as it transitioned from Article 185 TFEU public-public partnership¹ to Article 187 TFEU Joint Undertaking² in line with the new legal framework establishing the JU. These changes restricted funding eligibility rules (i.e., imposed new eligibility requirements for funding and financial coordination), expanded the scope of the Global Health EDCTP3's mandate, revised its governance model and funding mechanism and simplified its work with third parties.

While there were no specific institutionalised measures foreseen by the Council Regulation (EU) 2021/2085³ for the transition from EDCTP2 to Global Health EDCTP3 JU, a number of ad hoc measures and procedures have been put in place during the process to enable each legal entity to achieve its objectives, understand and implement their key roles and responsibilities and engage in internal and external communication and coordination. In addition, a series of challenges affected the transition such as the lack of clarity about the new roles of certain stakeholders in the process as well as the issues that emerged in relation to questions raised internally (about the redefined roles) and externally by the beneficiaries, contributing partners and the global health community more generally. These constraints may delay the achievement of the two overarching priorities of the transition. EDCTP2 may take longer than initially anticipated to successfully complete its ongoing projects.

Introduction

This case study provides an in-depth analysis of the **transition from EDCTP2 to the Global Health EDCTP3 JU.** Among the key aspects analysed are the transition measures and lessons learned from the predecessor. This involves the efforts undertaken to sustain the successes and incorporate the lessons learned as well as the effective communication to external stakeholders about the activities of both phases of the programme, among others. The scope of the case study has been defined and confirmed by the EC Policy Officers in February 2023. This topic has been selected for the case study to ensure that any successes and lessons learned in the process could be considered during the remaining period of the transition and beyond where relevant in line with the Council Regulation⁴ establishing the Global Health EDCTP3 JU. The case study covers the time period between November 2021 when the JU was established and EDCTP2 moved into the phase of managing current projects to successful completion until 2026 when the mandate of EDCTP2 is set to expire. This time period was selected for the review in this case study in collaboration with the European Commission because both phases of the programme are set to operate at the same time during it. The case study in particular considers the **transition period from November 2021** when the Global Health EDCTP3 JU was established and EDCTP2 moved into the phase of managing current projects to completion **until the end of2023** for which the information is already available. Moreover, forward-looking considerations were made anticipating that the mandate EDCTP2 is set to expire in 2026. The findings from the case study aim to not only provide the EC and other key stakeholders with an overview of the progress made and lessons learned during the transition but also inform the first interim evaluation of the Global Health EDCTP3 JU which focused on its performance during its initial phase of operations between November 2021 and February 2024, with data collection efforts showing the situation until the end of 2023.

The **methodological approach** to addressing two key evaluation criteria, namely Phasing out preparedness and Effectiveness, involved a combination of:

- **Desk research** was based on the review of various legal, policy and other types of documents published by EDCTP2, Global Health EDCTP3 JU, European Commission or the EDCTP Association which are cited throughout the document.
- Analysis of administrative and monitoring data calls launched and projects funded by EDCTP2 and the Global Health EDCTP3 JU to the extent possible based on the data available as of early September 2023.
- Feedback obtained through 12 interviews with representatives of the European Commission, EDCTP2 Secretariat, Global Health EDCTP3 JU Secretariat, and EDCTP Association Board. Interviews were also held with representatives of the contributing partners as well as the members of the GH EDCTP JU Scientific Committee and Stakeholder Group who have also been involved in previous phases of the EDCTP or expressed some views regarding the transition between EDCTP2 and the Global Health EDCTP3 JU and its impact on the EDCTP programme as a whole. The interviews helped obtain an in-depth understanding of the transition, including the key challenges and needs relating to phasing-out-preparedness and the critical success factors as well as lessons learned.

A few factors, which are primarily related to the early phase of the Global Health EDCTP3 JU, affected the preparation of the case study. Firstly, the monitoring and administrative data was available only for a small sample of projects (26) funded by the Global Health EDCTP3 JU which was not sufficient yet to inform the development of any meaningful conclusions (in comparison, for EDCTP2 we analysed 435 projects). Secondly, the lack of a systematic summary of progress achieved by the Global Health EDCTP3 JU in its key areas of activities during the early phase of the Global Health EDCTP3 JU's operations (November 2021- end of 2023), for instance in the form of annual activity reports, limited the availability of information for the evaluation. For an overview of evaluation questions, indicators, and data sources/methods, refer to Appendix 1.

Context

The EDCTP programme **consistently grew over the past 20 years** therefore the implementation of its evolving mandate required adjustments in the legal bases establishing

each new phase of the programme based on which its implementing structures were also set up. The EDCTP programme was initially launched in 2003 (EDCTP1) as a European Economic Interest Grouping (EEIG)⁵, while the financial support from the EU was provided in line with Article 169 of the Treaty establishing the European Community.⁶ Meanwhile, EDCTP2 was established in line with Article 185⁷ of the Treaty on the Functioning of the EU, under Horizon 2020, allowing the EU's participation in research programmes jointly undertaken by several EU countries. The second EDCTP programme was established with Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 which extended its governance framework to allow partnership between European and African countries and the scope of the programme to cover more diseases. To preserve and further advance the EDCTP programme, the proposal for the establishment of the EDCTP2 successor programme under Horizon Europe, the Global Health EDCTP3 JU (or EDCTP3), was announced on 23 February 2021. Since EDCTP2 and EDCTP3 operate as different legal structures, the Global Health EDCTP3 JU is not a direct extension of the EDCTP2 but rather an evolution and a new legal structure that builds on the successes and lessons learned from its predecessors which operated under the same programme.

While EDCTP1 and EDCTP2 operated as public-public partnership in line with Article 185 (and its corresponding Art. 169 in the prior Treaty) of the Treaty on the Functioning of the EU,⁸ the GH EDCTP 3 JU (or EDCTP 3) was **established on 19 November 2021 as Article 187 TFEU Joint Undertaking** in line with the Council Regulation⁹ establishing it (along with other Joint Undertakings under Horizon Europe). The Global Health EDCTP3 JU is set to run from 2021 to 2031. One of the key reasons for the change in the legal basis from public-public partnership established in line with Article 185 TFEU to the JU set up in line with Article 187 TFEU¹⁰ was to form a legal partnership between the EU on the one hand, and European and African countries on the other hand, with the EDCTP Association participating as the private partner.

Critical success factors and perceived challenges

To achieve a successful transition, it is important for all the involved stakeholders to adapt to the key changes introduced by the new legal framework establishing the Global Health EDCTP3 JU, adopt and use the measures and conditions set out for the orderly transition from EDCTP2 to the Global Health EDCTP3 JU and address the key challenges and needs arising during the transition. These measures should facilitate the implementation of **two key priorities** that guide the transition:

- Successful closure of ongoing projects by EDCTP2: Since 2021, EDCTP2 moved into the phase of managing current projects to completion and therefore did not launch any new calls. Despite some organisational and budgeting challenges relating to the approaching end of EDCTP2's mandate, the updated second interim evaluation showed EDCTP2 was running smoothly between 2017 and early September 2023. The key objective of EDCTP2 during this transition period is to successfully close all the ongoing projects by the end of 2025 and complete their reporting procedures by the end of 2026, including through the final evaluation of EDCTP2.
- Establishment of the Global Health EDCTP3 JU as a new legal autonomous entity building on the achievements and lessons learned from its predecessors: Since its establishment in November 2021, the Global Health EDCTP3 JU has been at the initial set-up and implementation stage, including recruitment of staff and establishment of various organisational bodies. During this stage, the JU has operated under the responsibility of the EC (while the indicative target for the shift to autonomy is foreseen by the end of November 2023). The implementation of the Global Health EDCTP3 JU is ensured by the programme

office, which is in the process of being established in Brussels under the leadership of an interim Executive Director and permanent Executive Director starting from the 16th of November 2023. On 23 November 2023, the Global Health EDCTP3 achieved financial autonomy from the European Commission. In total, the Global Health EDCTP3 JU has already launched 14 calls for proposals, including 7 in May 2022 and another seven between May and June 2023.¹¹

There are also several **internal and external factors** that have affected the transition from EDCTP2 to the Global Health EDCTP3 JU to date:

Long-standing commitment of the EDCTP programme to the principles of equity, diversity and inclusion: One of the key features of EDCTP has been that the programme operates as a 'partnership of equals' between African and European partners.¹² Since its establishment, the programme has dedicated extensive efforts to ensure that its work is closely aligned with African priorities and advocated strongly for African ownership of health research in the region. More balanced participation of all Participating States, co-ownership and co-leadership provided by European and African Participating States were identified during the second interim evaluation of EDCTP2 as critical to the impact and sustainability of the programme.¹³ Furthermore, it has promoted diversity and inclusion across the programme's operations and activities (e.g., by addressing institutional capacity/human capital needs in sub-Saharan Africa), working to ensure that they are free from discrimination (e.g., by involving less active countries that have less experience in participating in the EU calls for proposals and developing new partnerships that extend beyond the established historical links and overcome language barriers) and by supporting the participation of any vulnerable parties (e.g., by funding studies targeting populations that are hard to reach or often excluded from clinical studies but have major medical needs such as breastfeeding women, and newborns and young children).

Overall, EDCTP is still viewed as a programme with considerable contributions towards addressing the issues of global health inequalities through its efforts to respect the principles of the co-ownership and co-leadership of both European and African Participating States. Certain changes in the legal framework establishing the Global Health EDCTP3 JU have raised questions among the interviewed stakeholders about the extent to which the programme presents the continued commitment to upholding its long-standing commitment to these principles through its third phase.

- **Impact of the COVID-19 pandemic:** The pandemic has further highlighted that, with the increased connectivity of different regions in the world through world trade and tourism, infectious diseases can rapidly spread all over the world further emphasising the importance of the EDCTP's mandatec This will allow the timely conclusion of all EDCTP2 projects by the time the mandate of EDCTP2 ends.
- Impact of the war in Ukraine: The contributions of Participating States to EDCTP have been at least partially affected by the war in Ukraine since 2022. Since then, Participating States indicated intentions, according to the interviewed stakeholders, to reduce their cash contribution (while at the same time increasing their in-kind contributions).¹⁶ As a result, Participating States' cash contributions to the Global Health EDCTP3 JU may be smaller.
- Effect of the withdrawal of the UK from the EU: Given the UK's significant contributions to the global health sector, its withdrawal from the EU has played a role in the evolution and implementation of the EDCTP programme. According to

some interviewed stakeholders, the UK's withdrawal from the EU was an important factor in the decision to change the public-public partnership operating in line with Article 185 TFEU¹⁷ to Article 187 TFEU Joint Undertaking¹⁸ to find a potentially more effective way to collaborate with the Participating State that provides some of the most significant contributions to the programme. The involvement of entities based in the UK has still been affected by some challenges, for instance in relation to their eligibility for participation on the one hand, and their non-eligibility for receiving EU funding on the other. However, the UK's Association to Horizon Europe framework programme has been agreed on 7 September 2023. Association with Horizon Europe will allow researchers and organisations in the UK to participate in the Horizon Europe programme on equal terms with researchers and organisations from EU MSs, including in the Global Health EDCTP3 JU. The new status came into effect from 2024.

Please refer to the subsequent section for a more detailed discussion of the impact of these factors on the transition between EDCTP2 and the Global Health EDCTP3 JU.

Reflections on evaluation criteria

Effectiveness criteria

While there has been a high level of thematic continuity between EDCTP2 and the Global Health EDCTP3 JU, there were **five key changes** that occurred in the EDCTP programme during its transition from Article 185 TFEU public-public partnership¹⁹ to Article 187 TFEU Joint Undertaking²⁰ in line with the new legal framework establishing the JU, including:

- Restrictive funding eligibility rules
- Expanded scope of the mandate
- Revised governance model
- Revised funding mechanism
- Simplified work with third parties

Restricted eligibility rules for funding

Since the launch of the GH EDCTP 3 JU under Horizon Europe in line with Article 17(2) of the Horizon Europe Regulation,²¹ its **funding is restricted to legal entities** established **in EU Member States, Associated Countries or constituent states of the EDCTP Association**. The Regulation foresees that the entities established in other sub-Saharan African (SSA) and other Third Countries should still be able to participate in the calls as associated partners to grants without receiving funding. It also sets out a few exceptions²² which make it possible for the entities established in countries other than members of the EDCTP Association to be eligible for funding.

Initiatives were undertaken to mitigate the impact of these changes. An effort has been made to invite more countries in Africa to join the EDCTP Association. This has borne fruit as the membership of the EDCTP Association has been expanded to 28 countries from sub-Saharan Africa as of February 2024. In addition, a number of exceptions exist that allow funding of legal entities in SSA countries that are not members of the EDCTP Association: declaration of participation; provisions in the work programme; as well as calls for proposals addressing a public health emergency. Overall, according to the legislative measures imposed by Article 187 TFEU²³, each initiative, including the Global Health EDCTP3 JU is flexible to adjust its funding rules. Further mitigation measures that could be considered to be included are the coordination efforts with other research funders to include participants from Africa or countries that are not members of the EDCTP Association.

Restricted eligibility rules for the role of financial coordinator

Article 110(2) of the Council Regulation 2021/2085²⁴ foresees that only those entities from Third Countries that are established in a country that has concluded a bilateral Science and Technology (S&T) agreement with the EU can be considered as (financial) coordinators of a project in line with Article 7 of the Model Grant Agreement (MGA). In addition, individual payments always have to be made to the coordinator instead of beneficiaries. As of early September 2023, South Africa is the only member of the EDCTP Association (that is not an EU Member State) that has signed a S&T agreement with the EU. These restrictions represented a significant change in terms of the eligibility of the entities to receive funding from EDCTP as the entities from all countries in SSA could receive funding and participate as financial coordinators in EDCTP1 and EDCTP2.

Overall, the impact of these fundamental changes in the eligibility rules on the success of the EDCTP programme remains to be assessed in the future. There is currently no monitoring and administrative data available to the evaluation team (as of early October 2023) to estimate the impact of these changes on the participation levels of legal entities established in SSA countries without S&T agreements in place. Nearly all the interviewed stakeholders expressed concerns that the general perception within the global health community is that these changes represent regress in the EDCTP programme despite its long-standing commitment to the principles of the co-ownership and co-leadership of both European and African Participating States, which have been identified as critical to the impact and sustainability of the programme. The majority of interviewed stakeholders expected the negative perception of the potential beneficiaries about the restricted eligibility rules to be reflected in the decreased number of entities from SSA without S&T agreements in place in the coming years. They also emphasised that financial coordination of projects represented one of the capacity-building tools for institutions in the SSA which, without the capacity of these institutions to exercise these capacities according to the constraints of the new legal framework, is likely to result in significantly deteriorated or lost progress in this area.

To ensure that all partners in the funded consortia, including sub-Saharan African entities, would have equal opportunities to lead the scientific work of the projects funded by the Global Health EDCTP3 JU, the Governing Board has approved a new approach that would establish a 'Scientific Project Leader' role within each consortium. In the 2023 work programme of the Global Health EDCTP3 JU, further clarifications about the tasks that this role entailed were specified.²⁵ If the coordinator is not established in a country in SSA, the new provisions foresee that the designation of a scientific project leader established in an SSA country member of the EDCTP Association is mandatory and thus a work package on 'scientific project leadership' must be included. While the introduction of the new Scientific Project Leader role has been widely recognised among the interviewed stakeholders as a positive move, it was not considered a sufficient measure to address the risk presented by these fundamental changes in the legal framework. Other interviewed stakeholders noted, however, that the appointment of a scientific coordinator (different than a financial coordinator) is not unusual in Joint Undertakings that, for instance, involve SMEs, start-ups, or other organisations. This process does not undermine coordinators' scientific competences and capabilities. However, more time is needed to reinstate the trust in a scientific coordinator's role among the Global Health EDCTP3 JU's funded beneficiaries. Despite these challenges, the membership to the Global Health EDCTP3 JU has grown, with 27 African countries and 15 European countries joining as of mid-October 2023.

Other potential mitigation measures may thus need to be considered regarding communication and extended roles. In the area of communication, these measures may include continued efforts to communicate about the new legislative changes to sub-Saharan stakeholders, including communications in other languages than English (e.g., French,

Portuguese); further clarify how the scientific leadership role should be implemented by the African entities, for instance, whether scientific coordinators view that they are truly in the lead; continue organising (financial) workshops that help to explain the Global Health EDCTP3 JU financial and management aspects for the beneficiaries, as well as continue explaining the differences between EDCTP2 and the Global Health EDCTP3 JU; and remain transparent and clear about the Global Health EDCTP3 JU financing rules regarding external strategic partners. In the area of **extended roles**, potential measures may include the establishment and increased involvement of the EDCTP Association, and particularly its Africa Office or any other African entity to manage financial coordination in SSA; or establishing an agency in South Africa or the EU that exclusively performs the financial management role without participating in research. It is important to note that some of the core mitigation activities, such as further change of the legislation, would extend beyond the scope of the GH EDCTP JU's activities and could be achieved only at the higher political level.

Expanded scope of the EDCTP mandate

In the context of the Commission's priorities of the **UN Sustainable Development Goals (SDGs)**, in particular, **SDG 3**²⁶, and the joint communication from the Commission of 9 March 2020 entitled 'Towards a Comprehensive Strategy with Africa',²⁷ the EU is committed to contribute to ensuring healthy lives and promoting well-being for all, to building an even stronger partnership between the two continents and to supporting the development of research and innovation capacities within Africa. In light of these priorities, there is a need to address the lack of appropriate diagnostics, treatments and vaccines, among other health technologies, to address infectious diseases, such as HIV, malaria and tuberculosis, but also other poverty-related and neglected infectious diseases, that are prevalent in Africa, especially in sub-Saharan Africa. The COVID-19 pandemic has further highlighted that the increased connectivity of different regions accelerated the spread of infectious diseases all over the world. Developing health technologies is therefore crucial to limiting the spread of infectious diseases, as well as fighting them once they have spread, and protecting the health of citizens in the countries concerned and in the EU.

According to the Strategic Research and Innovation Agenda (SRIA) 2022²⁸, the Global Health EDCTP3 JU will **maintain the focus on poverty-related infectious diseases** and successful approaches established in the EDCTP1 and EDCTP2 programmes but **extend beyond** it to reflect changing global, regional, and national contexts as well as advances and lessons learned for clinical research studies and related technology platforms in response to the COVID-19 pandemic. In order to achieve a stronger global health leadership than the preceding EDCTP2, **the scope of the GH EDCTP JU was extended** to cover response to emerging infectious diseases threats, the increasing problems of AMR and non-communicable diseases co-morbidities. All the interviewed stakeholders have agreed with **a high degree of relevance** of the Global Health EDCTP3 JU's objectives, considering the current needs and challenges within the field. They called for more efforts to **consider the potential synergies and complementarities** between the activities undertaken and other EU/international priorities and flagship initiatives.

Revised governance model

The governance of the Global Health EDCTP3 JU is led by a Governing Board, in which both the EDCTP Association and the European Commission have equal votes. The Governing Board, which is made up of 12 members (six from the EU, where the EC's vote is indivisible, and six from the EDCTP Association Board), is the overall decision-making body of the Global Health EDCTP3 JU. The implementation of the Global Health EDCTP3 JU is ensured by the Secretariat, which is in the process of being established in Brussels under the

leadership of an interim Executive Director and permanent Executive Director starting from the 16^{th of} November 2023. The Global Health EDCTP3 JU is advised by a Scientific Committee and a Stakeholders Group.

These revisions of the governance model in the EDCTP programme aimed to bring a stronger political and operational role for the African countries in the partnership and a better-defined role for the EC in the governance of the partnership. While the EU has participated as an observer in EDCTP2 in line with the Delegation Agreement from the EU, the EDCTP Association has previously been involved as the implementing body, with the overall decision-making body being in the hands of the General Assembly and the overseeing and supervision of activities in the hands of six members of the Board. These changes have also resulted in certain challenges, for instance, relating to a different role, coordination and decision-making on the side of the EC and the EDCTP Association, which brings together a diverse group of Participating States according to the interviewed respondents. Furthermore, there were questions raised about the role of the Africa Office (in Cape Town) during the transition from EDCTP2 to the GH EDCTP JU and the extent to which it is still viewed as a critical and integral part of the EDCTP programme, which tangibly provides the regional presence of EDCTP in Africa and consequently represents EDCTP not as a foreign organisation to stakeholders in SSA. Potential measures which could better define the future role of the EDCTP Association as well as the Africa Office, as suggested during stakeholder consultations, include:

- For EDCTP Association: implementing grants (as financial coordinator), cofinancing participants from non-eligible SSA or other countries; overseeing and ensuring that EDCTP2 is fully completed; establishing internal governance or structures to come up with potential strategic priorities, while suggesting and discussing them in the Governing Board; attracting and maintaining funding (members fees, funding from DG INTPA programmes, etc).
- For Africa Office: being involved in the Global Health EDCTP3 JU as an observer; continuing to work towards an increased engagement and visibility of the EDCTP programme in Africa, including the collaboration with African organisations such as African CDC, African Union, and the African Medicines Agency; guiding African countries in their participation in the Global Health EDCTP3 JU; contributing to the discussions about potential strategic priorities with the EDCTP Association.

Revised funding mechanism

The total budget of the Global Health EDCTP3 JU is expected to amount to approximately EUR 1.6 billion (see Table below).²⁹ The EU's financial contribution to the Global Health EDCTP3 JU, including EEA appropriations, to cover administrative and operational costs will be EUR 800 million.^{30 31} The EDCTP Association will contribute at least EUR 400 million and contributing partners, such as philanthropic organisations and industry, will add up to EUR 400 million. The total funding for the previous EDCTP2 programme (2014-2020) was over EUR 1.4 billion, with a contribution of EUR 683 million from the EU.

Table 105. Funding partners and their expected contributions within Global Health EDCTP3 JU

Funding partners	Expected contributions, EUR, millions
European Union	800
EDCTP Association	At least 439
Third Parties	Up to 400
Total	Approximately 1 639

Source: adopted based on the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe.

During EDCTP2, several European Participating States have contributed to calls for proposals launched by EDCTP with EU funding, increasing the number of projects that could be financed and the chances to better tackle the challenges (please refer to Appendix 2 for a more detailed presentation of the trajectory of EDCTP2 project funding). Between 2014-2020, African Participating States dedicated approximately EUR 5.4 million to EDCTP2, and European Participating States (including the United Kingdom) contributed EUR 1 141 million (including PSIAs). Pooling of balanced funding across Participating States has been challenging. The revisions made to the funding mechanism mean that SSA countries can participate and benefit financially from the Global Health EDCTP3 JU only if they are members of the EDCTP Association. As a result of these changes and thanks to the role played by the EDCTP Association Africa Office and EDCTP2 High Representative(s) in communicating the benefits of the membership by talking to country representatives one by one, it has grown from 16 to 25. There are 9 new members and 2 additional ones in the process of signing up. The revised funding mechanism is thus expected to ensure greater financial sustainability of the partnership even though the cash contributions from certain individual Participating States compared to EDCTP2 may be smaller as discussed in Section 3.

Simplified work with third parties

With the change to Article 187 TFEU JU³², in addition to Participating States and Associated Countries, **other key global players are able to join the initiative** and contribute to the partnership, leveraging investments from different types of partners and bringing together the unique strengths of the partners. These are philanthropies (e.g., BMGF, Wellcome Trust, etc.), foundations (e.g., CEPI), industry (e.g., EFPIA, etc.) and other Third Countries (e.g., United Kingdom, Japan, etc.) and they can participate on an ad-hoc basis. Moreover, all these partners' contributions should be matched by the EU contribution, increasing the leveraging effect and the coherence of the initiative. Through the 2022 work programme of the Global Health EDCTP3 JU, the **first such collaboration was implemented with the Bill & Melinda Gates Foundation** for a joint programme on genomic epidemiology for surveillance and control of infectious diseases.

Phasing out preparedness criteria

Overall, the transition from EDCTP2 to the Global Health EDCTP3 JU has been smooth. However, a number of **challenges have caused delays** in terms of the progress made towards the key priorities. While there were no specific institutionalised measures set out by the Council Regulation (EU) 2021/2085³³ to facilitate the transition between EDCTP2 and the Global Health EDCTP3 JU, there were a number of ad hoc measures and procedures put in place during the process to enable each legal entity to achieve its objectives, understand and implement their key roles and responsibilities and engage in internal and external communication and coordination. A number of challenges affected the progress achieved during the transition. These challenges may result in considerable consequences for both EDCTP2 and the Global Health EDCTP3 JU during the remaining period of this transition and beyond.

In light of the five key changes in the EDCTP programme, there were efforts to set out a number of **measures and conditions** for the orderly transition from EDCTP2 to the Global Health EDCTP3 JU.

Measures adopted to enable EDCTP2 to successfully close the ongoing projects

The key objective of EDCTP2 during the transition period, was to successfully close all the ongoing projects by the end of 2025 and complete their reporting procedures by the end of 2026, including through the final evaluation of EDCTP2. While the overall trajectory of EDCTP2 projects (based on their original end dates) was set to gradually decrease from 376 in 2021 to none actively running in 2026, COVID-19-related delays further shifted the timeline as certain projects could not be closed in time, as shown in Appendix 2. As a result, the number of projects actively running is estimated to be somewhat higher in 2024 (180 instead of the initially estimated 147) and almost double in 2025 (85 instead of 44). The number of active projects is estimated to be 14 in 2026, while initially, no active projects were foreseen for this year. If a 6-month post-closure review period is factored in, the estimated number of projects per year is expected to be about the same in 2023 but somewhat higher in 2024 (229 instead of 203) and significantly higher in 2025 (132 instead of 87). The number of projects that are expected to be able to complete fully after the post-closure review is estimated to be 55 instead of 18 in 2026, and 6 projects are estimated to be able to complete fully only in 2027, while initially, no projects were foreseen to close this year.

COVID-19-related delays, especially in clinical trials, implied the need for additional funding. This has already been addressed to some extent by financial contributions (in total around EUR 14 million) from some EDCTP Participating States such as the UK, Germany, Sweden and South Africa, and also the Global Health EDCTP3 JU launching a dedicated call for proposals as part of its 2023 Work Programme. According to the interviewed member of the EDCTP2 Secretariat, while there were many questions and requests for support raised by the beneficiaries of the ongoing projects, priority had to be given to those projects which were most severely affected, considering the limited additional budget dedicated to them. Notably, most of the projects from a selected subset for additional funding have already recruited study participants who, in some cases, underwent medical interventions requiring follow-up.

Measures adopted to enable the Global Health EDCTP3 JU to set up as a new legal autonomous entity

A set of relevant measures was put in place to allow the Global Health EDCTP3 JU to set up its organisational structure and launch its activities while running under the responsibility of the EC.³⁴ During its initial phase of operations, the EC was responsible for the establishment and initial operation of the Global Health EDCTP3 JU until it had the operational capacity to implement its own budget in line with Article 173.³⁵ Therefore, DG RTD has helped the JU to launch its first calls in 2022 and evaluate the proposals received. The Global Health EDCTP3 JU relied extensively on the existing Commission tools and resources in line with the arrangements amongst the legacy JU, for instance, in the areas of IT and HR.³⁶ In addition, the JU also used other established procedures at the EC, in particular in DG RTD, for a range of other support operations, such as internal control, record management, data protection, or access to documents are assured by.³⁷ Overall, the active involvement and support received from the EC during the initial phase of operations has been appreciated by the interviewed members of the Secretariat. Some respondents highlighted that there were certain challenges that occurred during the handover of tasks between the EC officials and the new members of the Secretariat, for instance, relating to the timely exchange of know-how and provision of access to EC systems for newly recruited staff members of the JU Secretariat.

According to the interviewed stakeholders, an important factor in the establishment of a new legal entity of the Global Health EDCTP3 JU and the roll-out of its initial operations has been the high dedication of the staff from the European Commission involved in the initial operations as well as the newly hired staff of the JU. A well-experienced interim Executive Director was appointed. Despite the constrained resources, fundamental changes that had to be accommodated when establishing the new legal entity and various other factors which affected the process, he has been effectively leading the operations of the Global Health EDCTP3 JU during its initial phase while remaining in close collaboration with the EC.

The **recruitment of a permanent Executive Director**, which is run centrally by the EC HR services, **has been significantly delayed.** The appointment of a permanent Executive Director was announced in October 2023. Dr Michael Makanga, who is currently the Executive Director of the Secretariat of the EDCTP Association, was appointed as the permanent Executive Director. Dr Makanga assumed his post on 16 November 2023. The appointment of a permanent Executive Director will end the uncertainty which affected the performance of the JU during the transition period. This also enabled the completion of the autonomy process on 23 November 2023 and is expected to ensure continuity in visibility to the external stakeholders, practical operations and technical content due to Dr Makanga's long-term presence and expertise accumulated within the EDCTP programme.

Overview of the key roles and responsibilities

Currently, EDCTP2 and the Global Health EDCTP3 JU operate as two separate legal entities. However, they collectively organise some of the activities, such as through the organisational committee of the EDCTP Forum, where they both sit and the drafting of the call dedicated to the funding of EDCTP2 projects that experienced COVID-19-related delays. Although there is no formal agreement between the two entities in place to facilitate the flow of information, there are designated staff members that are part of a mailing list dedicated to matters of common interest to both EDCTP2 and the Global Health EDCTP3 JU to facilitate the sharing of information between the two Secretariats. Certain staff members of EDCTP2 have been heavily involved in helping with the specific tasks during the transition. This involves the preparation of inputs into the Global Health EDCTP3 JU's work programmes dedicated to in-kind additional activities (IKAAs), which are the types of contributions from Participating States managed by the EDCTP Association. There has also been a good level of collaboration between the two EDCTP2 Secretariat Executive Director and the Interim Executive Director of the Global Health EDCTP3 JU. However, there could be more direct collaboration between the Secretariats of EDCTP2 and the Global Health EDCTP3 in some areas. This could be improved as Dr Micheal Makanga has now been appointed as a permanent Executive Director to Global Health EDCTP3 JU.

The **Governing Board**, which is made up of 12 members (six from the EU and six from the EDCTP Association Board), is the overall **decision-making body of the Global Health EDCTP3 JU**. From the EC side, as noted by some of the interviewed stakeholders, the involvement of different DGs, such as DG RTD, DG INTPA, DG SANTE, DG GROW, and DG HERA, is important for increased collaboration from the EU. The six board members of the EDCTP Association also constitute the six-member Board of the EDCTP Association.³⁸ From the European side, the current Chair is from Germany, the first Vice Chair from Sweden, and the third board member from France. From the African side, there is the second Vice Chair of the Board from South Africa and two other Board members from Zambia and Uganda. This also facilitates information because all these members of the Governing Board

receive input from the rest of the JU Committee, which is the subset of the EDCTP Association General Assembly member countries that participate in EDCTP3 activities. The Governing Board also has relevant contact points in both Secretariats.

There were **differing views** among the interviewed stakeholders in terms of the **role played by** the **EDCTP Association** in the transition. While some respondents stated that the EDCTP Association has been at the forefront of the transition, others expressed concerns about the Global Health EDCTP3 JU being viewed as primarily the 'EU body' where the role of the EDCTP Association is very limited, particularly compared to EDCTP2 where it has played a leading role. Despite the lack of clarity about its role, the EDCTP Association has undertaken a number of specific actions to accommodate the transition, including the creation of a **specific working group**. This WG took steps to operationalise the role of the EDCTP Association in the Global Health EDCTP3 JU. One of the actions the WG took was to revise the statutes of the EDCTP Association³⁹ to include not only the activities of EDCTP2 but also the activities of the Global Health EDCTP3 JU. Since it was important to define the members that constitute the JU Committee (including the whole General Assembly without those that are only participating in EDCTP2), three sets of members⁴⁰ of the EDCTP programme were defined in Article 4.

According to the new measure introduced by the EDCTP Association, the Participating States receive annual invoices for contributions towards the administrative costs of the EDCTP Association's activities as it must meet the administrative reporting obligations under the Global Health EDCTP3 JU. Considering the administrative reporting obligations and the expertise accumulated on the side of the EDCTP2 Secretariat in conducting this type of reporting, a few members of the EDCTP2 Secretariat in the Hague are expected to be minimally maintained beyond 2026 strictly to run the activities of the EDCTP Association in relation to the Global Health EDCTP3 JU. These activities will include the provision of support to reporting activities of the EDCTP Association Board, the activities of the General Assembly, and the reporting activities of the Participating States.

The questions have been raised during the interviews about the extent to which the role of the EDCTP Association Africa Office has changed as the programme entered its third phase. Since it was originally set up in 2004, the Africa Office (based in Cape Town) was primarily responsible for maintaining the visibility of the EDCTP programme in SSA and serving as a point of contact for African researchers, policy makers, and other stakeholders as well as potential partnerships operating in SSA such as the AU, Africa CDC, WHO. In January 2023, the Global Health EDCTP3 JU awarded a three-year grant of EUR 1 million per year to the Africa Office to support the implementation of a broad range of JU-related activities, aimed at ensuring increased engagement and visibility of the programme in the SSA. In the capacity of a grant-holder, the Africa Office supports the Global Health EDCTP3 JU communication and dissemination activities. for in its instance. the organisation/moderation of the Info Days about the JU as well as the project management and financial coordination training for new grantees of the JU. There were questions raised regarding the extent to which the role of the Africa Office has changed as the programme transitioned from EDCTP2 to Global Health EDCTP3 JU. There was a sentiment communicated during the interviews that the Africa Office may not be regarded as an integral part of the EDCTP programme by some external stakeholders after it has been defined as a grant holder from the Global Health EDCTP3 JU. Therefore, there is a need to establish more clarity both internally and externally about the role of the Africa Office, how it has evolved from EDCTP2 to the Global Health EDCTP3 JU, and specifically their capacity to represent the EDCTP programme in SSA. Interviewed stakeholders noted that the Africa Office is one of the first plays to be contacted by African stakeholders if any questions emerge. The links between the Africa Office and the rest of the Global Health EDCTP3 JU may be further strengthened through the invitation of their representative to participate in the meetings of the SC and Stakeholder Group as observers to allow them to support the development of the work programme and other relevant matters.

Internal and external communication

According to the interviewed representatives of the Global Health EDCTP3 JU, the key changes between EDCTP2 and the Global Health EDCTP3 JU have been communicated in meetings and other outreach activities, such as through videos on social media platforms, involving both internal and external stakeholders. A number of the interviewed stakeholders highlighted that these efforts have not been sufficient considering various issues that have emerged. This can primarily be attributed to the lack of resources during the initial phase of operations when other activities had to be prioritised. Nevertheless, the interviewed stakeholders highlighted a few specific areas where both internal and external communication and collaboration should be improved.

Nearly all the interviewed stakeholders agreed that there is an urgent need to advance efforts to explain the evolution of the EDCTP programme, and the key changes introduced as the programme transitions from EDCTP2 to the Global Health EDCTP3 JU both internally and externally. Its importance and urgency have been highlighted since there have been cases where both the internal and external stakeholders expressed concerns or confusion over the links between the different phases of the programme, the roles of the EC funding or the EDCTP Association and its African Office in the programme and the lack of sufficient or timely communications between various organisational bodies of the Global Health EDCTP3 JU. There were also numerous concerns about the overall negative perception within the global health community about certain changes introduced in the new legal framework establishing the Global Health EDCTP3 JU, for instance in relation to the restricted eligibility rules and the revised governance model, and cases where various stakeholders questions whether they may represent the shift in terms of the EDCTP's longstanding commitment to uphold the principles of co-ownership and co-leadership of both European and African Participating States through its third phase. There is a need to develop and implement an internal and external communication strategy for the Global Health EDCTP3 JU that would enhance its capacity to mobilise actions through various communication, engagement, and dissemination activities. These actions should aim to address these emerging issues and concerns before they materialise in any further consequences for the short-term but also long-term operations and impact of the programme.

Another area where some communication issues have emerged to date according to the interviewed stakeholders is in relation to the operationalisation of the calls launched by the Global Health EDCTP3 JU to support EDCTP2 projects which have been affected by COVID-19. For instance, there were questions received from the beneficiaries of these projects on how their extension/grant start date requests could be formulated. However, the interviewed representatives of EDCTP2 thought that there was not sufficient involvement and collaboration of both entities in formulating an effective response despite the potential overlaps between the funding from both EDCTP2 and the Global Health EDCTP3 JU during the transition period but also other aspects such as the specificities of the ongoing clinical trials. These cases may suggest a need to create additional or reinforce the use of existing internal communication and collaboration mechanisms between the EDCTP2 Secretariat and the Global Health EDCTP3 JU Secretariat that could be used to align the position of both entities and suggest effective solutions to beneficiaries in similar cases. Certain improvements may be needed in relation to external communication and collaboration with contributing partners. Since the EDCTP programme has undergone a significant number of fundamental changes, the interviewed stakeholders have noted the need for additional guidance not only on the strategy of the Global Health EDCTP3 JU in securing the potential partnerships but also in assisting the potential or existing contributing

partners in navigating around the key changes in the EDCTP programme in order to preserve their long-standing collaboration in some cases with the EDCTP programme during its evolution. In such cases, the **use of a Memorandum of Understanding (MoU) among other tools may be considered** to facilitate the communication and collaboration of the potential contributing partners to clearly set out the roles and responsibilities as well as the key requirements for them in light with the new legal framework establishing the Global Health EDCTP3 JU.

Finally, most of the interviewed stakeholders suggested to dedicate **more attention to preserving the impact of the achievements of the EDCTP programme** to date. The key expectation detected during the consultations was that as the budget that is tapering down within the EDCTP2 programme and the capacity of EDCTP2 to implement various activities decreases, the **Global Health EDCTP3 JU would assume the primary role** in sustaining the impact of the achievements of the EDCTP programme. A **few staff members of EDCTP2** have already been **recruited by the Global Health EDCTP3 JU to bring a certain level of know-how and institutional memory** from managing EDCTP2 and ensure a reasonable level of continuity.

Key lessons learned and other important observations

There are **two overarching priorities** in the transition, namely the successful closure of ongoing projects by EDCTP2 and the establishment of the Global Health EDCTP3 JU as a new legal autonomous entity building on the achievements and lessons learned during the previous phases of the programme. Overall, the findings of the case study demonstrate that the **transition from EDCTP2 to the Global Health EDCTP3 JU has been smooth** between November 2021 and early September 2023, however, a number of changes and challenges among other factors have limited the progress made towards these two priorities.

While there has been a high level of thematic continuity between EDCTP2 and the Global Health EDCTP3 JU, five key changes mostly falling in the areas of technical and administrative operation of the EDCTP programme occurred as it transitioned from an Article 185 TFEU public-public partnership⁴¹ to Article 187 TFEU Joint Undertaking⁴² in line with the new legal framework establishing the JU. These changes restricted funding eligibility rules, expanded the scope of the Global Health EDCTP3's mandate, revised its governance model and funding mechanism and simplified its work with third parties.

There was a number of ad hoc measures and procedures were put in place during the process to enable each legal entity to achieve its objectives, understand and implement its key roles and responsibilities and engage in internal and external communication and coordination. In addition, a series of challenges affected the progress achieved during the transition such as COVID-19 or recruitment delays, lack of clarity about the new roles of certain stakeholders in the process as well as the issues that emerged in relation to questions raised internally (about the redefined roles) and externally by the beneficiaries, contributing partners and the global health community more generally. These challenges may limit the capacity of EDCTP2 to ensure the completion of its ongoing projects and the Global Health EDCTP3 JU to assume autonomy in line with a foreseen timeline.

A series of potential actions have been derived from the review of the transition between EDCTP2 and the Global Health EDCTP3 JU that followed the assessment of effectiveness and phasing out preparedness-related evaluation questions. The potential actions that would be most relevant in the short and long term include:

• EDCTP2 and the Global Health EDCTP3 JU should collectively ensure better operationalisation of the call for proposal aiming to address the COVID-19-

related delays in EDCTP2-funded projects through the more active use of existing internal collaboration mechanisms between EDCTP2 Secretariat and the Global Health EDCTP3 JU Secretariat or development of new ones.

- The Global Health EDCTP3 JU should **urgently develop and implement an internal and external communication strategy** to advance efforts to improve the communication about the evolution of the EDCTP programme and the key changes introduced as the programme transitions from EDCTP2 to the Global Health EDCTP3 JU both internally and externally. At the same time, the JU should consider advancing its communication and collaboration with contributing partners through additional tools such as the MoU. These measures could provide additional guidance not only on the strategy of the Global Health EDCTP3 JU in securing the potential partnerships but also in assisting the potential or existing contributing partners to navigate around the key changes in the EDCTP programme.
- Following the recruitment of the permanent Executive Director who has assumed his position in November 2023, efforts should be dedicated to recruitment for remaining senior management positions to enable the key functions as soon as possible.
- The EDCTP Association, including its Africa Office, should dedicate further efforts • to redefine its role within the new governance model of the Global Health EDCTP3 JU. The focus could be dedicated to engagement with the external stakeholders regarding the key changes and other factors that affected the transition from EDCTP2 to the Global Health EDCTP3 JU. The EDCTP Association should aim to maintain the funding from the EDCTP member states which is needed to carry out the coordination of the countries that are members of the EDCTP Association and that are participating in the Global Health EDCTP3 JU as well as attract and maintain funding from other sources (e.g., DG INTPA funding programmes). Furthermore, the EDCTP Association could assume a primary role in the identification of ways to ensure that the principles of the co-ownership and coleadership of European and African Participating States would be upheld in the third part of the programme despite the restrictions set out by the new legal framework. It could further internally discuss potential strategic priorities and bring them forward to the Governing Board for further discussions. A particular role could be played by its Africa Office, as it is one of the first places to be contacted by African beneficiaries, however, its links to the rest of the Global Health EDCTP3 JU should be strengthened. Potential measures for the future role of the EDCTP Association could include the Association implementing grants (as financial coordinator) and co-financing participants from non-eligible SSA or other countries as well as overseeing and ensuring that EDCTP2 is fully completed. Meanwhile, the Africa Office could be involved in the Global Health EDCTP3 JU as an observer and continue working towards an increased engagement and visibility of the EDCTP programme in Africa, including collaboration with African organisations such as the African CDC, African Union, and the African Medicines Agency, and to guide African countries in their participation in the Global Health EDCTP3 JU.
- With regards to the legislative changes which restricted funding eligibility rules concerning the financial coordination of projects, further efforts could be made to find solutions, for instance:
 - Further, the Scientific Committee, particularly its Equity and Diversity work group, should be involved in identifying suitable solutions as they are

already discussing the various questions relating to the implementation of the new legal basis and how they may be addressed.⁴³

- Explore the funding rules of other global health funders (e.g., NIH in the United States) and their solutions towards coordination and involvement of different stakeholders and countries in the financed projects. For instance, countries that cannot be financial coordinators could find potential collaborators through a dedicated and established platform similar to the NIH's *Matchmaker*⁴⁴ that shows potential programme officials, principal investigators, review panels, and other funding information for applicants who are seeking collaborations with the institutions from the United States.
- Continue to consistently communicate about the new legislative changes and differences between EDCTP2 and the Global Health EDCTP3 JU to sub-Saharan stakeholders, including communications in other languages than English (e.g., French, Portuguese).
- Discuss with beneficiaries how the scientific leadership role should be implemented and how it is viewed by the African entities, for instance, whether scientific coordinators view that they are leading projects.
- Continue organising (financial) workshops that help to explain the Global Health EDCTP3 JU financial and management aspects for the beneficiaries.
- Discuss the possibilities and capabilities of establishing an agency in South Africa or the EU that exclusively performs the financial management role without participating in research.
- The Global Health EDCTP3 JU should assume the primary role in **sustaining the impact of the achievements of the EDCTP programme since its establishment**. The focus should be not only on further efforts to ensure thematic continuity but also on utilising the internal and external know-how built during the implementation of the EDCTP when addressing the key changes and other factors affecting its performance.

Appendix 1: Overview of Evaluation Questions, Indicators, Data Sources & Methods

Evaluation questions	Indicators	Data sources/methods
Are there any factors that are more or less effective than others, and if so, what lessons can be drawn from this?	Identification of key changes and other factors that affected the transition from EDCTP2 to the Global Health EDCTP3 JU Overall perceptions of key stakeholders about the key changes and other factors affecting the transition from EDCTP2 to the Global Health EDCTP3 JU	Desk research Analysis of monitoring and administrative data Interviews
What are the foreseen measures and conditions set for the orderly phasing-out of the Partnership from the Framework	The extent to which appropriate measures and conditions were set out for the orderly transitioning from EDCTP2 to the Global Health EDCTP3 JU, including: • Measures adopted to enable EDCTP2 to successfully close the ongoing projects and allow the Global Health EDCTP3 JU to	Desk research Analysis of monitoring and administrative data Interviews

Programmeset up as a new legal autonomous entityfunding?building on the achievements and lessonsAre these measureslearned during the previous phases of the			
 appropriate with regard to a possible phasing-out (or renewal) of the partnership? Internal and external communication mechanisms adopted to facilitate collaboration between the key stakeholders involved in the transition Internal perceptions of key stakeholders about the extent to which the transition from EDCTP2 to the Global Health EDCTP3 JU has been smooth to date Observations of the key stakeholders, such as the Governing Board, about the perceptions of the actual and potential beneficiaries about the transition from EDCTP2 to the Global Health EDCTP3 JU 	Programme funding? Are these measures appropriate with regard to a possible phasing-out (or renewal) of the partnership?	 set up as a new legal autonomous entity building on the achievements and lessons learned during the previous phases of the programme Measures setting out the key roles and responsibilities of the key stakeholders involved in the transition Internal and external communication mechanisms adopted to facilitate collaboration between the key stakeholders involved in the transition Overall perceptions of key stakeholders about the extent to which the transition from EDCTP2 to the Global Health EDCTP3 JU has been smooth to date Observations of the key stakeholders, such as the Governing Board, about the perceptions of the actual and potential beneficiaries about the transition from EDCTP2 to the Global Health EDCTP3 JU 	

Source: Compiled by the evaluation team based on the methodological approach.

Appendix 2: Trajectory of EDCTP2 projects based on their current and estimated end dates

The overall trajectory of EDCTP2 projects (based on their original end dates) was set to gradually decrease from 376 in 2021 to 267 in 2023 and 44 in 2025 to none actively running in 2026. The number of managed projects per year increased, however, if a 6-month post-closure review period needed to fully close the project was factored in. This brought the number of projects to 394 in 2021, 294 in 2023 and 87 in 2025. Importantly, it was estimated that 18 projects would still need to undergo reporting procedures to successfully close in 2026.



Figure 84. Trajectory of projects based on current end dates

Source: Prepared by EDCTP2 Secretariat.







Table 106. Progress achieved in terms of key operational activities by the Global Health EDCTP3 JU by mid-October 2023

Activity	Timeline	Completion/progress (as of early September 2023)
Interim Executive Director appointed	22 December 2021	Completed (22 December 2021)
Global Health EDCTP3 JU becomes operational with first meeting of the Governing Board held	12 January 2022	Completed (Governing Board launched on 11 January 2022)
Strategic Research and Innovation Agenda adopted	12 January 2022	Completed
Scientific Committee established	Q1 2022	Completed (slightly more members than indicated as the maximum in the Council Regulation (16) secured*, the first meeting of the SC took place on 18 March 2022)
Work programmes sent for approval to the Governing Board	Q2 2022/Q2 2023	Completed (approved in May 2022 and April 2023 respectively)
Executive Director selected	Ongoing/ application closing date of July 2022 Foreseen in October 2023	In progress
Offices available	July 2022	Completed
Stakeholders Group established	Q1 2023	In progress (10 members secured, new call for expression of interest was launched recently (with a deadline for application by 11 June 2023)
Global Health EDCTP3 JU website launched	Q2 2023	Completed (interim page was launched on the website of DG RTD in Q1** while the dedicated website was launched in May 2023)
17 staff members recruited	As of Q3 2023	In progress
Permanent Executive Director announced	October 2023	Completed
Permanent Executive Director assumed his position	November 2023	Completed

Note*: Article 55(2) of the Council Regulation establishing the Global Health EDCTP3 JU foresees that the SC should have no more than 15 permanent members.

Note**: An interim website hosted various information for external stakeholders, for example the calls for Expression of Interest for the SC and the SG, vacancies, work programmes, the Strategic Research and Innovation Agenda, notice of info days and others.

Source: compiled by the evaluation team with information on activities and timeline adapted from the European Commission. Update on Global Health EDCTP3 Joint Undertaking. Health NCP Meeting. 27 April 2023. Author: Elmar Nimmesgern – interim Executive Director Global Health EDCTP3 JU and the Council Regulation establishing the Global Health EDCTP3 JU.

Case Study No 6: Mission on Cancer: taking EU's positioning in cancer research beyond what was done in the past while ensuring coherence and synergies with other EU programmes

Executive Summary

This case study highlights the coherence of the Cancer Mission with other policy initiatives (Europe's Beating Cancer Plan) and funding instrument (EU4Health). It also emphasises the Mission's additionality in terms of its specific focus on the cancer disease, tackling the entire disease pathway and going beyond research and innovation. It also presents the timeliness of cancer research by conducting the historical analysis of cancer research in the current and past framework programmes, as well as identifies where the concentration of cancer research is the most concentrated when considering the FP7, Horizon 2020 and Horizon Europe framework programme parts.

The case study follows a mixed-methods approach, including desk research, interviews, and unstructured data analysis to analyse the EU contributions to cancer research in previous framework programmes and international funders (National Institute of Health and Wellcome Trust).

Coherence with Europe's Beating Cancer Plan

Cancer Mission is an integral part of Europe's Beating Cancer Plan. Both Cancer Mission and EBCP tackle the entire disease pathway. Cancer Mission and Europe's Beating Cancer Plan have numerous thematic synergies, ensuring their coherence and avoiding overlaps through the clear division of roles and responsibilities. Both initiatives work closely, having different communication channels (Commission Services Group, Cancer Subgroup, Stakeholder group). Interviews with national representatives underscored the need for enhanced communication with National Contact Points to delineate the responsibilities of both initiatives. Simultaneously, discussions with EC Officials emphasised the ongoing efforts to gradually achieve clarity and coherence between the two organizations at the national level.

Coherence with EU4Health

EU4Health and Horizon Europe funding instruments work closely with cancer-related calls. Regular communication between the Cancer Mission and EU4Health is ensured. In addition, the HaDEA agency was introduced, overtaking the Cancer Mission's and EU4Health's calls for implementation and coordination. As for proposals, the area for improvement still exists, as applicants now decide where to put a more detailed proposal, and the risk of overlap between the programmes remains. Closer collaboration in drafting the proposals could be one of the solutions.

Introduction

The case study is completed as part of the Evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe (hereafter – Resilient Europe study), feeding into the interim evaluation of Horizon Europe. Five missions (i.e., Adaptation to Climate Change, Cancer Mission, Restore our Ocean and Waters by 2030, 100 Climate-Neutral and Smart Cities by 2030, and A Soil Deal for Europe) have been introduced under the Horizon Europe programme as a new way to bring concrete solutions to some of our greatest challenges. They have ambitious goals and will deliver concrete results by 2030²²³.

The overarching goal of Cancer Mission is to improve the lives of more than 3 million people by 2030 through prevention and cure and for those affected by cancer, including their families, to live longer and better²²⁴. Cancer Mission includes calls covering stages from cancer prevention to the quality of life of the survivors and their relatives. To implement this goal, the Cancer Mission has established synergies with other EU policy initiatives. This includes not only other Horizon Europe instruments and actions but also a close collaboration with other funding instruments working on cancer-related calls (e.g., EU4Health, the Digital Europe Programme, the Euratom Programme, and the Interregional Innovation Investments funding instrument)²²⁵.

Purpose of the case study

This case study provides a deep dive into the Cancer Mission from two perspectives:

- 1. **Highlighting the instrument's complementarity and synergies.** The case study is dedicated to analysing and highlighting coherence and complementarities with other EU policy initiatives and funding instruments (i.e., Europe's Beating Cancer Plan and EU4Health) addressing the demand for cancer research.
- 2. Assessing the Mission's additionality in terms of its specific focus on the cancer disease, tackling the entire disease pathway, and going beyond research and innovation.

Additionally, the case study has a **complementary Appendix of the historical analysis of cancer research in the current and past framework programmes** (i.e., Framework Programme 7 and Horizon 2020), which facilitates the analysis of the timeliness of cancer research in the Framework Programmes, especially when compared to other international funders. It also allows to depict where the concentration of cancer research is the most prominent/concentrated when considering the specific framework programme parts.

Scope of the case study

The analysis includes the two Mission's Work Programmes (2021-2022 and 2023-2024), the Cancer Missions Implementation Plan and the external evaluation of the Missions, published in August 2023²²⁶. As such, **the case study covers the period from the Mission's initiation in 2021 to the emerging findings that can already be reported in the second quarter of 2023**. The assessment of synergies includes Europe's Beating Cancer Plan policy initiative and EU4Health funding instrument. Europe's Beating Cancer Plan (hereafter, EBCP) and EU4Health were selected due to their close collaboration with the Cancer Mission (hereafter, Mission) in their calls, activities, shared initiatives and projects.

Synergies with EBCP are primarily analysed in terms of the thematical similarities and the joint projects the programmes are working on. The analysis mainly highlights the

²²³ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizoneurope/eu-missions-horizon-europe en

²²⁴ European Missions, Cancer, Implementation Plan

²²⁵ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-

europe/eu-missions-horizon-europe/eu-mission-cancer_en

²²⁶ Horizon Europe: EU Missions (europa.eu)

complementarities (and potential overlaps) of Cancer Mission and EBCP in their shared initiatives, such as the following:

- European Initiative to UNderstand CANcer (UNCAN.eu.). The UNCAN.eu initiative is one of the 13 specific objectives of the Mission on Cancer and one of the ten flagships of Europe's Cancer Beating plan. The Coordination and Support Action (CSA) named "4.UNCAN.eu" is planned to generate a blueprint for UNCAN.eu.
- Federated digital platform supported by and for patients and cancer survivors to exchange real-world health data. Europe's Beating Cancer Plan has the flagship initiative 'Better life for cancer patients' aiming to create the 'European Cancer Patient Digital Centre', which supports exchanging patients' data and monitoring survivors' health conditions. Cancer Mission works together towards the creation of a European Cancer Patient Digital Centre. The blueprint of the digital platform is expected to be created by the end of 2023.
- Creation of 'National Comprehensive Cancer Centre(s)' in all Member States and EU networks by 2025. It's Europe's Beating Cancer Plan flagship initiative and one of Cancer Mission's Calls (Work Programme 2021-2022).

Concerning the coherence in the funding instruments, to this date, **EU4Health** has published 3 Work Programmes (2021, 2022, 2023). Out of these Work Programmes, there are several cancer-related calls: 4 in WP2021, 11 in WP2022, and 9 in WP2023. All of these actions are also reflected in Cancer Mission calls, ensuring the EU4Health and Horizon Europe funding instruments complementarities regarding cancer-related topics and activities.

In addition, the historical cancer analysis is conducted as an Appendix of this case study (Appendix 2). The Appendix includes two analyses: 1) the analysis of neoplasms publications using Medical Subject Headings classifications (MeSH)²²⁷. The analysis covers FP7 and Horizon 2020 programmes (Horizon Europe data is not available for this analysis yet), as well as two international funders – National Institutes of Health (NIH) and Wellcome Trust (WT); 2) analysis of cancer-related projects and EC contributions using the EU monitoring data, including the CORDIS projects data from FP7, Horizon 2020 and Horizon Europe. Here, due to the availability of data, Horizon Europe projects are covered until the end of 2022. Cancer-related projects were filtered out by the projects' abstracts, including 'oncology' and/or 'cancer' keywords.

Methodological approach

The case study is developed using a twofold approach:

- First, the case study analyses the relevance of the Cancer Mission and its coherence with the selected policy initiative (EBCP) and funding instrument (EU4Health).
- The second part mainly focuses on the relevance and timeliness of research through the historical cancer analysis across the predecessor framework programmes (Appendix 2). It provides the quantitative analysis of unstructured data used to analyse the EU contributions to cancer research in previous framework programmes, namely Framework Programme 7 and Horizon 2020, and international funders NIH and WT. A

²²⁷ https://www.nlm.nih.gov/mesh/meshhome.html

more detailed methodological approach to the data analysis is provided in Appendix 2 of this Case Study.

The case study will analyse the Mission in light of the following evaluation questions:

Evaluation questions

Relevance: Has the Cancer Mission tackled the right issues given the positioning of the European Union in this area since the programme started and over time?

Coherence: How coherent has the Cancer Mission been with other EU programmes serving similar objectives (Europe's Beating Cancer Plan, EU4Health)?

Coherence: What is the positioning of Cancer Mission within the overall European research and innovation landscape (incl. R&I funds at national, regional and European levels) and beyond (at the international level)?

Coherence: What could be done to improve the coherence of the Cancer Mission interventions with other initiatives to better deliver on the European Union policy objectives?

To assess these questions, the study team has done an in-depth assessment of the position of the Cancer Mission in Horizon Europe and the overall European research and innovation landscape. The analysis mostly relies on qualitative methods, including extensive desk research (involving, among others, the Mission on Cancer Interim report, Work Programmes 2021-2022 and 2023-2024, the evaluation of Horizon Europe Missions, Open Public Consultation (OPC) analysis, and interviews). Additionally, the analysis will be supplemented by the survey results.

In total, **11 interviews with various EC Officials (e.g. DG SANTE, DG RTD, HaDEA) and other stakeholders (National Contact Points, members of Cancer Mission Board)** were conducted. In addition, regular communication and relevant exchanges with the Resilient Europe Cancer Mission coordinators were made.

Context and background to the case study

Cancer Mission

EU Missions were created as a novel way to bring concrete solutions to the greatest challenges EU citizens face. The impact is delivered by **pooling the necessary resources to combine research and innovations with new forms of governance and collaboration**, including the industry, research organisations, governments, and citizens²²⁸. The Commission launched 5 EU Missions for 2021-2027, including the Cancer Mission. In the Missions Work Plan of Horizon Europe 2021-2022, **EUR 255 million were allocated to Cancer Mission**²²⁹.

To ensure the impact within the ten years (2021-2030), Cancer Mission has the following **five** guiding principles²³⁰:

²²⁸ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizoneurope/eu-missions-horizon-europe en

²²⁹ https://research-and-innovation.ec.europa.eu/system/files/2023-02/ec_rtd_eu-missions-cancer-leaflet-en.pdf

²³⁰ European Missions, Cancer, Implementation Plan

Ensure equity and access to knowledge, research and care between and within countries, regions, and between people of different socio-economic backgrounds, genders, and age groups.

Promote innovation: social innovation, novel approaches to public procurement such as precommercial procurement, Living-Labs and other methodologies should be systematically pursued to stimulate innovation and out of the box solutions in healthcare and related sectors.

Allow for risk taking: not all innovative approaches will deliver, but we can learn from failure and avoid repeating past mistakes.

Work with "the coalition of the willing": Not all Member States and associated countries have to work on all specific objectives, but equally, national and regional differences in Europe should be taken into account. A group of Member States may decide to advance on certain intervention areas and implement actions, sharing their experiences and best practices.

Communication and citizen engagement: An informed and engaged citizen community, including cancer patients and survivors. Mission through national mission hubs and annual events.

The Mission on Cancer, together with <u>Europe's Beating Cancer Plan</u>, aims to provide a better understanding of cancer, allow the earlier diagnosis and optimisation of treatment, and improve cancer patients' quality of life during and beyond their cancer treatment²³¹. **The Mission addresses all ages and all cancers, including rare²³² and poorly understood cancers²³³.** It also addresses the cancer control continuum – from prevention, early diagnosis, and treatment to palliative and end-of-life care.

Intervention logic

Cancer Mission Implementation Plan indicates its **expected outcomes, targets, and indicators** for each of the specific objectives (see Figure 86):

1. Improve the understanding of cancer. Expected outcome:

²³¹ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizoneurope/eu-missions-horizon-europe/eu-mission-cancer_en

²³² Rare cancers are identified as those with an incidence of less than 6 per 100,000 persons per year,

https://www.esmo.org/policy/rare-cancers-working-group/what-are-rare-cancers/definition-of-rare-cancers

²³³ Both common and rare cancers, or cancer subtypes, at all stages of cancer, any age or part of society,

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-miss-2021-uncan-01-01

- a. The creation of the UNCAN.eu²³⁴ new understanding gained from analysing this wealth of data could be applied to other diseases beyond cancer.
- b. Buy-in and rational integration (synergies) with European Strategy Forum on research infrastructures (e.g. BBMRI29, EUBi, EATRIS30, ELIXIR31), European Health Data Space, EORTC Specta platform, Lifetime, the 1+ Million Genomes initiative, the Cancer Imaging Initiative, the One Million Microbiomes from Human Project, research institutes, Comprehensive Cancer Infrastructures, patient organisations, and international genetic consortia.

The target to monitor progress on the UNCAN, eu platform by 2030 is 500 000 cancer-healthy tissue paired samples available in the platform with complete clinical outcome data.

- 2. Prevention, including early detection and screening. Expected outcome:
 - a. For prevention, at least 5 new health promotion and prevention strategies were developed, tailored to the needs of vulnerable populations (including but not limited to people with disabilities, migrants and ethnic minorities, homeless people, children, pregnant women, the elderly and other socioeconomically disadvantaged groups).

Progress monitoring indicator: the number of prevention programmes addressing childhood and adult populations established in each Member State by 2030 for all 27 Member States and Associated Countries

b. **For screening**, at least 5 validated early detection methods are ready to be included in screening programmes.

Progress monitoring indicator: by 2030, the number of national or regional population-based screening programmes, including risk-based approaches.

- 3. Optimise diagnostics and treatment. Expected outcomes:
 - a. A clinical trial network throughout the EU-27 to support the sustainable conduct of academic trials.

Progress monitoring target: 90% of eligible cancer patients have access to Comprehensive Cancer Infrastructures (CCIs) by 2030.

- 4. Support and quality of life. Expected outcomes:
 - a. A better understanding of the unmet needs of cancer patients, survivors and their families;
 - b. Better supportive and end-of-life care and counselling, reducing societal costs and achieving a better quality of life focusing on cancer patients, survivors and their families;
 - c. Better access to supportive and end-of-life care and counselling services throughout the EU-27;
 - d. Creation of innovative jobs and growth in the area of supportive care and counselling, including for food, sports, services, diagnostics, med-tech and pharmaceutical industries.
 - e. One living lab will be set up in each Member State to discuss 'quality of Life with cancer' metrics for regular surveys by 2030;

²³⁴ an initiative to understand cancer, to have a platform that bring all relevant players and information together

The targets including indicators to monitor the progress: Member States reports on the Quality of life (QoL) survey by 2023; Better supportive and endof-life care and counselling, with reduced societal and financial costs, achieving a better quality of life for at least 50% of cancer patients, survivors and their families throughout the EU-27 by 2030.





* Quantitative and qualitative targets, based on evidence and monitored through a set of output, outcomes, impact indicators

Source: Cancer Mission Implementation Plan²³⁵.

Europe's Beating Cancer Plan

Europe's Beating Cancer Plan (EBCP) is another policy initiative, a key pillar of a stronger European Health Union and a more secure and resilient EU. EBCP, in the same way as Cancer Mission, focuses on cancer prevention, treatment and care²³⁶. The 4 key action areas where the EU can add the most value, according to the EBCP, are:

- Prevention
- Early detection
- Diagnosis and treatment
- Quality of life of cancer patients and survivors

In terms of funding, over the next 7 years, EBCP receives the following:

• EUR 1.25 billion in funding from the EU4Health programme²³⁷;

 $https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf$

²³⁵ https://research-and-innovation.ec.europa.eu/system/files/2021-09/cancer_implementation_plan_for_publication_final_v2.pdf 236 Europe's Beating Cancer Plan, Communication from the commission to the European Parliament and the Council,

²³⁷ https://research-and-innovation.ec.europa.eu/system/files/2023-02/ec_rtd_eu-missions-cancer-leaflet-en.pdf

- EUR 250 million from the Digital Europe Programme to cancer-related projects and other digital health investments;
- Up to EUR 500 million from the Marie Sklodowska Curie actions for projects in education, training and research on cancer, and national funds and private investments.

The policy objectives of EBCP are supported by the 10 flagship initiatives and multiple supporting actions, providing expertise and resources to be shared across the EU. A more detailed approach to EBCP will be overviewed in the next section on the coherence with the Cancer Mission.

EU4Health

EU4Health programme was established under <u>Regulation (EU) 2021/522</u> and adopted as a response to COVID-19 to reinforce crisis preparedness in the EU²³⁸. It is an unparalleled EU financial support in the health area with a budget of EUR 5.3 billion during the 2021-27 period.

Actors involved in EU4Health activities are EU countries, Third Countries, stakeholders (patient's associations, academics and healthcare professionals), the European Parliament, the European Commission, and the Health and Digital Executive Agency (HaDEA). It has synergies and complementarities with other funds, including Horizon Europe for health research. In this case study, cancer-related calls will be primarily discussed.

Findings according to the evaluation questions

Relevance

Relevance: 'Has the Cancer Mission tackled the right issues given the positioning of the European Union in this area since the programme started and over time?';

Cancer is among the key research areas in Horizon Europe²³⁹ and one of the key actions in the EU Health Union's priorities²⁴⁰ for several reasons:

- Cancer affects everyone regardless of age, gender or social status and represents a tremendous burden for patients, families, and societies at large;
- According to the European Cancer Information System, 2.7 million people are diagnosed with cancer, and 1.3 million die from cancer in Europe every year. If no further action is taken, the number of people newly diagnosed will increase by over 24% (or 3.24 million) by 2035.²⁴¹

The current projects and priorities of the Cancer Mission reveal that the Cancer Mission is tackling cancer through innovative solutions for cancer prevention and treatment, which aligns with the broader Horizon Europe goals. Furthermore, the Mission's goals

²³⁸ https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en

²³⁹ https://research-and-innovation.ec.europa.eu/research-area/health_en

²⁴⁰ https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en

²⁴¹ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizoneurope/eu-missions-horizon-europe/eu-mission-cancer_en

closely align and reflect the current challenges that Europe is facing. For instance, the ongoing projects address underlying and insufficiently addressed challenges such as lack of equity, innovation, childhood cancers and personalised medicine. The review of ongoing projects and their mapping to the specific objectives of the Cancer Mission illustrates that the present activities are very closely aligned with the goals of the Mission.

Specific objectives	Ongoing projects
Understanding of cancer	BCAST aims to identify women with a moderate to high risk of developing breast cancer by combining genetic and lifestyle information. It helped empower women and doctors with better knowledge of different subtypes of breast cancer and to build more individualised strategies for prevention and treatment. PrECISE developed predictive computational technology that uses molecular and clinical data to improve our understanding of disease mechanisms and to inform clinicians about the best strategies for therapeutic intervention.
Prevention and early detection	<u>MyPEBS</u> is the world's second-largest risk-based breast cancer screening trial. It could potentially improve the individual benefit/harm ratio of screening - such as earlier cancer detection and less intensive treatments in high-risk women, fewer false positives and over-diagnoses in low-risk ones. <u>FORECEE</u> project was based on Women's cancer risk Identification (WID) tests that predict a woman's individual risk of developing female cancers. Investigate the best ways to incorporate WID tests into large-scale, cost-effective screening and prevention programmes.
Diagnosis and treatment	UNCOBIOME uses cohorts of more than 3 000 patients with cancer across 10 countries to identify microbiome signatures related to cancer occurrence, prognosis and response to therapy. EUROSCARC aims to carry out innovative clinical trials to change clinical practice for childhood and adult patients with bone and soft tissue sarcomas. It enabled the development of a unique portfolio of clinical trials on sarcomas and the development of translational research projects.
Quality of life for patients & their families	<u>SurPass.</u> The Survivorship Passport (SurPass) solution was developed to provide survivors with a complete overview of their treatment and personalised recommendations, ensuring that medical professionals have access to all necessary information for future health issues. <u>eSMART</u> positively impacted services and patient outcomes in the five countries of the study by giving patients and professionals virtual means to assess and manage symptoms during chemotherapy in a home care setting.

Table 107. Cancer Mission's ongoing projects within the specific objectives

Source: Compiled by the study team based on the presentation EU MISSIONS, CANCER.²⁴²

To this date, out of 17 actions listed in the Mission on Cancer Implementation Plan, 9 are already in the implementation phase²⁴³. This means that while there are no closed projects yet, more than half of the projects have started their implementation stage in the first 2.5 years. As the Cancer Mission's main goals are set for 2030, it seems promising that the rest of the actions will also be implemented in the near future.

During the interviews, all interviewed stakeholder groups (Mission Board, EC Officials, and National Contact Points) **agreed that the relevance of the Cancer Mission is apparent**. The interviewees suggested that Mission is a very successful story in terms of its organisation and implementation due to its unique governance structure. Compared to other initiatives within the European Commission, the Mission was developed by joining national

²⁴² SLIDES: EU MISSIONS, CANCER: create solutions for our greatest challenges. https://research-and-

innovation.ec.europa.eu/system/files/2023-02/ec_rtd_eu-missions-cancer-leaflet-en.pdf

²⁴³ European Missions, Cancer, Implementation Plan

governments, public organisations, research institutes, industry, small and medium-sized enterprises (SMEs) and citizens together for one specific goal. The assessment of the Mission's progress (*EU Missions two years on: assessment of progress and way forward,* hereafter – Missions' assessment)²⁴⁴ found that a year-long Missions development process was the factor which **ensured that various leaders and stakeholders could participate in the selection process and to involve into co-design of Missions**. The inclusion and close collaboration with citizens and patients allow the Mission to be more visible in every Member State, which, according to the Mission's assessment, is critical for the Mission's development. As most of the Mission's projects are directly related to cancer patients and their relatives, their diagnoses, treatments, and stories are crucial to developing the targeted tools and programmes.

Examples of citizen engagement include the 2-week long dialogue online during the Covid-19 and various focus group discussions bringing together citizens from 26 countries²⁴⁵. In the external study's survey, 64% of the respondents agreed that the Mission encourages broad engagement and active participation of stakeholders and citizens²⁴⁶. In addition, the interviews with National Contact Points suggest that **Mission can be seen as an external pressure on the Member State government bodies to take further actions in their cancer-related research and promote the necessary developments faster.**

The relevance of cancer and, in particular, the timeliness of research are analysed in Appendix 2. The Figure below illustrates that the share of cancer-related projects increases over the framework programmes: 6.1% in FP7, 6.29% in Horizon 2020, and 6.78% in Horizon Europe. The current share of cancer-related projects in Horizon Europe is subject to change, as this is only an interim assessment of the programme. Still, the progress so far suggests that there is an increasing focus towards projects related to cancer. In addition, the EC contributions to cancer-related projects under Horizon Europe already comprise more than half of those in FP7.

As indicated in the Appendix 2 analysis, the Europeans are disproportionately affected by cancer. Looking at the global context, Europeans are 10% of the world population but have about 25% of all annual cancer cases. The fact that the contributions of the priorities in cancer-related publications and projects from the EU align with the contributions of the biggest funder, such as the National Institute of Health (NIH), underlines that **the EU tackles the right issues given the position of the European Union since the programme started and over time** (e.g., the highest share of cancer-related publications are focused on the breast cancer site, which is the most common cancer).

²⁴⁴ EU Missions two years on: An assessment of progress in shaping the future we want and reporting on the review of Mission Areas and areas for institutionalised partnerships based on Articles 185 and 187 TFEU

²⁴⁵ EU Missions two years on: An assessment of progress in shaping the future we want and reporting on the review of Mission Areas and areas for institutionalised partnerships based on Articles 185 and 187 TFEU

²⁴⁶ EU Missions two years on: An assessment of progress in shaping the future we want and reporting on the review of Mission Areas and areas for institutionalised partnerships based on Articles 185 and 187 TFEU

Table 108. Overview of cancer-related projects and EU contributions in FP7, Horizon 2020, and Horizon Europe

Prog ram me	Total number of projects	Cancer- related projects	Share of cancer- related projects	EC contribution to cancer-related projects (EUR, million)	EC contribution (total) (EUR, million)
FP7	25 790	1 574	6.1	2.4	46.0
H202 0	35 856	2 254	6.29	3.3	68.3
HE	9 459	641	6.78	1.4	24.6

Source: Compiled by the study team using EC administrative and monitoring data.

Among the areas for improvement to increase its relevance, the interviewees mentioned insufficient Cancer Mission's communication with general public. For instance, some suggested that it would be beneficial to organise some large-scale events, in addition to the communication in national languages in each Member State, and more information campaigns on social media are necessary. This would allow the Cancer Mission to better reach the patients and their relatives and raise awareness about the Cancer Mission, as this is one of the Mission's key elements (include all stakeholder groups when implementing the projects and get the relevant feedback).

Coherence with other EU programmes serving similar objectives

- How coherent has the Cancer Mission been with other EU programmes serving similar objectives (Europe's Beating Cancer Plan, EU4Health)?
- What is the positioning of Cancer Mission within the overall European research and innovation landscape (incl. R&I funds at national, regional and European levels) and beyond (at the international level)?
- What could be done to improve the coherence of the Cancer Mission interventions with other initiatives to better deliver on the European Union policy objectives?

Coherence with Europe's Beating Cancer Plan

Cancer Mission is an integral part of Europe's Beating Cancer Plan. Both Cancer Mission and EBCP tackle the entire disease pathway²⁴⁷. According to the Cancer Mission's implementation plan, one of the key elements to its success is ensuring coordination with and supporting the **implementation of Europe's Beating Cancer Plan**. The Mission aims to support and accelerate novel approaches to research and policymaking and ensure the implementation of proposed flagships and actions. It aims 'to spar cross-sectoral collaboration on an ambitious European scale, in order to integrate fundamental, translational, clinical, and interventional research, and innovation in new ways'²⁴⁸. Initiatives are working in close coordination, proposing activities that facilitate the implementation of the initiatives, including the network of Comprehensive Cancer Infrastructures and the Cancer Patient Digital Center.

²⁴⁷ https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf

²⁴⁸ European Missions, Cancer, Implementation Plan, p. 4

Since coordination with Europe's Beating Cancer Plan is part of the Cancer Mission implementation plan, it is important to look at their thematical synergies and to ensure that the initiatives complement each other but not duplicate their efforts. The Mission on Cancer supports the EBCP in enabling and accelerating new research and policymaking approaches in the field. They do this through funding from the Cancer Mission and the research activities performed within the Cancer Mission in the joint projects as preparatory actions for further policy implementations done by the EBCP. The Mission aims to ensure that EBCP's actions will be successfully implemented in an integrated approach to increase their impact in several ways:^{249 250 251}

- The Mission is delivering innovative concepts and solutions allowing the implementation of specific parts of the EBCP, going beyond research & innovation;
- The Mission generates knowledge and evidence for the implementation of new actions in the main areas of both the Mission and the Plan: understanding, prevention, diagnosis, treatment, and quality of life;
- The Mission on Cancer has National Contact Points (NCPs) to directly contact European citizens who are fully involved in co-creating specific activities. Citizen engagement activities at the national level add real value to both initiatives by providing direct citizens' feedback on the proposed initiatives.
- The Cancer Mission Board is the scientific advisory group for Europe's Beating Cancer Plan. The Chair and Vice-Chair have observer status in the Member States' subgroup on cancer, which consists of experts from health and research ministries.

The specific objectives of the Cancer Mission align with the EBCP goals, proving the complementarities of their work:

Increasing knowledge and understanding

- February 2022: Cancer Inequalities Registry
- June 2021: Knowledge Centre on Cancer

Boosting preventative measures

- February 2022: Joint Action on HPV vaccination
 - September 2021: HealthyLifestyle4All initiative

Improving treatment:

- December 2021: EU Network of Comprehensive Cancer Centres
- February 2021: Strategic Agenda for Medical Ionising Radiation Application (SAMIRA)

Helping everyone enjoy a high quality of life

• February 2022: EU Network of Youth Cancer Survivors

In addition, various flagship initiatives have already been implemented **under the EBCP and** Cancer Mission that complement the objectives of both programmes. As stated in the

²⁴⁹ https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/ncp

²⁵⁰ https://www.efpia.eu/news-events/the-efpia-view/blog-articles/mission-on-cancer-sustainable-science-based-efficient-approach-toward-reducing-cancer-burden-and-inequities-in-the-eu/

²⁵¹ https://www.horizon-europe.gouv.fr/establishing-national-cancer-mission-hubs-and-creation-network-support-mission-cancer-30515

Cancer Mission's Work Plan 2021-2022, coherence is ensured between the Cancer Mission and EBCP, complementing each other's work and objectives. The thematic and activities-related relationships are illustrated in Appendix 1, where the mapping of Europe's Beating Cancer Plan actions and Cancer Mission calls (WPs 2021-2022 and 2023-2024) is presented. EBCP has a total of <u>42 actions</u>, out of which 26 were mapped with calls from the Cancer Mission. The close collaboration, communication and the synergies in topics and activities for both initiatives complement their work. Cancer Mission is bringing knowledge, feedback and ideas from the national governments, as well as bringing research-related tools needed for EBCP to implement their flagship initiatives. In addition to that, the Cancer Mission facilitates the implementation process of 7 out of 10 Europe's Beating Cancer Plan flagship initiatives, which are also part of the ECBP actions. While both policy initiatives work closely together, their research and policy implementation roles differ slightly. Therefore, both initiatives work in close synergy in terms of their thematic relationship and complement the overall goal of the Cancer Mission.

The survey of Horizon Europe beneficiaries, conducted on May-July 2023, asked the participants working on the Cancer Mission projects, '*To which of the following key Europe's Beating Cancer Plan action areas does your project contribute?*'. A total of 150 participants answered this question. As illustrated in the Figure below, although the answers are scattered as the Cancer Mission projects tend to contribute to all EBCP priorities, the majority of respondents (59.1%) indicated that their projects especially contribute to the EBCP priorities linked to improving access to innovative cancer diagnosis and treatments. This was followed by 45.5% who noted that their projects contribute to the early detection of cancer objective, 40.9% to the diagnosis and treatment by ensuring quality care and medicines objective, and 31.8% to improving the quality of life of cancer patients and survivors. Those survey responses indicate not only that Cancer Mission and Europe's Beating Cancer Plan are working on the same priorities but also that the common projects that both are working on together, such as UNCAN.eu and the National Comprehensive Cancer Centre(s), work in action areas fostering the implementation of those initiatives.



Figure 87. EBCP and Cancer Mission coherence

Source: Compiled by the study team based on the survey programme, N=150.

The close coordination and collaboration allow the Cancer Mission and EBCP to clearly divide their roles and see which part of activities they should participate in and where and when the Horizon Europe funding or the EU4Health funding is needed.

The synergies between the Mission and the EBCP were discussed in the interviews. The common perception was that the two policy initiatives work very closely, given their shared activities and close thematic nature. During the adoption of the EBCP, there was an agreement between DG SANTE and DG RTD for the governance mechanisms, with the establishment of 3 groups, where all meetings are joint sharing:

- 1. Commission Services Group (Cancer Mission and EBCP implementation group) to coordinate within the Commission, where the Mission manager (from DG RTD) and the deputy mission manager (from DG SANTE) are participating;
- 2. Cancer Subgroup to bring all relevant members from Member States;
- 3. Stakeholder group, established under the Commission's Health policy platform.

Another example of collaboration and utilisation of different mechanisms is the <u>Network of</u> <u>Youth Cancer Survivors</u> established under the EBCP (DG SANTE), which DG RTD uses for consultations on their work on cancer survivorship.

Cancer Mission and EBCP have been working together since their establishment, and their synergies and efforts to avoid the overlaps are apparent from the beginning. With the decision to develop a Mission approach, DG RTD established the Cancer Mission Board. Meanwhile, the development of the EBCP started later on, and the EBCP used the Cancer Mission Board as an independent advisory body to consult on the development of their Plan.
Some main elements were taken from Mission, including the calls that the initiatives are now working together (UNCAN, European Cancer Patient Digital Centre, National Comprehensive Cancer Centres). Interviewees agreed that the EBCP's participation in all of the Cancer Mission activities, official and unofficial meetings, allowed both teams to distinguish their roles, avoid duplication of efforts, and see where the synergies could be ensured. It was mentioned in all interviews that, at least so far, the work together for the same initiatives is complimentary but not overlapping. In addition, having two initiatives focusing on cancer raises the visibility of cancer overall.

There is a division of work between the Cancer Mission and EBCP, as **Cancer Mission** works more on research-related tasks, while EBCP works more on a policy level. For instance, the UNCAN project is mainly research-focused, analysing how cancer develops and spreads in the human body. The research part is under the Cancer Mission. Then, the results of the project will feed into the policy level (EBCP). In addition, in the call for Comprehensive Cancer Centres and Infrastructures, two policy initiatives (Cancer Mission and Cancer Plan), together with two funding instruments (EU4Health and Horizon Europe) are working together, as it requires include the research activities, the provision of cancer care, integration of clinical research trials and uptake translation of results into standard practices.

While the coherence and avoidance of overlapping actions are ensured at the EC level, some areas for improvement in the synergies between the Cancer Mission and EBCP were noted in the Missions' assessment and interviews. The Missions' assessments indicated that for some stakeholders, the link between Mission Cancer and the EBCP is unclear²⁵². While the separation between policy on the one side (EBCP) and research on the other (Cancer Mission) is indicated, the Mission itself was not created only for the research. At the national level, as shown in the assessment, the representatives of the Member States get confused about which of the two should be prioritised. The interview programme also revealed that national stakeholders do not receive sufficient communication to be able to easily draw a line between EBCP and Cancer Mission on their priorities, activities and responsibilities.

Coherence with EU4Health

The <u>EU4Health (2021-2027)</u> programme provides financial and technical support to the Member States, helping efforts to strengthen health systems. EU4Health is addressing the resilience of European healthcare systems and is investing in urgent health priorities, including EBCP. As indicated in the interview, EU4Health upscales innovation has been proven effective and successful by Horizon Europe.

Cancer is a cross-cutting key area of focus in EU4Health. The Table below provides an overview of the thematic and project similarities between EU4health and Cancer Mission Calls. Calls were mapped out based on their topics; only 4 EU4Health calls were not mapped out with Cancer Mission Calls. The Table below indicates that EU4Health and Cancer Mission are working together or have similar thematic areas in case of screening and early detection, life of patient survivors, better understanding of the impact of risk factors and health determinants on the development and progression of cancer; prevention of cancer; Comprehensive Cancer Infrastructures; quality of life of childhood patients.

²⁵² EU Missions two years on: An assessment of progress in shaping the future we want and reporting on the review of Mission Areas and areas for institutionalised partnerships based on Articles 185 and 187 TFEU

Table 109. EU4Health and Cancer Mission Calls

EU4Health Calls	Cancer Mission Calls
Improving early detection (WP 2021) Monitor and strengthen implementation of innovative approaches to prostate, lung, and gastric cancer screening (WP 2022) IARC: to update the European guidelines for quality assurance in cervical cancer screening (2022) Direct grants to Member States' authorities: Implementation of cancer screening programmes (WP 2023) Call for proposals to support the implementation of the SAMIRA (WP2 2023) Direct grants to Member States' authorities: to support the implementation of SAMIRA (2023) Development of EU guidelines and quality assurance scheme for lung, prostate and gastric cancer screening (WP2023)	Develop new methods and technologies for cancer screening and early detection.
Development of a code of conduct on fair access of cancer survivors to financial services (WP2022) Study on obstacles for cancer survivors to return to work (WP2022) Action grants on mental health challenges for cancer patients and survivors (WP 2023)	Develop and validate a set of quality of life and patient preference measures for cancer patients and survivors.
Tobacco control policy, implementation and modernisation of tobacco control legislation (WP2022) Study on the effectiveness of health information on alcoholic beverages (WP2022) Study on the evaluation of the EU Action Plan on childhood obesity (WP2022) Evaluation study: use of sunbeds and cancer risk (WP 2023) Study on the quality of life of cancer survivors (WP 2023) Special Eurobarometer: attitudes of Europeans towards alcohol consumption as well as on the labelling of alcoholic beverages with respect to health policies (WP 2023)	Better understanding of the impact of risk factors and health determinants on the development and progression of cancer
Saving lives through sustainable cancer prevention (WP 2021) Direct grants to Member States' authorities: to establish an EU network of Comprehensive Cancer Infrastructures and new networks of expertise on cancers and cancer conditions (WP 2023)	Improving and upscaling primary prevention of cancer through implementation research Strengthening research capacities of Comprehensive Cancer Infrastructures.
Improving the quality of life for cancer patients, survivors and carers, including reducing inequalities in cancer care and childhood cancers (WP2021)	Establish best practices and tools to improve the quality of life for childhood cancer patients, survivors and their families in European regions.

Source: Compiled by the study team.

During the interview programme, the synergies between the Cancer Mission and EU4Health were identified in terms of their close-collaboration and communication, thematic-related calls and actions. However, the risk of overlap between programmes was identified as an area for improvement.

The interviews with EC Officials from DG RTD and DG SANTE underlined the **importance** of regular communication, with bi-weekly meetings between unit heads of the Cancer Mission (DG RTD), EBCP, and EU4Health (DG SANTE) to ensure smooth communication and coordination. Even more, when needed, other units also are included. For instance, DG CONNECT and JRC discussed the guidelines for implementing cancer screening and the interpretation of medical images. A forum with the European Investment Bank was also

established, focusing on new cancer therapies like proton therapy, with joint leadership from the European Investment Bank and DG SANTE.

To foster better synergies between EU4Health and the Cancer Mission, **the executive agency (HaDEA) was introduced**. HaDEA was established in 2021 and has teams working with cancer research for EU4Health and Cancer Mission. Interviews revealed that within the HaDEA units, a high level of coordination is ensured through systematic meetings (first occurring in June). It is on the way to becoming even more organised, systematic, efficient, and effective. HaDEA does not work on the drafts of the Work Programmes itself, but it coordinates all proposals related to EU4Health and Horizon Europe, bringing the health-sector proposals under the same roof, connecting the programmes working for the same purposes and fostering synergies. This approach is meant to add value to the implementation of the programmes (in terms of people, processes and initiatives), maximise coherence and avoid duplications. The new HaDEA setup helps facilitate the implementation of the programme for the applicants. It increases visibility to pertinent communities who do not know yet that an agency is responsible for cancer-related questions (for EU4Health and Cancer Mission).

Even though HaDEA is in place, the grey area between the two organisations exists because both EU4Health and Horizon Europe predominantly operate on calls for proposals. While the broader area of action is defined in the Work Programmes, it is up to applicants of the call where they decide to put a more detailed proposal. In other words, **proposals create a risk of overlap between the programmes, and there is an area for improvement.** Some interviewees indicated that there are certain mechanisms to avoid duplications of effort:

- Before the EU4hHealth Work Programme is adopted, possible priorities are discussed with other DGs in health funding interservice groups on the intentions in a general way and indicating main areas of possible interactions.
- Interservice consultations EU4Health annual work programmes and biannual work programmes from Horizon Europe are coordinated, and it is the final stage where the potential duplications are removed.

However, even with these mechanisms in place, other **interviewees with EC Officials suggested that the coordination between the directors from both sides is insufficient** and that drafting the Work Plans together would allow them to decide exactly what needs to be included in the calls. One interviewee suggested that for the Cancer Mission and EU4Health, independent governance structures with different timing, people, and procedures make coordination difficult in practice. In addition, the interviews identified that the potential improvements in synergies between the Mission and the EU4Health were related to the shortage of staff who can ensure better communication and **coordination at the national level.**

So far, at the national level, the Cancer Mission is under the responsibility of the Ministries of Research, while EU4Health is under the Ministries of Health. Interviews with EC officials revealed that it was the will of national governments not to join the different ministries to work together from the beginning. Such division is sometimes an obstacle for all, but mostly for the national governments themselves, as without ensured communication, the implementation of activities is not as efficient as it could be. The European Commission is working on ensuring the synergies between the Ministries by organising regular meetings where representatives of both ministries join together.

The perspective of the NCPs also emphasises the need for better and more transparent communication of the differences and responsibilities of each policy initiative /

funding instrument. So far, at the national level, the representatives would benefit from more recommendations and guidelines of practicalities on how to implement certain cancerrelated policy initiatives. Some conferences to disseminate the newest updates and share good examples and obstacles are already organised (e.g., Baltic conferences where the main organisers are NCPs, inviting researchers, patients' representatives, officials, practitioners and EC officials). Still, according to the interviews, the number is insufficient yet. The interview with the EC Official also identified that the organisation of high-profile events (i.e., conferences) could be held to showcase to the Commission and the external stakeholders how the cancer-related projects are synergising and how to make the best of it. The broad dissemination could incentivise an expanded pool of applicants to apply for more welltargeted projects. During the interview with the EC Official it was also pointed out, that the European Commission is fully aware that the people need to understand the synergies between the Cancer Mission, Europe's Beating Cancer Plan and EU4Health and the Commission is gradually building that understanding by identifying the different groups at the national level that need to be informed. For instance, several good practices of better communication between the countries were provided in the interviews with NCPs' and EC Officials.

A good example of collaboration is Estonia, where the National Network on Cancer Mission was initiated. The network organises events to disseminate information about the cancer mission and set goals, activities, and roles for the national network. The network brings together academia, different Ministries and other institutions, such as:

- The University of Tartu (which is also the leading research centre)
- Ministry of Social Affairs (that also takes care of healthcare)
- National Institute for Health Development (that takes care of National Cancer Registry maintenance)
- Estonian Research Council
- North Estonian Medical Centre (that is the biggest hospital in Estonia with increasing emphasis on research)
- Tartu University Hospital
- Ministry of Education and Research
- Ministry of Environment

Additionally, the interview with the EC Official provided another national-level collaboration example in cancer, called the Mirror Group (so far, 5 countries have introduced this initiative - Spain, Austria, Belgium, Germany and France). These groups are collaborative platforms comprising a diverse array of stakeholders, including government ministries (health and research), cancer charities, industry representatives, healthcare providers, and research institutions. Their primary role is to facilitate cross-stakeholder dialogue, focusing on aligning and coordinating various aspects of cancer research and treatment. This includes discussing policy development, setting research priorities, and strategising healthcare approaches. Each country's Mirror Group has its specific focus; for instance, Spain's group emphasises broad stakeholder dialogue, while Belgium's group may concentrate more on the research aspect. These groups ensure that different perspectives are integrated, efforts are well-coordinated, and resources are effectively utilized, avoiding duplication.

Conclusions

This case study demonstrates the relevance and coherence of the Cancer Mission and, in particular, the synergies between Cancer Mission, Europe's Beating Cancer Plan policy initiatives and the EU4Health funding instrument. The analysis includes the interview programme, extensive desk research and the supplementary quantitative historical analysis of the cancer-related projects, publications and funding over different framework programmes (FP7, Horizon 2020, and Horizon Europe) and international funding instruments National institutes for Health (NIH) and Wellcome Trust (WT).

The relevance analysis reveals that Cancer Mission tackles the right issues given the position of the European Union since the programme started and over time. Cancer Mission uses innovative solutions for cancer prevention and treatment, aligning with the broader Horizon Europe goals. The issues of lack of equity, personalised medicine and childhood cancers are reflected in the calls and proposals. The unique structure of the Cancer Mission was emphasised during most of the interviews as the facilitating factor to achieve better results. Cancer Mission was developed by joining national governments, public organisations, SMEs, researchers, and citizens together for one specific goal.

The analysis of the coherence identifies that the Cancer Mission is highly coherent with Europe's Beating Cancer Plan and the EU4Health.

Cancer Mission and Europe's Beating Cancer Plan:

- Cancer Mission is an integral part of EBCP, and both policy initiatives tackle the entire disease pathway. EBCP has a total of 42 actions, out of which 26 were mapped with calls from the Cancer Mission. Cancer Mission facilitates the implementation process of 7 out of 10 EBCP flagship initiatives, which are also part of the ECBP actions;
- The Mission on Cancer supports the EBCP in enabling and accelerating new research and policymaking approaches in the field. The Mission and EBCP together work on the same projects, such as UNCAN.eu; European Cancer Patient Digital Centre, and National Comprehensive Cancer Centres;
- For the coordination between the DG RTD and DG SANTE, there are adopted governance mechanisms: 1) Commission Services Group (Cancer Mission and EBCP implementation group) to coordinate within the Commission; Cancer Subgroup to bring all relevant members from Member States; 3) Stakeholder group, established under Commission's Health policy platform.

Cancer Mission and EU4Health:

- All EU4Health Work Programmes have cancer-related calls, and it has similar thematic areas with Cancer Mission in case of screening and early detection; life of patient survivors; better understanding of the impact of risk factors and health determinants on the development and progression of cancer; prevention of cancer; Comprehensive Cancer Infrastructures; quality of life of childhood patients.
- The interviews with EC Officials from DG RTD and DG SANTE underlined that regular communication is ensured. The regular meetings occur every 2 weeks between the heads of units working with the Cancer Mission (DG RTD), EBCP and EU4Health (DG SANTE) to ensure smooth communication and coordination.

• The introduction of the HaDEA agency supports the implementation and coordination of both Cancer Mission's and EU4Health calls. It enhances the synergies between the funding instruments and facilitates the avoidance of overlaps.

Lessons learned

- To increase the Cancer Mission's additionality to the EU citizens and to reach its aim of improving the lives of more than 3 million people by 2030, communication with the general public should be improved. It could be done through large-scale events, communication in national languages in each Member State, or more comprehensive information campaigns on social media. This would allow the Cancer Mission to better reach the patients and their relatives and raise awareness about the Cancer Mission. As for now, the Cancer Mission is more known only among the EC officials, National Contact Points, and those directly involved in its implementation.
- The synergies between the Cancer Mission and Europe's Beating Cancer Plan should be better communicated with National Contact Points and other representatives at the national level. As for now, the information on their synergies and the division of activities is not clear enough.
- Coordination between the EU4Health and Horizon Europe programmes on the cancer questions, especially when it comes to drafting the calls for the Work Programmes of EU4Health and Cancer Mission should continue to be ensured, as appropriate. Applicants decide on their own where to put a more detailed proposal and the risk of overlap between the programmes remains. Closer collaboration in drafting the proposals could be one of the solutions.

Appendix 1

Europe's Beating Cancer Plan actions	Cancer Mission Calls
Flagship: Launch the European Initiative to Understand Cancer (UNCAN.eu).	Preparing UNCAN.eu, a European initiative to understand cancer
 Flagship: New 'EU Cancer Screening Scheme': (1) Revision of the Council Recommendation on cancer screening, including its update and proposal for possible extension to other cancers; (2) Cancer Imaging Initiative to support the development of new computer-aided tools to improve personalised medicine and innovative solutions; (3) Develop Guidelines and Quality Assurance schemes on cancer screening, diagnosis, treatment, rehabilitation, follow-up and palliative care for colorectal and cervical cancer, and updating the existing guidelines on breast cancer, including accreditation/certification programmes. Update the European Cancer Information System to monitor and assess cancer screening programmes. Mainstream equality action in areas addressed by Europe's Beating Cancer Plan such as screening and high-quality cancer care. 	Develop new methods and technologies for cancer screening and early detection
 Launch a study addressing issues related to the return to work; Address in the Strategy on the Rights of Persons with Disabilities 2021-2030 the rights of cancer patients and survivors considered as persons with a disability; Ensure full implementation of the Directive on work-life balance for parents and carers 	Develop and validate a set of quality of life and patient preference measures for cancer patients and survivors.
 Create a 'Tobacco Free Generation': by reviewing (1) Tobacco Products Directive; (2) Tobacco Taxation Directive; and (3) the legal framework on cross border purchases of tobacco by private individuals in view of legislative proposals; and (4) Update the Council Recommendation on Smoke-Free Environments; (5) Support Member States in full implementation of the Framework Convention on Tobacco Control. 	Better understanding of the impact of risk factors and health determinants on the development and progression of cancer
Intensified EU support to Member States and stakeholders with the implementation of best practices and capacity building to reduce alcohol related harm: (1) Review of EU legislation relating to the taxation of alcohol and cross- border purchase of alcohol products; (2) Proposal for mandatory labelling of the list of ingredients and nutrition declarationon alcoholic beverage label, as well as health warnings; (3) Support Member States in the implementation of evidence-based brief interventions; (4) Reduce the exposure of young people to online marketing of alcoholic beverages through monitoring the implementation of the Audiovisual Media Service Directive	

(1) Review of EU school fruit, vegetables and milk scheme;

(2) Propose mandatory front-of-pack nutrition labelling;

(3) Commission report on the implementation of the provisions of the Audiovisual Media Services Directive (AVMSD) including those on commercial communications on unhealthy food and drinks;

(4) Develop and implement guidance for codes of practice on reducing unhealthy food marketing to children, including online marketing through the provisions of AVMSD and a Joint Action of best practices in nutrition ("Best ReMap"):

(5) Publication of a study mapping fiscal measures and pricing policies on sugars, soft drinks and alcoholic beverages

Further reduction of the presence of carcinogenic contaminants in food by setting maximum level limits for more of these contaminants.

(1) HealthyLifestyle4All support to promotion of healthy lifestyles for all generations;

(2) Initiatives under the Sustainable Urban Mobility Planning Guide on linking transport and health;

(3) Revision of the Urban Mobility Package to promote and support sustainable and healthy transport and mobility. Align the EU's air quality standards more closely with the WHO guidelines.

Measures towards zero-emission mobility and reducing environmental pollution from transport under the Sustainable and Smart Mobility Strategy.

Adopt a new Occupational Safety and Health Strategic Framework 2021-2027

Reduce workers' exposure to carcinogenic substances through the amendments of the Carcinogens and Mutagens Directive.

Revise EU limits for asbestos to further reduce workers' exposure.

Survey on exposure of workers to risk factors for cancer.

Support Member States in the implementation of the requirements of Council Directive on protection from ionising radiation, particularly from Radon.

Explore measures to prevent exposure to ultraviolet radiation including from sunbeds.

Launch Horizon Europe Partnership on Assessment of Risks from Chemicals to strengthen EU capacities for chemical risk assessment.

Flagship: 'Helping Children with Cancer Initiative': Create an 'EU Network of Youth Cancer Survivors'.

Launch the 'Childhood cancers and cancers in adolescents and young adults: cure more and cure better' project to boost the transformation of paediatric cancer care.

Create a 'Tobacco Free Generation': by reviewing (1) Tobacco Products Directive; (2) Tobacco Taxation Directive; and (3) the legal framework on cross border purchases of tobacco by private individuals in view of legislative proposals; (4) Update the Council Recommendation on Smoke-Free Environments; (5) Support Member States in full implementation of the Framework Convention on Tobacco Control. Intensified EU support to Member States and stakeholders with the implementation of best practices and capacity building to reduce alcohol related harm: (1) Review of EU legislation relating to the taxation of alcohol and cross- border purchase of alcohol products; (2) Proposal for mandatory labelling of the list of ingredients and nutrition declarationon alcoholic beverage label, as well as health warnings; (3) Support Member States in the implementation of evidence-based brief interventions; (4) Reduce the exposure of young people to online marketing of alcoholic beverages through monitoring the implementation of the Audiovisual Media Service Directive (1) Review of EU school fruit, vegetables and milk scheme; (2) Propose mandatory front-of-pack nutrition labelling; (3) Commission report on the implementation of the provisions of the Audiovisual Media Services Directive (AVMSD) including those on commercial communications on unhealthy food marketing to children, including online marketing through the provisions of AVMSD and a Joint Action of best practices in nutrition ("Best ReMap"); (5) Publication of a study mapping fiscal measures and pricing policies on sugars, soft drinks and alcoholic beverages Further reduction of the presence of carcinogenic contaminants in food by setting maximum level limits for more of these contaminants.	Improving and upscaling primary prevention of cancer through implementation research
Flagship: (1) Creation of Matienal Community Concert Contro (c)' in all Member States and EU naturaly by 2025.	Strengthening research capacities of
 (1) Creation of National comprehensive Cancer Centre(s) in all Member States and EU network by 2025; (2) New cancer Reference Networks on cancer and cancer conditions in addition to the four existing ERNs; (3) EU cancer 'Treatment Capacity and Capability Digital Mapping' project. 	Comprenensive Cancer Infrastructures.
Flagship: 'Cancer Diagnostic and Treatment for All' initiative to improve access to innovative cancer diagnosis and treatments.	
Implementation of the legal framework for clinical trials.	Pragmatic clinical trials to optimise treatments for patients with refractory cancers

 Flagship: 'Better life for cancer patients' initiative: (1) Create a tailor made 'Cancer Survivor Smart-Card; (2) Create the 'European Cancer Patient Digital Centre' supporting the exchange of patients' data and monitoring of survivors' health condition. 	Towards the creation of a European Cancer Patient Digital Centre (The overall goal of the Mission on Cancer189 and the Europe's Beating Cancer Plan190 includes a better quality of life for patients and their families living with, and after, cancer)
	Establishing of national cancer mission hubs and creation of network to support the Mission on Cancer
Flagship: 'Helping Children with Cancer Initiative': Create an 'EU Network of Youth Cancer Survivors'.	Addressing poorly-understood tumour-host interactions to enhance immune system-centred
Launch the 'Childhood cancers and cancers in adolescents and young adults: cure more and cure better' project to boost the transformation of paediatric cancer care.	adolescent, adult and elderly cancer patients
Create a 'Tobacco Free Generation': by reviewing (1) Tobacco Products Directive; (2) Tobacco Taxation Directive; and (3) the legal framework on cross border purchases of tobacco by private individuals in view of legislative proposals; and (4) Update the Council Recommendation on Smoke-Free Environments; (5) Support Member States in full implementation of the Framework Convention on Tobacco Control. Intensified EU support to Member States and stakeholders with the implementation of best practices and capacity building to reduce alcohol related harm: (1) Review of EU legislation relating to the taxation of alcohol and cross- border purchase of alcohol products; (2) Proposal for mandatory labelling of the list of ingredients and nutrition declarationon alcoholic beverage label, as well as health warnings; (3) Support Member States in the implementation of evidence-based brief interventions; (4) Reduce the exposure of young people to online marketing of alcoholic beverages through monitoring the implementation of the Audiovisual Media Service Directive (1) Review of EU school fruit, vegetables and milk scheme; (2) Propose mandatory front-of-pack nutrition labelling; (3) Commission report on the implementation of the provisions of the Audiovisual Media Services Directive (4) Develop and implement guidance for codes of practice on reducing unhealthy food marketing to children, including online marketing through the provisions of AVMSD and a Joint Action of best practices in nutrition ("Best ReMap");	Enhance primary cancer prevention through sustainable behavioural change. The Mission on Cancer and Europe's Beating Cancer Plan aim to exploit the potential of primary cancer prevention by addressing key risk factors and health determinants58.

(5) Publication of a study mapping fiscal measures and pricing policies on sugars, soft drinks and alcoholic beverages	
Further reduction of the presence of carcinogenic contaminants in food by setting maximum level limits for more of these contaminants.	
 HealthyLifestyle4All support to promotion of healthy lifestyles for all generations; Initiatives under the Sustainable Urban Mobility Planning Guide on linking transport and health; Revision of the Urban Mobility Package to promote and support sustainable and healthy transport and mobility. 	
Present SAMIRA Action plan to ensure quality and safety of radiation technology and the supply of radioisotopes of medical importance for diagnostic and treatment.	Pragmatic clinical trials on minimally invasive diagnostics
Flagship: Launch a 'European Cancer Imaging Initiative' to support the development of new computer aided tools to improve personalised medicines and innovative solutions.	
Flagship: 'Helping Children with Cancer Initiative': Create an 'EU Network of Youth Cancer Survivors'.	Establish best practices and tools to improve the quality of life for childhood cancer patients,
Launch the 'Childhood cancers and cancers in adolescents and young adults: cure more and cure better' project to boost the transformation of paediatric cancer care.	survivors and their families in European regions

Appendix 2: Data analysis

The historical data analysis Appendix for the Case Study on Cancer Mission was selected as an additional source of information for both the Case Study and the main Resilient Europe study report analysis, primarily feeding into evaluation questions of relevance, coherence and effectiveness. The historical analysis of cancer research as a reference point allows us to examine how cancer-related projects and publications performed in different framework programmes and benchmark that to other international funders. For instance, the analysis illustrates how the relevance of the cancer-related projects changed overtime thematically and how this fits in the context of other international initiatives such as the National Institute of Health (NIH) and Wellcome Trust (WT). Even more, the analysis could help answer the question of whether cancer could potentially be or has the potential to become one of the key strategic areas of the EU.

The analysis also refers to the projects database looking at the share of projects and EU contribution to different programme parts of FP7, Horizon 2020 and Horizon Europe. This part of the analysis allows us to understand better how cancer-related projects are distributed among the programme parts over the years (i.e., 2007-2022) and to observe which programme parts receive the most significant EU funding.

Methodological approach and contextual part

The overall approach to the analysis

Two types of analyses were used to perform the historical cancer analysis.

- First, the analysis of the publications using the Medical Subject Headings classification - (MeSH), a controlled and hierarchically-organised vocabulary produced by the National Library of Medicine. It is used for indexing, cataloguing, and searching for biomedical and health-related information. MeSH includes the subject headings appearing in MEDLINE/PubMed, the NLM Catalog, and other NLM databases.²⁵³
- 2. Second, the **analysis of projects** and EU contributions using the EU monitoring data, including the CORDIS project data from FP7, Horizon 2020, and Horizon Europe.

Scope

The analysis focuses on the three EU framework programmes: FP7 (2007-2013), Horizon 2020 (2014-2020) and Horizon Europe (2021-2022). These are benchmarked based on the operational years of the international funders – the US's NIH and the UK's WT.

When performing the MeSH classification, Horizon Europe was not included, as the data for the publications and projects in the MeSH categorisation system is not yet available.

²⁵³ https://www.nlm.nih.gov/mesh/meshhome.html

Methodological approach using MeSH classification

The classification of the MeSH categorisation system was used as part of the historical analysis of cancer research. The 'neoplasms^{254'} category was selected when counting the publications related to cancer²⁵⁵. Later, the publications were analysed in terms of the neoplasm types²⁵⁶ and sites²⁵⁷.

To identify cancer research trends within the Framework Programmes (FP) and beyond them, 2 FPs and 2 international funders were analysed: FP7, Horizon 2020, the NIH and WT. Important to note is that for the NIH and WT, different analysis periods were selected (2007-2013 and 2014-2021) according to the duration of FP7 and H2020 (2007-2013 and 2014-2020, respectively). In addition, the data for the programme parts was included to identify the performance within the FP7 and Horizon 2020. The fractional counting for the publications was not applied; thus, each publication was applied only to one of the MeSH classes.

The data analysis was utilised to establish the research and funding trends of cancer research over time and to determine which cancer types and sites FP7 and H2020 prioritised compared with the NIH and WT.

Methodological approach using the CORDIS project-level data

The second part of the quantitative data analysis was completed to analyse the share of projects and EC contributions to the cancer-related projects in different programme parts in FP7, Horizon 2020 and Horizon Europe. The CORDIS project database was used for the analysis. First, only the projects with the 'cancer' and 'oncology' key words in the project abstracts were filtered out. Then, based on the Framework Programme (FP7, Horizon 2020 and Horizon Europe), different programme parts were selected, and the share of projects and the EC contribution to those programme parts were calculated.

Contextual approach

As historical analysis includes the data for two international funders – NIH and WT – it is important to provide a short contextual information for both programmes.

The NIH is a research agency based in the United States supporting the discovery of research into health-related sciences. In the case of cancer-related projects, NIH established the National Cancer Institute (NCI) in 1973, which is now one of 11 agencies within the Department of Health and Human Services²⁵⁸. NCI's mission is to 'lead, conduct, and support cancer research across the nation to advance scientific

²⁵⁴ New abnormal growth of tissue,

https://www.ncbi.nlm.nih.gov/mesh?Db=mesh&Cmd=DetailsSearch&Term=%22Neoplasms%22%5BMeSH+Terms%5D 255 Neoplasms,

https://www.ncbi.nlm.nih.gov/mesh?Db=mesh&Cmd=DetailsSearch&Term=%22Neoplasms%22%5BMeSH+Terms%5D

²⁵⁶ E.g., Lymphoma, Nerve Tissue, Connective and soft tissue (https://www.ncbi.nlm.nih.gov/mesh/68009370)

²⁵⁷ a collective term for precoordinated organ/neoplasm headings locating neoplasms by organ, such as brain neoplasms;

duodenal neoplasms; liver neoplasms; etc. (Neoplasms by site, https://www.ncbi.nlm.nih.gov/mesh/68009371)

²⁵⁸ https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-cancer-institute-nci

knowledge and help all people live longer healthier lives²⁵⁹. NCI takes part in a broad range of activities, including the management of research, training and information dissemination, intending to reach the entire country and meet the needs of all demographics. NCI has a significant budget for cancer research, which is increasing overtime. In 2007, the funding was almost USD 5 billion, growing to USD 6 billion in 2020²⁶⁰.

Wellcome Trust (WT) is a global charitable foundation. They focus on health and improving science, innovation, and society. WT has a budged of GBP 37.8 billion to give researchers the time and resources to work on various research, taking the 'three biggest health challenges facing humanity – climate change, infectious disease and mental health'²⁶¹. WT does not indicate their separate priority for cancer-related projects, and the overall funding for cancer-related projects is not published. However, the foundation is open to applicants for cancer-related projects and has partnerships with organisations working with cancer (for instance, the partnership with Cancer Research UK (CRUCK)).

In addition to that, the different programme parts of the FP7, Horizon 2020 and Horizon Europe are included in the analysis. The programme parts were selected by the top 5 programme parts in terms of the highest share of cancer-related publications, the top 5 programme parts in terms of the highest share of cancer-related projects and the top 5 programme parts in terms of the highest share of EC contributions. Thus, the Table below indicates how the three main programmes for this analysis elaborate over time and provides a short context about them and other parts.

Table 110.	The	three	main	programme	parts	for	cancer-related	publications	and
projects									

Framework Programme 7	Horizon 2020	Horizon Europe
FP7-PEOPLE	MSCA	MSCA
FP7-HEALTH	SC1-Health	Cluster 1
FP7-IDEAS-ERC	ERC	ERC

Source: Compiled by the study team.

FP7-PEOPLE, which was later succeeded by Marie Skłodowska-Curie Actions (MSCA), 'the European Commission funds research and innovation projects to boost top researchers' careers through mobility and innovative doctoral and postdoctoral training.'²⁶² **FP7-IDEAS-ERC**, in later FPs, called **ERC**, is the abbreviation of the European Research Council. It is 'the premier European funding organisation for excellent frontier research', funding researchers of any nationality and age to run projects across Europe²⁶³. Those two programmes differ from **FP7-HEALTH** (later succeeded by **SC1** in Horizon 2020 and **Cluster 1** in

²⁵⁹https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-cancer-institute-

 $nci\#:\sim:text=NCI's\%20 mission\%20 is\%20 to\%20 lead, people\%20 live\%20 longer\%2C\%20 healthier\%20 lives. \\ \& text=As\%20 a\%20 mission\%20 is\%20 to\%20 lead, people\%20 live\%20 longer\%2C\%20 healthier\%20 live\%20 live\%20 longer\%2C\%20 healthier\%20 live\%20 longer\%2C\%20 healthier\%20 live\%20 healthier\%20 healthier\%20 live\%20 healthier\%20 live\%20 healthier\%20 healthier\%20 live\%20 healthier\%20 healthier\%20 live\%20 healthier\%20 healthier$

federal%20 agency%2C%20 NCl%20 receives%20 its%20 funds%20 from%20 Congress.

²⁶⁰ NCI Budget Fact Book, https://fundedresearch.cancer.gov/nciportfolio/

²⁶¹ Wellcome Trust, https://wellcome.org/who-we-are

²⁶² https://rea.ec.europa.eu/funding-and-grants/horizon-europe-marie-sklodowska-curie-actions_en

²⁶³ https://erc.europa.eu/about-erc/erc-glance

Horizon Europe) in the sense that the applicants could freely choose the specific areas for the broader topics related to public health, engineering, or life sciences²⁶⁴ ²⁶⁵ ²⁶⁶, while in FP7-HEALTH, SC1 and Cluster 1, there are specific calls related to cancer research and innovation to which applicants should apply.

Other programme parts that are included in the analysis are:

- FP7-REGPOT Specific Programme for the Research potential of Convergence Regions. It was created to make the research more balanced across the whole EU by reinforcing the capacity of the existing research institutions located in the Convergence and Outermost Regions of the EU and enabling their full participation in the European Research Area (ERA)²⁶⁷.
- **FP7-JTI** Joint Technology Initiatives are used as a 'means to support transnational cooperation in key areas where research and technological development can contribute to European competitiveness and quality of life.'²⁶⁸
- **IL-LEIT** (Horizon 2020) is a Leadership in Enabling and Industrial Technologies programme, contributing to 'boosting competitiveness, creating jobs and supporting growth'²⁶⁹.It has an emphasis on research and innovations in the strong industrial dimension.
- **Twinning (Horizon 2020)** has been enhancing the networking activities between 'research institutions of the Widening countries acting as coordinators and top-class leading counterparts at the European Union level by linking at least two research institutions from two different Member States or Associated Countries.'²⁷⁰

Results

The historical analysis of cancer-related publications in FP7, Horizon 2020, NIH and WT $\,$

According to the International World Cancer Research Fund, **in 2020, there were 18.1 million new cancer cases around the world**²⁷¹. The European data indicates **about 4 million new cancer cases in Europe in 2020**. About 1.9 million people are estimated to have died from cancer in Europe that year²⁷². As the European Commission published, Europeans are disproportionately affected by cancer. Looking at the global context, Europeans are 10% of the world population but have about 25% of all annual cancer cases. Historically, cases of cancer are growing all over the world.

²⁶⁴ https://cordis.europa.eu/project/id/615905

²⁶⁵ https://cordis.europa.eu/project/id/256639

²⁶⁶ https://cordis.europa.eu/project/id/617312

²⁶⁷ https://www.kowi.de/Portaldata/2/Resources/fp7/fp7-capacities-report.pdf

²⁶⁸ https://cordis.europa.eu/programme/id/FP7-JTI

²⁶⁹ https://www.h2020.md/en/content/leadership-enabling-and-industrial-technologies

²⁷⁰ https://rea.ec.europa.eu/funding-and-grants/horizon-europe-widening-participation-and-spreading-

excellence/twinning_en

²⁷¹ https://www.wcrf.org/cancer-trends/worldwide-cancer-data/

²⁷² Cancer in Europe: 5 things the data tells us, https://joint-research-centre.ec.europa.eu/jrc-news-and-updates/cancereurope-5-things-data-tells-us-2022-01-13_en

Large funders, such as European Commission Framework Programmes²⁷³, NIH and WT, are making efforts to fund cancer-related research in order to achieve their results, minimise the existing cases and prevent the growth of the cases.

The Table below overviews the cancer-related publications, and the results are divided into two periods: 2007-2013 (duration of the FP7 programme) and 2014-2021 (duration of Horizon 2020). The first column presents the number of cancer-related publications selected by the 'neoplasms' category in the MeSH classification. The third column is the share of cancer-related publications from the total number of publications each funder produced.

The results indicate that, in relative terms, taking into account the budget allocations presented below, the EU FPs allocated 0.5-1.25 times less resources to cancer research compared to NIH.

Funder	No of cancer-related publications	No of total publications	Share of cancer-related publications (%)
2007-2013			
FP7	14 219	350 975	4.1
NIH 2007-2013	14 203	90 828	15.6
WT 2007-2013	1 705	24 739	6.9
2014-2020			
H2020	6 768	207 924	3.3
NIH 2014-2021	32 757	217 140	15.1
WT 2014-2021	4 583	60 247	7.6

Table 111. Overview of cancer-related publications

Source: Analysis by the study team using OpenAlex and OpenAIRE data.

As can be seen from the Figure below, although, in both selected periods, NIH produced the largest number of cancer-related publications (15.6% and 15.1%) compared to 4.1% in FP7 and 3.3% in Horizon 2020, **the budget of the programmes differs significantly**. FP7 total budget was around EUR 53.5 billion²⁷⁴, Horizon 2020 had a budget of nearly EUR 80 billion²⁷⁵, while the NIH's budget²⁷⁶ in 2007-2013 and 2014-2021 was around EUR 207 billion and around EUR 237 billion, respectively. This is almost 3 times higher. Notably, the National Cancer Institute (NCI), which works under the NIH, is the largest funder of cancer research in the world, having a number of divisions and centres conducting research or managing research programmes²⁷⁷. Therefore, while the publications and projects shares within the Framework Programme are changing depending on the current priorities and emerging needs, the NCI is always working with cancer-related publications with a substantial budget. The total budget numbers on WT are not available, as it works as an investment portfolio²⁷⁸.

²⁷³ Cancer research happens in HE by ensuring maximum synergies with EU4Health funding instrument and Europe's Beating Cancer Plan initiative.

²⁷⁴ https://www.bayfor.org/en/eu-funding/fp7-review.html

²⁷⁵ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-

calls/horizon-2020_en

²⁷⁶ https://report.nih.gov/nihdatabook/category/1

²⁷⁷ NCI Budget Fact Book, https://www.cancer.gov/about-nci/budget/fact-book

²⁷⁸ https://wellcome.org/who-we-are/investments

It can be noticed that in the FP7, 4.1% of publications were related to neoplasms, while in Horizon 2020, this number slightly declined (to 3.3%). This can be explained by the emerging health crises (e.g., Ebola, Zika virus and more recently, the COVID-19 pandemic) that affected the public health sector and demand to urgently re-prioritise resources to respond to these unprecedented circumstances.



Figure 88. Share of cancer-related publications in FP7, H2020, NIH and WT

Source: Analysis by the study team using OpenAlex and OpenAIRE data.

The study team also analysed the distribution of cancer-related publications within different FP7 and Horizon 2020 programme parts. The Figure below illustrates the distribution of cancer-related publications within the FP7 and Horizon 2020 programme parts. To calculate the share of publications in each programme part, the total number of cancer-related publications was included accordingly (the total number of cancer-related publications in FP7 was 14 219, and in Horizon 2020, it was 6 768). For illustration purposes, the Figure includes only the top 5 programme parts that had the largest share of cancer-related publications within each programme part. In addition, only those programme parts with more than 200 publications were selected.

Within the FP7, FP7-HEALTH produced the most cancer-related publications (39.3% out of all FP7 cancer-related publications), while within Horizon 2020, it was ERC (39.3% out of all Horizon 2020 cancer-related publications). In both FPs, the most cancer-related publications were produced by the same programme parts – FP7-PEOPLE (later ERC), FP7-PEOPLE (later MSCA) and FP7-HEALTH (later SC1-Health). Over time, the share of cancer-relation publications resulting from ERC did not change significantly, while the publications from FP7-HEALTH to SC1-Health dropped from 39.3% to 18.2%. As mentioned earlier, this could be explained by the emerging needs that especially shifted focus in Horizon 2020 Societal Challenge 1,

which had to concentrate its efforts towards the unprecedented health crises caused by COVID-19, as well as Ebola and Zika viruses.



Figure 89. Share of cancer-related publications within FP7 and H2020 programme parts

Source: Analysis by the study team using OpenAlex and OpenAIRE data.

Share of publications by neoplasms histological type

To understand better the distribution of types of cancer that each programme part targets historically, we also looked at the share of cancer-related publications by neoplasm histologic type. For this analysis, only the top 5 histologic types based on the share of cancer-related publications were included (the same top 5 overlapped in all selected funders and periods). The share of cancer-related publications was calculated, taking into account the total publications for each funder. Again, the Figures are divided by the time periods of the according programmes.

The analysis found that **the majority of the analysed publications were related to the glandular and epithelial neoplasms type**. These results apply to both assessed periods (2007-2013 and 2014-2021). The research paper on epithelial cancer by NIH indicated that most cancer arises in epithelia, a type of tissue that lines all body cavities²⁷⁹. In 2007-2013, 21.5% of NIH's publications were related to the epithelial neoplasms type. Similarly, 19.4% of FP7's publications and 18.1% of WT's publications were linked to the epithelial neoplasms type. In the next period, 2014-2020, the numbers remained almost the same, with a slight drop of 20.6%, 17.2% and 15.4%, respectively. This suggests that FP7 and H2020 continued to produce cancerrelated publications and keep up with the research trends of the major international funders.

Historically, there were only small shifts in the cancer-related publications within each neoplasm type (the selected top 5 and other neoplasm types), with the increased share

²⁷⁹ Hinck, L. And Nathke, I., (2014), Changes in cell and tissue organization in cancer of the breast and colon, NIH, https://ncbi.nlm.nih.gov/pmc/articles/PMC3927155/

of cancer-related publications from FP7 to Horizon 2020 on leukaemia, germ cell and embryonal, nerve tissue and nevi and melanomas types. For NIH, the share of cancerrelated publications dropped over the different periods, meaning that publications might shifted towards different types. This shows us that cancer research priorities are slightly changing when looking at the share of cancer-related publications in different histologic types, moving from one period to another. In addition, it can be noted that FPs keep up with the NIH, having a similar share of cancer-related publications in terms of the top 5 neoplasm types and in most cases (except for nevi melanomas in 2007), FPs outperform WT.



Figure 90. Share of cancer-related publications by neoplasms histologic type

Source: Analysis by the study team using OpenAlex and OpenAIRE data.

How does the research on different neoplasms evolve within the FPs?

To see the extent to which the share of cancer-related publications evolved within the FP7 and Horizon 2020, the study team selected the same histological types of neoplasms and the top 5 programme parts within each FP with the highest share of cancer-related publications. The total number of publications was counted as the total number of cancer-related publications of FP7 and Horizon 2020.

The results revealed that **4 out of 5 most cancer research producing programme parts produced publications on the same type of neoplasms** - glandular and epithelial (between 14.6% and 24.5%). The picture slightly shifts in Horizon 2020, where the Twinning programme part had the largest contributions of cancer-related publications in the leukaemia type. It means there was more collaboration between at least two institutions from two different Member States or Associated Countries, which were published for the leukaemia neoplasm type. Looking at the individual programme parts, we can see that:

- In FP7-HEALTH and the successor SC1, their share of cancer-related publications within FP7 and Horizon 2020 slightly decreased overtime for leukaemia (6% and 4%), germ cell and embryonal (from 10% to 9.8%), and for glandular and epithelial type (21.1% and 20.6%). However, the share of cancer-related publications increased in nevi and melanomas type (2.6% and 4.7%);
- In FP7-IDEAS-ERC and the successor ERC, the share of cancer-related publications significantly increased for the leukaemia type (from 5.1% to 9.2%), and other types remained around the same.
- In FP7-JTI and the successor IL-LEIT, the share of cancer-related publications increased for all but glandular and epithelial types, where there was a drop from 17.2% to 14.6%.
- In FP7-PEOPLE and the successor MSCA, there was an increase in the share of cancer-related publications in germ cell and embryonal (12.1% and 14.6%), nerve tissue (11.5% and 14.5%), and nevi and melanomas (3.8% and 6.9%) types. In other types, there was a slight negative change from 5.9% to 4.3% in leukaemia, and from 18.9% to 17.7% in glandular and epithelial types.
- The twinning programme was not the successor of FPT-REGPOT.
 - In FP7-REGPOT, during the 2007-2013 period, the largest share of cancer-related publications contributed to the glandular and epithelial type (24.5%), having the highest share of cancer-related publications among all programme parts.
 - For the 2014-2020 period, the twinning programme contributed the largest share of cancer-related publications to leukemia (22%) and was a second-largest contributing programme to nevi and melanomas (5.9%).



Figure 91. Share of cancer-related publications within FP7 and H2020 programme parts by histological type

Source: Analysis by the study team using OpenAlex and OpenAIRE data.

Share of publications by neoplasms site

As part of the analysis, we also looked at the share of publications by the neoplasms site, which shows us the concentration of research based on the anatomic site that is involved.

The Figure below presents the top 5 neoplasm sites based on the share of cancerrelated publications included (as it was for the histologic types, the same top 5 sites overlapped in all selected funders and periods). The share of cancer-related publications was calculated, taking into account the total publications for each funder. The Figures are divided by the time periods of the programmes.

We found that, with a small exception of WT between 2007 and 2013, most publications on cancer in all funders are **concentrated on breast cancer**. This is not surprising, as according to the International World Cancer Research Fund, **in 2020**, **breast cancer was the most common cancer worldwide**, contributing 12.5% of the total number of new cases²⁸⁰. Lung cancer (belonging to thoracic neoplasms), which

²⁸⁰ https://www.wcrf.org/cancer-trends/worldwide-cancer-data/

is the second most common cancer, contributing 12.2% of the total number of new cases, was also among the top 5 cancer sites receiving the largest share of cancerrelated publications from both FPs and international funders. A large share of cancerrelated also concentrated on digestive system neoplasms, which, according to the Institute for Health Metrics and Evaluation, 2019 was the third most deadly cancer.²⁸¹



Figure 92. Share of cancer-related publications by neoplasm site

How do the neoplasm sites differ historically across the different FP parts?

To see the difference in the cancer-related publications contribution by different parts of FPs, the study team selected the top 5 programme parts within each FP with the highest share of cancer-related publications. The total number of publications was counted as the total number of cancer-related publications of FP7 and Horizon 2020.

The study team found **notable shifts in the types of neoplasm sites addressed in cancer-related publications across different programme parts**.

 Looking at breast neoplasms, we observe an almost 5% increase from FP7-HEALTH cancer-related publications (10.6%) to SC1 (16.5%) (dark blue colour). Interestingly, this was not a usual trend across all programme parts. For example, for MSCA (purple colour) and ERC (red colour), the share of

Source: Analysis by the study team using OpenAlex and OpenAIRE data.

²⁸¹ https://ourworldindata.org/grapher/total-cancer-deaths-by-type

cancer-related publications decreased compared to their predecessors (MSCA from 11.1% to 10.6% and ERC from 10.8% to 7.1%).

 For the digestive system neoplasms, the share of cancer-related publications within the FP7-HEALTH/SC1 has increased for all three programme parts (FP7-HEALTH 10.4% vs. SC1-Health 19.7%, FP7-PEOPLE(MSCA) 7.4% vs. MSCA 9.4% and FP7-IDEAS-ERC 8.5% vs. ERC 8.6%).



Figure 93. Share of cancer-related publications within FP7 and H2020 programme parts by neoplasm site

Source: Analysis by the study team using OpenAlex and OpenAIRE data.

How does the concentration of cancer-related research look in terms of projects funded by the framework programmes?

Publications produced by the FPs are important scientific results; however, the study team also wanted to see the distribution of cancer-related projects that were funded

by each framework programme. This allows to see the evaluation of cancer as a priority area for each FP and their programme parts.

Overall, **we observe a gradual increase in the share of cancer-related projects** from FP7 up until the mid-term results of Horizon Europe. Interestingly, when we looked at publications, we found that the number of publications relating to cancer slightly declined in Horizon 2020 compared to the predecessor. However, in terms of projects funded and the resources allocated, the picture is rather different.



Figure 94. Share of cancer-related projects and EC contributions from FP7 to Horizon Europe

Source: Compiled by the study team using EC administrative and monitoring data.

The Table below illustrates that the share of cancer-related projects within each FP increased from 6.1% in FP7 to 6.78% in Horizon Europe. In addition, to this date, the share of EC contribution to cancer-related projects increased from 3.8% to 5.7%.

Programme	Total number of projects	Cancer- related projects	Share of cancer- related projects (%)	EC contribution (total) (EUR, million)	EC contribution to cancer- related projects (EUR, million)	Share of EC contribution to cancer- related projects (EUR, million)
FP7	25 790	1 574	6.1	46.0	2.4	3.8%
Horizon 2020	35 856	2 254	6.29	68.3	3.3	4.8%
Horizon Europe (mid-term results)	9 459	641	6.78	24.6	1.4	5.7%

Table 112. Overview of cancer-related projects and EU contributions in FP7, Horizon2020, and Horizon Europe

Source: Compiled by the study team using EC administrative and monitoring data.

What does the concentration of cancer-related projects look like at the programme part level?

The pie chart below presents the distribution of the cancer-related projects within the different programme parts of each FP. As for publications, the top 5 programme parts

producing the largest share of cancer-related projects were included in the analysis. The share of cancer-related projects was counted by dividing the number of projects in each programme part by the total number of cancer-related projects from each of the FPs.

FP7 programme parts

When analysing the FP7 programme parts and the concentration of cancer researchrelated projects and dedicated funding, we found that **the programme part with the most cancer projects does not correspond to the programme part with the most cancer-research funding**.

The largest share of cancer-related projects within FP7 was concentrated in FP7-PEOPLE (54.6%), followed by FP7-IDEAS-ERC (26.4%) and FP7-HEALTH (10.2%). During 2007-2013, FP7-PEOPLE implemented projects that attracted various researchers or helped those who sought to become researchers, including but not limited to health-related research. Making Europe more attractive for researchers is mentioned as one of the strategic objectives in the FP7-PEOPLE Work Programme 2010²⁸². It was mainly done through Marie Curie Actions, which focused on fundamental research and career development fellowships. Some examples where cancer-related projects were implemented under this programme part included:

- the development of the Initial Training Networks;
- a 'new generation of researchers and experts able to create the platform on which next-generation cancer therapy will be built'²⁸³;
- establishment of the International Agency for Research on Cancer (IARC)²⁸⁴.

FP7-Ideas-ERC aimed to 'reinforce excellence, dynamism and creativity in European research and improve the attractiveness of Europe for the best researchers from across the world, as well as for industrial research investment'²⁸⁵. While the calls in the work programmes were not directly related to the health sector and cancer-related projects, applicants have been able to freely choose the specific areas for the broader topics related to public health, engineering, or life sciences²⁸⁶ ²⁸⁷ ²⁸⁸. It differs from the FP7-HEALTH, which had calls related to cancer research and innovation (<u>Work Programme 2007</u>).

FP7-HEALTH ex post evaluation indicated that FP7-HEALTH cancer was among the target research activities on its legislative basis²⁸⁹. Although the share of cancer-related projects is smaller compared to FP7-PEOPLE (10.23% vs. 54.6% respectively), FP7-HEALTH cancer-related projects received more funding (34.2% vs

²⁸² FP7-PEOPLE Work Programme 2010,

https://ec.europa.eu/research/participants/data/ref/fp7/89110/m_wp_201002_en.pdf

²⁸³ https://cordis.europa.eu/project/id/608163

²⁸⁴ https://www.developmentaid.org/organizations/awards/view/371669/iarc-international-fellowships-programme-iarc-fellows-ii

²⁸⁵ FP7-Ideas-ERC Work Programme, 2013

²⁸⁶ https://cordis.europa.eu/project/id/615905

²⁸⁷ https://cordis.europa.eu/project/id/256639

²⁸⁸ https://cordis.europa.eu/project/id/617312

²⁸⁹ PPMI (2017), Ex post evaluation of the Health theme in FP7: final report

13.8% respectively), this implies that FP7-HEALTH projects were focused on translation research rather than fundamental research, as the former is often more resource-demanding research.



Figure 95. Cancer-related projects and contributions for FP7

Source: Compiled by the study team using EC administrative and monitoring data.

Horizon 2020 programme parts

Very similar findings were for the Horizon 2020 programme parts, where, again, most projects were linked to fundamental cancer research (e.g., MSCA and ERC). Still, most resources were allocated to translational cancer research (e.g., ERC and SC1).

In the case of the H2020-MSCA, we have a similar case as in the FP7-PEOPLE. In the Work Programme of Marie Sklodowska-Curie, it is stated that actions are open to all domains of research and innovation addressed under the EU and that 'research and innovation fields, as well as sectors, are chosen freely by the applicants in a fully

bottom-up manner^{'290}. Therefore, similarly to the FP7-PEOPLE, among the work programmes of MSCA (<u>WP2014-2015</u>, <u>WP2016-2017</u>, <u>WP2018-2020</u>), there were no specific calls targeting cancer and/or oncology. However, applicants could provide ideas for the projects and get funding to implement them in cancer-related research.

The Horizon 2020 ERC (European Research Council) Work Programme also has a bottom-up approach and no specific calls targeting cancer and/or oncology, being a successor of FP7-IDEAS-ERC (WP14, WP15, WP16, WP17, WP18, WP19, WP20). Here, however, we observe that a significant share of funding, compared to other programme parts, was dedicated to cancer research projects (34.8%). This could be explained by the action types of the ERC, which receives the EC funding for cancerrelated projects. Three action types (ERC-STG, ERC-COG, and ERC-ADG) receive 90.9% of all allocated budgets to cancer-related projects within ERC (see Table below). Those three action types differ from those in Horizon 2020 and are specifically dedicated to supporting excellent Principal Investigators at different career stages. Thus, even though the ERC comprises the largest share of cancer-related projects and receives the largest share of EC contributions to cancer-related projects within Horizon 2020, the calls funded under this programme part are not necessarily related to establishing new knowledge or exploring the feasibility of a new or improved technology, product, service or solution (which is the case for Research and Innovation action type).

Table 113. Budget for cancer-related calls in ERC

	Budget for cancer-related projects (EUR, million)	Share of budget for cancer-related projects (%)
ERC-STG	318,9	28,4
ERC-COG	393,4	35,1
ERC-ADG	307,3	27,4
Total	1121,4	100

Source: Compiled by the study team using EC administrative and monitoring data.

In SC1 Work Programmes (<u>2014-2015</u>, <u>2016-2017</u>, and <u>2018-2020</u>), cancer was included at least in one of the calls. These calls covered mostly Research and Innovation (RIA) types of actions, which explains the larger share of funding allocated to a smaller number of projects compared to other programme parts.

²⁹⁰ H2020-MSCA Work Programme 2014-2015,

https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/main/h2020-wp1415-msca_en.pdf



Figure 96. Cancer-related projects and contributions for Horizon 2020

Source: Compiled by the study team using EC administrative and monitoring data.

Horizon Europe programme parts

When looking at the share of projects in different programme parts, the Figure below indicates that 35.9% of cancer-related projects were in ERC, 34.9% in MSCA and 12.2% in Health programme parts. The trends of the European Research Council and Marie Sklodowska-Curie Actions, taking the largest share of cancer-related projects, remain the same as in other framework programmes (FP7, Horizon 2020 and Horizon Europe). Again, researchers and all applicants applying for the funding under Horizon Europe could choose to apply under the ERC and/or MSCA due to the broader thematic areas.

When it comes to funding, Cluster 1 Health received 43.4% of EC contributions to cancer-related projects, followed by ERC (24.9%) and EIC (14.4%). An increased amount of EC contributions to cancer-related projects within Cluster 1 can be directly

related to the introduction of the Cancer Mission and the actions related to the implementation of Europe's Beating Cancer Plan.



Figure 97. Cancer-related projects and contributions for Horizon Europe

Source: Compiled by the study team using EC administrative and monitoring data.

Looking at the action types and the share of EC contributions to different action types in Horizon 2020 and Horizon Europe, it can be noted that RIA received the largest share of EC contributions to cancer-related calls in both Horizon 2020 (30.7%) and Horizon Europe (40.2%). However, in Horizon 2020, 3 out of 5 the most contributions received calls were from ERC, which received 31.4% of Horizon 2020 projects contributions to cancer-related projects.

Hor	izon 2020		Horizon Europe			
	Action type	EC contribution to cancer-related projects (EUR million)	Share of EC contribution to cancer- related projects (%)	Action type	EC contribution to cancer- related projects (EUR million)	Share of EC contribution to cancer- related projects (%)
1.	RIA	1 005	30.7	RIA	549	40.2
2.	ERC-COG	399	12.2	ERC	295	21.6
3.	MSCA- ITN-ETN	344	10.5	EIC	108	7.6
4.	ERC-STG	321	9.8	EIC-ACC- BF	89	6.5
5.	ERC-ADG	308	9.4	CSA	86	6.3

Table 114. Action types and EC contributions to cancer-related projects

Source: Compiled by the study team using EC administrative and monitoring data.

Case Study No 7: Research on democracy in practice

Executive Summary

The case study examines the engagement of non-academic stakeholders and actors in Horizon Europe Cluster 2 on 'Culture, Creativity and Inclusive Society' Destination democracy projects (call 2021). This topic is motivated by the findings of the Horizon 2020 Societal Challenge 6 'Europe in a changing world - Inclusive, innovative and reflective societies' evaluation study291, highlighting the insufficient participation of non-governmental organisations (NGOs) and civil society in the previous Framework Programme. In this case study, the research team investigates the extent to which the situation has evolved under the Horizon Europe Programme.

The case study also looks at the continuity of Destination democracy and SC6 projects in democracy and governance, as well as the synergies and collaborations that have emerged during this stage of the project implementation.

The analysis found that:

 Many projects have prioritised large networks of NGOs or umbrella organisations instead of smaller and local NGOs. Despite the drawbacks it can have on smaller and local NGOs, this approach is considered more appropriate in non-democratic settings and the European Neighbourhood Policy (ENP) region²⁹² where project members lack networks and face language barriers.

https://data.europa.eu/doi/10.2777/60819.

²⁹¹ European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D.,

Zharkalliu, K., et al., Evaluation study of the European framework programmes for research and innovation for a resilient Europe: final report: phase 1, Denham, S.(editor), Publications Office of the European Union, 2023,

²⁹² All ENP countries can be found here https://neighbourhood-enlargement.ec.europa.eu/european-neighbourhoodpolicy_en

- The case study also indicates that the degree of **involvement of different** target groups and stakeholders varies not only based on the research topics of the project but also among different regions and contexts. In nondemocratic settings, some stakeholders are more involved than others.
- **Political actors and consultancies** were regarded by beneficiaries as the least relevant and **least involved stakeholders** in their project activities. However, a few projects with consultancies in their consortium perceived them as appropriate for the project's communication and dissemination activities.
- The case study also observes that projects under the Destination democracy have developed various R&I activities for civil society from an early phase of project implementation. This comes in contrast with SC6 R&I activities, where civil society often participated in such activities at the end of the projects.
- Regarding the continuation of Destination democracy and SC6 projects on democracy and governance, the findings indicate that there is, to some extent, a continuity between the two Framework Programmes.
- At the same time, the case study found that **Destination democracy** projects have started to build synergies and collaborations with various programme parts from Horizon Europe (Cluster 2; Cluster 3: Civil Security for Society; Cluster 6: Food, Bioeconomy, Natural Resources, Agriculture and Environment; Marie Skłodowska-Curie Actions and European Research Council) and other EU funding programmes such as Erasmus+.

Nevertheless, given the early stage of the implementation and the relatively small sample of projects (17 projects) available by the time of this supporting study, an updated analysis would be beneficial.

In light of this analysis, the following lessons learned can be identified:

- Both the pandemic and the war in Ukraine are among the two recent crises that have disrupted many researchers' work and mental health. In this regard, creating a support network specifically designed for Horizon Europe researchers from all programme parts is recommended to offer the opportunity to share experiences and seek guidance on navigating research activities under challenging circumstances. This can be in the form of online forums, dedicated communication channels or regular meetings with project beneficiaries and experts/professionals for such issues.
- Given the concerns expressed by project coordinators regarding the potential threats and risks, both offline and online (such as members of far-right groups, anti-gender movements, individuals with different views) they face in genderrelated research, it is crucial to provide them with accessible and practical tools and training for risk assessment and management.
- Project beneficiaries working in the ENP region have noted the restrictions they encounter when conducting research outside of the EU in nondemocratic settings. Given the significant value of research in these locations, beneficiaries have suggested more flexibility and the development of guidelines on how consortia can overcome ethical considerations and freely carry out their research and innovation activities without compromising the quality of their work.

 Due to limitations imposed by social media channels on researchers' access and data sharing, project beneficiaries suggested that the European Commission's assistance disseminating project results would be welcome. Additionally, alternative data sources should be employed so researchers can continue their R&I activities. This could involve exploring other social media channels and public data repositories that offer similar datasets and are open and accessible to researchers.

Introduction

Cluster 2 - Destination democracy objectives

Under Horizon Europe, **the aim of Cluster 2 destination** 'Innovative Research on **Democracy and Governance** is to develop knowledge, data, and evidencebased recommendations **to revitalise democratic governance and enhance trust in democratic institutions**. In the long term, democratic governance is expected to be "reinvigorated by improving the accountability, transparency, effectiveness and safeguarding trustworthiness of rule-of-law based institutions and policies and through the expansion of active and inclusive citizenship empowered by safeguarding fundamental rights"²⁹³. R&I activities under this destination will attempt to expand political participation, promote social dialogue and inclusion, encourage civic engagement and foster gender equality²⁹⁴. Additionally, the destination aims to harness the expertise of social sciences and humanities (SSH) to analyse and respond to the consequences of Ukraine's invasion by Russia and the evolving geopolitical landscape of European neighbourhood and enlargement policies.

In this context, civil society engagement and the involvement of social partners are key priorities of the EU's R&I policies. Such engagement is essential in strengthening trust in science, facilitating and securing the innovation process and its successful implementation and uptake of results by society²⁹⁵. To this end, this case study **investigates the engagement of non-research and non-education entities in Cluster 2 – Destination 1 projects** (Call 2021). In addition, it examines **the continuation of Horizon 2020 SC6 projects** concerning governance and democracy with Destination democracy projects, as well as synergies and collaborations with other programmes.

Policy context

As defined by the Horizon Europe Strategic Plan 2021-2024²⁹⁶, one of the key strategic orientations of the EU research and innovation is **to establish a European society that is resilient, inclusive and democratic**. The European Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities (Article

²⁹³ Horizon Europe Strategic Plan 2021-2024,

https://www.eeas.europa.eu/sites/default/files/horizon_europe_strategic_plan_2021-2024.pdf

²⁹⁴ Cluster 2 Work Programme, 2021-2022. https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-5-culture-creativity-and-inclusive-society_horizon-2021-2022_en.pdf

²⁹⁵ European Commission, Directorate-General for Research and Innovation, Horizon Europe strategic plan 2025-2027 analysis, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2777/637816

²⁹⁶ Horizon Europe Strategic Plan 2021-2024.

2 of the EU Treaty). Yet, **democratic institutions have been under threat** in recent years, a situation that was aggravated by the COVID-19 crisis and Russian aggression in Ukraine.

Cluster 2 destination democracy addresses three major identified challenges (see destination's intervention logic):

First, **democracies are becoming more fragile**, presenting a concerning trend compared to previous years. As indicated by Democracy Worldwide in 2021, the level of democracy experienced by the average global citizen has regressed to levels observed in 1989²⁹⁷. According to the Freedom in the World report by Freedom House in 2022²⁹⁸, democracy is in its 16 consecutive years of decline in global freedom. These developments signify regressed trends of the democratic progress achieved in the past decades.

Second, the political institutions also show a decline in the levels of trust. There has been a significant decline in trust across various EU Member States concerning political institutions, a trend further exacerbated during the pandemic²⁹⁹. Social media platforms have played a significant role in contributing to this erosion of trust. The decline in trust in political institutions poses a significant threat, creating fertile ground for the emergence of populist leaders and movements.

And third, **multilateral global governance is under historic stress**. Tensions between major powers are at a historic high while the world confronts complex and interconnected challenges such as climate change, economic inequalities and health crises.

²⁹⁷ Democracy Report 2022, Autocratisation Changing Nature?. University of Gothenburg https://vdem.net/media/publications/dr_2022.pdf

²⁹⁸ https://freedomhouse.org/sites/default/files/2022-02/FIW_2022_PDF_Booklet_Digital_Final_Web.pdf add full footnote

²⁹⁹ Eurofound (2022), Fifth round of the Living, working and COVID-19 e-survey: Living in a new era of uncertainty,

Publications Office of the European Union, Luxembourg.



Figure 98. Cluster 2: Destination Democracy Intervention Logic

Source: Compiled by the study team.

On a positive note, **democracy in the EU has demonstrated resilience, and citizens still believe in it**. Based on the European Parliament (EP) Eurobarometer results, **EU citizens attribute a high level of public attachment to democratic principles**. When asked about the values the EP should defend as a priority, democracy emerged as the most frequently mentioned value, with more than one-third of the respondents emphasizing its significance. **Protecting human rights within the EU and globally and preserving** freedom of speech and thought **also ranked high** among the respondents. The Special Eurobarometer on the Future of Europe³⁰⁰ also indicated that Europeans consider the EU's respect for democracy, human rights and the rule of law as the main strength of the EU, followed by its economic, industrial and trading power.

Through the **European Democracy Action Plan** (EDAP)³⁰¹, the **Commission reaffirmed its commitment to continue to support research to strengthen democracy**. The Commission will prioritise the promotion of an active civil society and democratic participation across various areas, such as EU citizenship, equality, non-discrimination, youth, education, culture, research policies and the mobilisation of EU funds. As highlighted by EDAP, "a healthy democracy relies on citizen engagement and an active civil society". To this end, the participation and active involvement of citizens and civil society are central to the focus of Cluster 2 R&I activities, which is also the primary focus of this case study.

Methodology

The case study examines the relevance and coherence of the Destination democracy projects, especially the 2021 call 'Protecting and nurturing democracies'.

The methodology employed for this case study involved conducting desk research on policy documents, reports, Work Programmes and other pertinent publications. Additionally, administrative and monitoring data provided by the EC were deployed to interpret and analyse the evaluation questions and key project information. Furthermore, 10 interviews were carried out with 17 persons in total. To explore the researchers' collaboration during the project implementation phase, network analysis was performed by the study team.

Although it is still too early to fully assess the impact of the projects at this stage, the study aims to identify lessons learned.

Key information on Destination democracy - 2021 call

The Table below presents the number of selected projects under Cluster 2 – Destination Democracy, call 2021 'Protecting and nurturing democracies'. The Table indicates the number of funded projects for each topic and their respective budgets.

³⁰⁰ https://ec.europa.eu/commission/presscorner/detail/en/IP_22_447

³⁰¹ European Commission (2020), On the European democracy action plan, COM(2020) 790 final, https://eurlex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0790&from=EN

Table 115. Selected projects under Cluster 2 – Destination democracy, Call 2021 Protecting and nurturing democracies

Торіс	No of funded projects	EU budget in EUR (millions)
Feminism for a new age of democracy	5	12.5
Politics and governance in a post-pandemic world	3	9
The future of liberal democracy in Europe	3	8.3
Economic models and modern democracies	3	8
Democratic politics in the EU's neighbourhood	3	7.8
TOTAL	17	45.6

Source: EC administrative and monitoring data.

In the first call of Horizon Europe Cluster 2 – **Destination democracy** (also the scope of this case study), 68 proposals were submitted for the five topics. Among these submissions, 17 projects were successful and received funding, **resulting in a success rate of 25%.** Each topic comprises 3-5 projects, with an overall budget of approximately EUR 46 million.

Regarding geographical coverage, the first call of Destination democracy encompasses a mix of EU and non-EU countries. Of the 37 countries participating in the 2021 call, 22 were EU Member States, while the remaining 15 were non-EU. The top five countries in terms of funding were Italy, Belgium, Germany, Spain and the Netherlands, indicating their relatively higher representation in the selected projects under this Destination. Other countries with less intense representation but still essential contributors to the projects included Poland, France, Hungary, Greece, Austria, Czechia, and Sweden. On the other hand, countries like Portugal, Cyprus, Finland, and Bulgaria had a lower level of participation in the funded projects, with only one organisation representing each country.

Regarding the participation of non-EU countries, the United Kingdom and Switzerland emerged as the dominant non-EU countries. Destination democracy's call on 'Protecting and nurturing democracies' also saw the involvement of the European Neighbourhood Policy (ENP) in countries such as Georgia, Lebanon, Palestine, Tunisia and Israel, highlighting the importance of such topics in the EU's Eastern and Southern neighbours.

The Figure below depicts a more detailed geographic coverage under the 2021 call of the Cluster 2 – Destination democracy programme.


Figure 99. Participant countries in Cluster 2 – Destination democracy (2021 call)

Source: EC administrative and monitoring data.

Case study key findings

Citizen engagement and the engagement of social partners and civil society actors are key priorities in the EU's R&I policies. Such engagement is critical to reinforce trust in science and facilitate and secure the innovation process and its uptake. Particularly in the context of democracy-related topics under Destination democracy, the involvement of these stakeholders becomes even more significant and relevant as they make the process more inclusive and participatory.

Most involved stakeholders under Cluster 2 – Destination democracy (call 2021)

Under Destination democracy (2021 call), **9% of participant organisations were** registered as 'OTHERS', including **non-governmental organisations** within this category. Among the five topics in this call, the involvement of NGOs varies (see graph below). The topic 'Economic models and modern democracies' had the highest percentage of NGOs among project members. This topic also had the lowest number of beneficiaries (26) but the highest number of NGO participants (5) compared to the other topics. While it is too early to extrapolate any conclusions, this initial observation suggests that NGOs are becoming increasingly significant in addressing the interconnectedness of democracy and human rights with the economic aspects. Beneficiaries from these projects specifically identified companies and social entrepreneurs as their primary target groups.

Figure 100. Participation of NGOs in Cluster 2 – Destination democracy topics in% (2021 call)



Source: EC administrative and monitoring data.

The case study observed that **many projects prioritise engaging large networks of NGOs or umbrella organizations rather than smaller, local NGOs**. This preference for NGOs with extensive outreach capacities and potential proves beneficial and practical for the projects, allowing them to reach a wider audience and gain increased visibility. Project coordinators, particularly for projects covering the ENP region, have emphasised the strategic importance of this approach. Since consortium partners often lack established networks and face language barriers in those countries, approaching a network or NGO platform is more effective. However, this approach excludes smaller NGOs with local expertise and knowledge due to their limited size and network.

Regarding the roles of NGOs in the project, there is significant variation in the responses from project coordinators. In more academically-oriented projects, the role of NGOs mainly revolves around organising communication and dissemination activities.. Additionally, projects have incorporated the expertise and guidance of NGOs by including them as members of the project's Advisory board.

However, not all interviewees agreed with NGOs being involved in the research activities of the projects.

"NGOs should be involved in ways that are meaningful for the project and also meaningful for them. They should be involved in a way that does not disrupt their really important work, which often is not research. For an NGO to also have the role of the researcher in the project, might not be appropriate", Destination democracy project coordinator.

The findings of the case study indicate that the degree of **involvement of various target groups and stakeholders varies** not only based on the topics of the project but also **among different contexts**. Specifically, when examining projects within the EU, the primary stakeholders and target groups commonly identified included the

research community, civil society organizations, local authorities and policymakers. As in SC6 projects, policymakers were reported by project beneficiaries as the most difficult stakeholders to reach. Based on the discussions with project coordinators on the topic of 'Democratic politics in the EU's neighbourhood', interviews revealed that civil society organizations, activists and social movements played a more prominent role compared to other actors. With their deep understanding of local dynamics and close connections to local communities, social mobilisation and activists play a crucial role in driving change and advocating for specific causes in the ENP region. Their engagement in R&I projects can provide valuable insights, perspectives and connections that contribute to the overall effectiveness and relevance of the initiatives. This could suggest that these actors have greater involvement in shaping democratic politics in the ENP region. These regional variations in stakeholder involvement underscore the importance of tailoring R&I approaches to specific regions and contexts.

Least involved stakeholders under Cluster 2 – Destination democracy (call 2021)

During the interviews, **political parties and political actors ranked as the least involved stakeholders**. The beneficiaries still acknowledged their significance but also expressed concerns that involving political actors in their activities can be risky or discourage other groups from participating in their R&I activities. Furthermore, project members prioritised maintaining neutrality and conducting unbiased scientific research as core principles. By engaging political actors in their R&I activities, projects could potentially alter their mission and compromise their impartiality. In some instances, particularly in projects on **gender-related issues or those targeting the ENP region**, it **proved challenging to engage political parties**. Some challenges that emerged during the interview underlined the difficulty of organising open events when presenting gender-related research findings, online hate speech and threats via social media by anti-gender movements, and ethical dilemmas to invite far-right political members for discussion, such as on migration. Other reported challenges were mentioned regarding physical barriers, such as countries or regions that are at war or marred in conflicts. The risky situation for

> "Political parties in our project? This is a good question. Can we have all these actors in the same room? If they are from different political spectrums, we are afraid that their engagement will turn into political lectures", Destination democracy, project coordinator.

During the interviews, **consultancies** were identified as **the least involved stakeholders after political parties**. The vast majority of project coordinators interviewed for this case study reported not using companies to write their proposals. Nevertheless, in a few cases where consultancies were part of the project team, they were considered important partners during the implementation rather than the proposal phase.

Destination democracy R&I activities

Compared to the Horizon 2020 – SC6 programme, the case study findings indicate a shift in the R&I activities deployed by projects to engage non-academic

stakeholders and target groups, **especially civil society.** This shift is observed in two different trends. First, non-academic target groups and stakeholders are involved in R&I activities from the early stage of the project implementation, not at the finalisation stage, as it was often reported in SC6 actions³⁰². Secondly, projects under Destination democracy have introduced inclusive and diverse ways and tools with the overarching goal of reaching out to relevant stakeholders. In this case, they are participating both as direct recipients of project activities (such as summer schools, online courses, citizens juries and fellowships). They are also providing feedback to consortia (via interviews and on-site and online public events) that, later on, will feed into projects' results and concrete policy recommendations.

"It is important that citizens become co-producers of science not just mere recipients of our activities. We want them to be producers of knowledge and feedback", Destination democracy project coordinator.

The Table below showcases specific examples of activities from Destination democracy projects that actively involve civil society in their activities.

Title	How?	For whom?	Why?	What?
National and transnationa l mini- publics/citize ns' juries	On-site meetings	Citizens	To empower citizens in EU policymaking for more democratic and resilient crisis governance.	Citizens will frame discussions and formulate policy recommendations, with particular attention to new communication technologies and their implications. Participants will formulate a verdict, which will be presented to the European Parliament.
National and transnationa I labs	Collaboration and training	Feminist actors and civil society	To bridge gaps between feminist movements and civil society on one hand, and institutional and party representative s on the other.	The co-creation with feminist movements and political actors from feminist civil society will be applied to both knowledge generation and to the development of innovative democratic actions, as well as to the elaboration of concrete solutions/tools and policy recommendations.

Table 116. R&I activities directly involving civil society and other relevant stakeholders under Cluster 2 – Destination democracy

³⁰² European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K., et al., Evaluation study of the European framework programmes for research and innovation for a resilient Europe: final report: phase 1, Denham, S. (editor), Publications Office of the European Union, 2023.

Gender Equality Fellowship in Brussels	Fellowship	Members of civil society	To enhance the network for the consortium and the project's visibility beyond EU borders for the local civil society in selected ENP countries.	The fellowship will be offered to participants from Ukraine, Georgia, Armenia, Tunisia, Palestine, Lebanon .
Talks series	A mix of in- person and live-streamed lecture	Civil society and academia	To promote the role of economic democracy in reducing inequalities and human rights.	A series of in-person and live-streamed lectures and workshops on human rights, corporate social responsibility and the private sector.
Interviews	Qualitative research	Teachers, civil servants in ministries and students	To gain in- depth insight from target groups and stakeholders	The interviews' aim is to help the consortium understand experiences from citizenship education. The findings will feed into the project's deliverables.
Citizen juries/assem blies	On-site	Citizens and students	To promote citizens' science in the EU	Four citizens juries with a duration of two days each. The consortium after a random selection of citizens, will discuss the concept of legitimacy issues during crises.
Open Innovation Labs	Event	Civil society, local administration and enterprises	To raise awareness of the implications of big tech giants on citizens' rights	The project will organise Open Innovation Labs at the city level in three European cities (Bologna, Bucharest and Barcelona) involving a set of stakeholders for the co- creation of experimental forms of governance able to tackle the disruptive effects of corporate political power and to trace possible alternatives.
Summer school	On-site and online modules	Feminist and grassroots organisations	To offer capacity building to feminist grassroots organisations	A summer school that strengthens peer learning opportunities for feminist organisations and integrates those with a more structured capacity- building approach.

Source: Compiled by the study team.

As it emerged during the interviews, Destination democracy consortia are **adapting R&I** activities to meet the specific needs of their relevant stakeholders and diverse contexts. This adaptability is more evident in non-EU countries, where certain alternative forms of activities have been found to be more effective and have reached a wider range of relevant audiences. For instance, in the case of Palestine, the use of radio as a communication tool has proven to be particularly impactful in engaging and reaching out to the relevant target audiences and stakeholders as compared to a more conventional dissemination activity (i.e. a conference, workshop, etc.).

Synergies and complementarities with other Horizon Europe Programme parts

In addition to the relevant stakeholders, the case study provides insights into the level of continuity between Destination democracy projects and SC6 projects in the realm of governance and democracy.

Based on the feedback gathered during interviews, several **projects have drawn inspiration from the Horizon 2020 SC6 projects** on democracy and governance. Although the topics proposed under Horizon Europe Cluster 2 are novel, many beneficiaries have reported that their projects have incorporated, to some extent, the findings or addressed the gaps identified in previous projects. Some interviewed project coordinators reported conducting joint sessions with recently concluded SC6 projects. This demonstrates the **continuity and knowledge transfer between the two Framework Programmes,** allowing for building previous research and experiences.

"We have invited to our ethics board the project coordinator from a Horizon 2020 project that had a similar focus area as our project. In that sense, there is some sort of continuity in this project from an SC6 project", the Destination democracy project coordinator.

In addition to SC6, two project coordinators stated that the initial idea of their projects resulted from a Jean Monnet Action on democracy, while another project drew inspiration from academic literature and research findings on democracy.

Based on the interview feedback, Destination democracy projects have led to **synergies and collaboration with other projects within the same destination and topics**. Under the guidance of the EC project officers, projects focusing on similar topics have been connected and have already organised sessions to share their implementation plans and explore any potential for synergies and collaborations. Interviewees highlighted that at this Phase, projects mainly explore the different ways they could benefit from each other. Examples of these synergies are meetings aligning projects content-wise, joint seminars, conferences and lectures, sharing expertise and data and co-hosting conferences, to name but a few. This proactive approach enables the exchange of projects from an early phase and cultivates a cooperative environment among the projects.

In addition to projects achieving synergies in the same cluster and destination, beneficiaries reported a few **projects that have initiated collaborations with projects from Cluster 3**, 'Civil security for society'. During the interview programme, project coordinators expressed their expectations of establishing synergies with Cluster 3 projects, particularly those addressing online disinformation and digital democratisation. Beneficiaries emphasised the significant potential for cooperation between the two clusters, as they address similar issues from distinct perspectives. While Destination democracy projects primarily focus on theoretical

aspects, Cluster 3 projects concentrate on technical matters and digital technologies. A few instances have already demonstrated mutual contributions between projects, highlighting the cross-cluster collaboration.

Figure 101. Synergies and collaborations between Cluster 2 - Destination Democracy (2021 call) and other programmes



Source: Compiled by the study team based on the interviews with CL2 project coordinators.

According to the feedback received during the interview programme, beneficiaries expressed their intentions to establish **synergies with projects under the Erasmus+ programme**. The prevailing form of collaboration in these instances often involves sharing and exchanging theoretical work and data and providing training support that Cluster 2 projects can benefit from Erasmus+ projects.

Former and current **Principal Investigators within the European Research Council (ERC) are also involved in Destination democracy projects**. While it is still early to extrapolate any conclusions for the final form of synergies with the ERC, the interviewees confirmed that findings and relevant data from these projects will be integrated into their own R&I activities.

Furthermore, the **network analysis** revealed the presence of **synergies** between Cluster 2 Destination democracy and the **Marie Skłodowska-Curie Actions**. Additionally, although **to a lesser extent**, synergies were observed **with Cluster 6** 'Food, Bioeconomy, Natural Resources, Agriculture, and Environment'.

Finally, beneficiaries highlighted the establishment of synergies with projects supported by national funding schemes, such as the **British Academy**.

Strengths and success factors, and challenges

This section highlights success factors and areas that, according to the case study findings, require further improvement in Destination democracy under Cluster 2. In the subsequent section, we will *elaborate more on these factors*.

Strengths

Integration of SSH dimension in Pillar II/Clusters: The project coordinators were rather positive regarding the novelty of Horizon Europe on the inclusion of SSH dimension in all Clusters under Pillar II. They acknowledged that this advancement has opened up more avenues for SSH participants and stakeholders to get involved and become more familiar with non-SSH-related areas. This new development has expanded their opportunities to engage and contribute to projects beyond the SSH domain and interact with non-SSH stakeholders. The project coordinators highlighted the increased potential for interdisciplinary collaboration, with SSH playing a vital role in driving project impacts in all clusters.

Increased budget for Cluster 2: Likewise, the beneficiaries of Cluster 2 expressed their strong appreciation for the increased budget allocated to the cluster (EUR 1.7 billion under Horizon 2020 to EUR 2.3 billion in Horizon Europe), enabling the funding of multiple projects within each topic. The increased budget is also translated into engaging more stakeholders and target groups in projects' R&I activities.

Lessons learned from the COVID-19 pandemic: Despite the negative implications triggered by the outbreak of the pandemic at all levels, beneficiaries noted, this experience has been very valuable in enhancing their adaptability. As a result, consortia now feel more proficient in adjusting to external factors by deploying flexible methodologies, including online tools. The decision to deploy such tools is made on a case-by-case basis, considering the political circumstances of each respective country. Notably, this approach was particularly evident among consortia whose R&I activities in the ENP region (i.e. Palestine, Ukraine). These consortia face unique challenges that limit their ability to effectively reach the relevant target groups. Nonetheless, they have demonstrated a solid commitment to implementing strategies that allow maximum engagement and impact within circumstance.

Flexibility to integrate new R&I dimensions: Recent developments, such as the war in Ukraine, have led projects to incorporate angles that were not anticipated during the proposal phase. SSH researchers are accustomed to dealing with unforeseen developments and, therefore, prepare their proposals in a manner that accommodates the incorporation of such events. Integrating these new aspects has taken place smoothly without derailing the projects' objectives and overall direction. The projects focused on the ENP region also reported a high degree of flexibility. A high degree of flexibility was reported to be necessary, especially in dissemination and communication activities with project coordinators, allowing ENP partners to decide what works better for their local/national contexts.

Areas for further improvement

The **war in Ukraine** has emerged as a significant disruptive factor for numerous projects. In particular, projects in the ENP region involving Ukrainian organizations have faced difficulties engaging relevant stakeholders and target groups as initially planned in their research and innovation activities. Despite these challenges, the project consortia successfully cope with the situation, although there have been delays in delivering project outcomes. However, dealing with the emotional weight of the conflict remains a more challenging aspect.

Considerations of ethics and freedom of research were identified as significant constraints for projects focusing on democracy topics, particularly in consortia involving non-EU countries. As noted by project beneficiaries, conducting research in

low-income countries, where institutions may not be as stable as those in high-income countries, presents challenges in R&I activities related to democracy. When studying democracy in non-democratic or authoritarian settings, obtaining permission from the authorities becomes a crucial step in conducting research. One issue arises from the absence of established ethics committees or similar procedures to ensure compliance with ethical regulations in such countries. Additionally, beneficiaries reported that it is not always easy to identify the appropriate authorities to approach. Consequently, obtaining an ethics permit before initiating research in these contexts becomes essential while it also generates constraints regarding the freedom of research among researchers.

During the interview programme with Cluster 2 project coordinators involved in **gender-related research have expressed concerns about the potential threats and risks** they may encounter throughout their project activities due to the sensitive topics they work on. Project coordinators said that they are aware of threats and risks (i.e. attacks either online via social media or physical attack against consortium members, specific researcher or organisation) that have been subject to such attacks. These projects often find themselves compelled to allocate resources towards mitigating these risks, spending much time on developing security approaches and thus diverting attention from their primary research focus. As noted by the beneficiaries, additional I effort is dedicated to communication startegy, additional meetings to discuss such issues, dissemination and data management plans, all of which require risk assessment and management. Consortia involved in these projects deploy extra resources that otherwise they would not use, primarily in intellectual labour and capacity and less in financial terms.

Social media restrictions on free data access³⁰³: In February 2023, Twitter announced that it would end free data access. Projects that rely on reviewing textual data and conducting social media analysis have expressed concerns about the significant implications these new restrictions have on their daily research activities. These changes not only hinder their work but also narrow the field and scope of certain projects, limiting their ability to proceed as planned. Additionally, the altered regulations have had a notable impact on the social media dissemination strategies of these projects, making the process more challenging.

Key lessons learned

The case study indicates four areas as lessons learned and lists a set of recommendations.

 Both the pandemic and the war in Ukraine are among the two recent crises that have disrupted many researchers' work and mental health. In this regard, creating a support network specifically designed for Horizon Europe researchers from all programme parts is recommended to offer the opportunity to share experiences and seek guidance on navigating research activities under challenging circumstances. This can be in the form of online forums, dedicated communication channels or regular meetings with project beneficiaries and experts/professionals for such issues.

³⁰³ Ledford, H (2023). 'Researchers scramble as Twitter plans to end free data access' in Nature, https://www.nature.com/articles/d41586-023-00460-z

- Given the concerns expressed by project coordinators regarding the potential threats and risks, both offline and online (such as members of far-right groups, anti-gender movements, and individuals with different views) they face in gender-related research, it is crucial to provide them with accessible and practical tools and training for risk assessment and management.
- Project beneficiaries working in the ENP region have noted the restrictions they encounter when conducting research outside of the EU in nondemocratic settings. Given the significant value of research in these locations, beneficiaries have requested more flexibility and the development of guidelines on how consortia can overcome ethical considerations and freely carry out their research and innovation activities without compromising the quality of their work.
- Due to limitations imposed by social media channels on researchers' access and data sharing, project beneficiaries suggested that the European Commission assist in disseminating project results. Additionally, alternative data sources should be employed so researchers can continue their R&I activities. This could involve exploring other social media channels and public data repositories that offer similar datasets and are open and accessible to researchers.

Case Study No 8: Cultural and creative industries

Executive Summary

This case study focuses on Horizon Europe calls in the cultural and creative industries (CCI) field. It is based on two main elements: (a) a quantitative analysis of the share that organisations from the CCI field represent among the participants and (b) a qualitative analysis of their experiences so far, based on interviewees with beneficiaries from the CCI field. The results are analysed and presented along the five evaluation criteria: effectiveness, relevance, efficiency, coherence, and EU added value of the funding.

The beneficiaries found EU funding calls to be aligned with their needs and interests, offering flexibility and opportunities for collaboration. The funding stimulated thematic and methodological shifts in their research, encouraging innovation and interdisciplinary collaboration. EU funding played a crucial role in supporting in-depth research, expanding networks, and driving societal impact.

Challenges faced by beneficiaries included the complexity of EU calls and limited access to funding for small and medium-sized enterprises. Efficient communication and management within diverse consortia were also highlighted as areas of improvement. The beneficiaries acknowledged the synergies and complementarities between EU funding and other funding opportunities at the EU and national levels.

EU funding provided collaborative opportunities, a global scope, larger funding sums, and prestige for beneficiaries. It enabled research and projects that would not have been achievable at the national level. The complementarity of national and EU funding was emphasised.

The study underscores the transformative potential of EU funding initiatives in driving sustainable innovation, preserving cultural heritage, and cultivating a sense of European identity. It emphasises the importance of continued support for research and

innovation in the cultural and creative sector and the need for improved access and communication for SMEs.

Introduction

Europe's abundant cultural heritage, characterised by shared values, a wealth of historical landmarks, and a vibrant diversity of traditions, arts, languages, and more, reflects our collective history and shapes our present and future. It serves as a powerful medium for nurturing independent thinking, fostering dialogue, and advancing our global interests. The accessibility to cultural heritage experiences contributes to social cohesion and inclusivity, reinforcing resilience, strengthening a sense of belonging, fostering unity, and enhancing overall well-being.

Within the Horizon Europe programme, specifically in the "Pillar II - Global Challenges and European Industrial Competitiveness", lies the "Cluster 2 Culture, Creativity and Inclusive Society." Under this cluster, the destination "Innovative Research on European Cultural Heritage and Cultural and Creative Industries – Building Our Future from the Past" highlights the importance of addressing research and scientific endeavours related to cultural heritage.

To ensure the effectiveness of proposals within this destination, the following aspects should be considered and actively promoted in a comprehensive and interdisciplinary manner:³⁰⁴

- Incorporating cutting-edge digital technologies and leveraging existing research outputs and available technologies to drive innovation and progress.
- Establishing sustainable engagement with stakeholders, social innovators, and citizens, promoting their active participation in research outcomes and recommendations.
- Contributing to the objectives of the European Green Deal, the New European Bauhaus, and the Sustainable Development Goals, emphasising the importance of sustainable management and the increased involvement of cultural and creative industries (CCIs) in achieving these objectives.

Proposals falling under this destination should aim to achieve the expected impact outlined in the Horizon Europe Strategic Plan: Realising the full potential of cultural heritage, arts, and the cultural and creative sectors as drivers of sustainable innovation and cultivating a sense of European identity. This can be achieved through continuous engagement with society, citizens, and economic sectors, coupled with enhanced protection, restoration, and promotion of cultural heritage.³⁰⁵

Against the above background, this case study examines the activities resulting from the calls at the mentioned destination. It is based on two main elements: (a) a quantitative analysis of the share that organisations from the CCI field represent among the participants and (b) a qualitative analysis of their experiences so far, based on interviewees with beneficiaries from the CCI field. The results are analysed and

³⁰⁴ Horizon Europe - Work Programme 2021-2022: Culture, creativity and inclusive society

³⁰⁵ Horizon Europe - Strategic Plan 2021-2024

presented along the five evaluation criteria: effectiveness, relevance, efficiency, coherence, and EU added value of the funding.

A list of the relevant calls can be found in the Appendix; the following chapter will give a general overview of the key data regarding the relevant calls.

Key Data

This case study focuses on the following relevant calls (see Appendix) and related projects:

- HORIZON-CL2-2021-HERITAGE-01
- HORIZON-CL2-2021-HERITAGE-02
- HORIZON-CL2-2022-HERITAGE-01
- HORIZON-CL2-2022-HERITAGE-02

The data provided account for 5601 applicants and 527 proposals, resulting in 44 funded projects. The overall funding volume for the relevant calls amounts to 156.146.448 \in . Figure 47 shows the participation in proposals by country, with Italy having the highest participation of 14.9%, followed by Spain (9.9%) and Greece (8.2%). The distribution for successful applications remains quite similar, with Italy having the highest participation of 12.4%, followed by Greece (9.2%) and Spain (7.7%) (see Figure 102).

Figure 102. Participation in proposals (successful and unsuccessful; n= 5601) by country



Source: Compiled by the study team.



Figure 103. Participation in proposals (successful; n= 612) by country

Source: Compiled by the study team.

Effectiveness, relevance, coherence, efficiency & and added value

Effectiveness

One of the key research questions underlying this case study has been determining the share of CCIs among the total number of beneficiaries within the relevant calls. This was done in two different ways.

First, we used a framework Dominic Power and Tobias Nielsén developed in the context of a Priority Sector Report for the "European Cluster Observatory" ³⁰⁶. This framework classifies organisations as CCI/non-CCI based on the 4-digit NACE code of the said organisation. The data provided through CORDIS was not proof sufficient for this purpose since it relied on self-disclosure through participants, resulting in a mixed level of detail and inconsistencies in reporting. Hence, the CORDIS data were matched with data from the ORBIS³⁰⁷ database, being able to provide the necessary NACE data for 61.0% (3419) of the applicants.

Based on this, the share of CCIs among the 3419 NACE-coded applicants was determined through the above framework as being 13.7%, and the share of non-CCIs accordingly as 86.3% (see Figure 104). When looking at successful applications (n=379) only, the share of CCIs (13.7%) remains almost identical. This indicates that members of the cultural and creative industries are neither favoured nor disadvantaged compared to non-members during the application process.

portal.org/smash/get/diva2:359744/FULLTEXT01.pdf.

307 https://orbis.bvdinfo.com/

³⁰⁶ Power, Dominic and Tobias Nielsén. Priority Sector Report: Creative and Cultural Industries – March 2010 - Deliverable D9-1; Methodological Appendix; Conceptual definition, page 3. S. https://www.diva-



Figure 104. Calculation of share of CCIs based on NACE code classification

Second, in order to address a possible selection bias within the NACE-coded applicants, we also drew a random control sample (n=200) from the 2182 non-NACE-coded applicants, which was then manually assessed. This was done by analysing the information on their respective websites and assessing whether their activities (roughly) corresponded to any relevant NACE codes. Based on this manual assessment, the control sample showed a CCI participation of $31.5\%^{308}$, i.e. almost 2.5 times as high as the sample of NACE-coded participants.

Source: Compiled by the study team.

³⁰⁸ The margin of error is 4.04 percentage points, with 95% confidence level.



Figure 105. Estimation of share of CCIs calls based on manually assessed samples

Source: Compiled by the study team.

Because of the enormous discrepancy between the 13.7% share identified among the 3419 NACE-coded applicants and the 31.5% identified among the random control sample of 200, we decided to test our approach by drawing a second random sample, this time drawn from the 3419 NACE-coded applicants and assessing them manually. This resulted in a share of 19.5%³⁰⁹ CCIs among the NACE-coded applicants.

In other words, there are two different discrepancies:

 One discrepancy concerns the difference *within* the set of 3419 NACE-coded applicants, i.e. between the 13.7% share calculated based on the NACE codes of all 3419 organisations and the 19.5% share calculated based on manual assessment of a random sample of 200 organisations from the same set of organisations.

Apart from the statistical margin of error, further analysis has shown that this discrepancy is due to several CCI-related organisations applying non-CCI-related NACE codes. This concerns, amongst others:

- Some associations and foundations active in the cultural and creative field are counted as professional membership organisations or institutes for tertiary education according to NACE;
- Some museum services are counted as travel/reservation services and retail according to NACE;
- Some freelancers are active in CCIs that are counted as "other professional, scientific and technical activities n.e.c." according to NACE.

³⁰⁹ The margin of error is 6.7 percentage points, with 95% confidence level.

2) A second discrepancy concerns the difference between the manually assessed sample taken from the 3410 NACE-coded applicants on the one hand and the manually assessed sample taken from the 2182 non-NACEcoded applicants (which indicated shares of 19.5% and 31.5%, respectively).

Apart from the statistical margin of error, this hints at a strong selection bias among the NACE-coded applicants. Indeed, it may be hypothesised that CCIs are less likely to classify themselves in official register data for two reasons:

- First, they may often simply not "fit" into standard categories. The term "cultural and creative industries" covers a wide range of many different, often very niche, activities that do not lend themselves to standardised classifications.
- Second, while this may be a stereotype, small organisations (and freelancers) in the cultural and creative sector may also have less will and capacity for "dry" administrative tasks such as indicating their NACE code in company registers.
- Of course, both points must be seen as hypotheses. This issue deserves further investigation, which could not be done within the scope of the case study.

In order to further investigate if the stated objective of increased CCI involvement is met, the analysis needs to be extended over the timeline. Although the above-cited framework proves to be a suitable and easy to use indicator for CCI participation, there is a need to enhance the data quality provided by the applicants for more in-depth analysis.

For the purposes of this case study, we need to content ourselves with a pragmatic approach. We calculate the weighted arithmetic mean of the two hand-assessed samples as follows:

 $\bar{x} = (3419 * 19.5\% + 2182 * 31.5\%) / 5601 = 24.2\%^{310}$.

In other words, acknowledging a margin of error of 5.3 percentage points, the share of CCIs participating in the relevant calls under Horizon Europe seems to be roughly one quarter.

Following this quantitative analysis, the subsequent sections present the findings of the qualitative analysis based on the interviews with beneficiaries.

Relevance

"In your view, do the call topics correspond to the actual needs and interests of beneficiaries?"

Across the interviews, several common themes emerged, highlighting areas of alignment between the funding call topics and beneficiary needs:

³¹⁰ The margin of error is 5.3 percentage points, with 95% confidence level.

- Flexibility and openness: Various beneficiaries acknowledged that the calls were formulated broadly, allowing for various possible angles that can be taken in the projects. This flexibility was seen as advantageous, providing room for niche themes.
- Cooperative approach and importance of partnerships: Many beneficiaries emphasised the cooperative approach and connection opportunities between different stakeholders, such as arts and tech companies, as one of the very positive aspects. This collaborative environment was valued by beneficiaries and contributed to a more comprehensive approach, linking conservation and innovation objectives with respect to cultural assets. Another beneficiary highlighted the significance of partnerships in EU-funded projects, especially for small and medium-sized enterprises lacking sufficient resources to lead proposals. They emphasised that strategic relevance determines their decision to contribute and that cooperation with partners from different sectors is crucial. This underlines the EU's emphasis on fostering cross-sector collaborations and leveraging diverse expertise to drive innovation.
- **Societal relevance**: All beneficiaries recognised the significance of their projects in contributing to societal impact. The projects focused on a range of topics, such as digitalisation, Artificial Intelligence, immersive experiences, heritage research, and gender balance in the music sector. The alignment of their endeavours with societal needs highlights the relevance and potential of EU funding to address pressing challenges.

At the same time, the interviews also revealed areas for improvement:

- Need for (even) more multidisciplinarity: Although recognising the importance of sustainability, social innovation, inclusion, and visionary topics, they expressed a need for more topics that bridge art, creative processes, and innovation, indicating a further desire for multidisciplinary collaboration and the creation of new opportunities.
- **Market needs and impact**: The relevance of EU funding in responding to market needs and connecting academic research with market circumstances was emphasised. They recognised the market impact of the project as a crucial measure of success, underscoring the importance of aligning research and innovation efforts with market requirements.

"Did the call topic stimulate you to go into a new direction of research (thematically and/or methodologically)?"

More specifically, the following aspects were mentioned by the interviewees:

- New research angles: Several beneficiaries emphasised that the call topic influenced their research direction, leading to thematic shifts in their work (e.g. by including sustainability-related aspects in their work). These responses indicate that the call topics acted as catalysts, encouraging beneficiaries to align their research with the EU's thematic priorities.
- New methods and approaches: Several beneficiaries pointed out that the calls' specifications had also triggered them to include new methods and approaches in their proposed projects. For example, one beneficiary mentioned how the relevant call had sparked them to bring foresight work into their project.

• Expanded reach and stakeholder engagement: One beneficiary mentioned that EU funding provided an opportunity to reach out to a broader range of market players. While a specific research project did not drive their initial motivation, they acknowledged their work's potential to change how they engage with stakeholders. This showcases the EU funding's role in expanding beneficiaries' networks and enhancing their interactions with various stakeholders.

Efficiency

"What are the challenges encountered by beneficiaries?"

Beneficiaries universally referred to the complexity of EU calls and the need for administrative expertise and resources to navigate them effectively. Additionally, they highlighted challenges faced by small and medium enterprises (SMEs), such as limited possibilities to provide co-funding and exclusion from consortia due to programme structures:

- Complexity and need for administrative expertise and capacity: All beneficiaries stressed the complexity of EU calls and the requirement for sufficient know-how and resources. The application and implementation processes were considered demanding and time-consuming. Universities were recognised as being well-equipped partners for such projects due to their legal experience and financial support. Additionally, several beneficiaries mentioned the importance of an experienced team responding effectively to the calls.
- Challenges for non-research actors: An intergovernmental organisation dedicated to cultural heritage conservation discussed their challenges in being accepted as a beneficiary. They expressed the need for a more streamlined process, advanced recognition for key organisations, and more flexibility in partner selection criteria.
- Challenges for small and medium enterprises (SMEs): Beneficiaries from various sectors highlighted the challenges faced by SMEs. One beneficiary specifically mentioned that start-ups and smaller entities faced difficulties in accessing EU funding due to being excluded from the consortium for not fulfilling the EU's criteria for the call. The entry barrier is perceived as discrimination in the programme structure by the beneficiary, as it neglects the contributions of SMEs and start-ups to innovative behaviour, leading to a loss of valuable knowledge and creative approaches.
- **Need for smaller-scale calls**: Linked to the previous point, another beneficiary specifically emphasised the need for smaller-scale calls that focus on specific topics and have shorter timeframes to facilitate SME participation through programme structures that are less resource intensive.
- **Communication and management:** Notwithstanding the many benefits of the large and diverse consortia, interviewees also pointed out the various challenges that come with it. The management of such diverse consortia posed challenges in terms of communication, coordination, and cultural differences. Consortium leaders, in particular, faced the demanding task of keeping pace with the management process, highlighting the need for efficient collaboration and project oversight.

Coherence

"Are there synergies or complementarities between the Horizon Europe call topics that you looked into and other funding opportunities at EU or national level?"

The beneficiaries highlight the importance of synergies, interconnectedness, and access to European networks and partnerships facilitated by EU funding and further recognise the global impact of European framework programs and the meaningful data and networks they provide. Furthermore, they stress the advanced nature of EU programmes and the alignment with EU priorities in areas such as sustainability and digital innovation. One common theme emerges from the beneficiaries' responses, showcasing shared challenges and improvements:

More specifically, with respect to synergies and complementarities with other funding programmes:

- Synergies and complementarity with Creative Europe: While several of the interviewees appreciated the research-oriented nature of Horizon programmes, they also highlighted the complementary, e.g. with respect to the Creative Europe programme. Leveraging different funding sources helped beneficiaries extend their projects, and the Beneficiary expects to be able to build upon the results achieved in Horizon Europe.
- Interconnectedness to other Horizon Europe programme parts: One of the interviewees pointed out interconnections with other programme parts within Horizon Europe, more specifically with Cluster 4, where they are involved in a project that also addresses the topics of art and technology.

EU added value

"Are the projects funded, through the European/ transnational dimension, likely to achieve things that would not be achievable at national level?"

The case study revealed both similarities and differences in the experiences of beneficiaries who received EU funding. All beneficiaries acknowledged the collaborative opportunities and global scope provided by EU programmes:

- **Collaborative opportunities**: Beneficiaries universally acknowledged that EU programmes provide a platform for collaboration and networking. The wide network offered by these programs facilitates interaction and knowledge exchange among participants, representing the spirit of European unity.
- **Global scope:** The beneficiaries recognised that EU funding calls provide a more global scope, allowing research and projects to address challenges beyond national boundaries. This broader perspective is particularly important, as it enables the exploration of innovative solutions, such as steering research towards environmentally friendly initiatives.
- Larger funding sums: Several beneficiaries expressed that EU funding offers larger sums compared to regional or national programs. This increased financial support contributes to the successful implementation of long-term projects, overcoming the limitations of short-term funding options available at the national level. Beneficiaries indicated that EU-level funding opportunities

provided critical support for their projects. They appreciated the innovation incentives offered by the funding programs and their impact on shaping industries.

More diverse opinions emerged concerning the limitations of national funding, the importance of complementarity between national and EU funding, and the prestige associated with European funding:

- National funding limitations: One beneficiary highlighted the limited opportunities available at the regional or national level, specifically in the cultural sector. National funding was described as more short-term and focused on technological aspects, potentially excluding other areas such as cultural enterprises.
- Complementarity of national and EU funding: Some beneficiaries pointed out the complete absence of similar funding opportunities at the national level. In contrast, another pointed out the lack of synergies and limited focus of policymakers on relevant topics in his country. This suggests a disparity in funding availability and illustrates the value of EU funding programmes for beneficiaries in countries with limited national opportunities. In opposition to that, another beneficiary emphasised the importance of complementarity between national and EU funding. They illustrated that national funding could effectively complement EU funding, as research activities have transcended national borders and require a platform to bring together stakeholders from various backgrounds.
- Increasing the impact of projects through funding from other programmes: Another beneficiary expressed strong interest in extending or developing their project beyond the current funding period by bringing up the potential for collaborations with other programmes, such as Creative Europe or Erasmus Plus, to create educational materials and guidelines based on their research. These are interesting suggestions for strengthening links and synergies with other relevant programmes.
- **Prestige and internationalisation:** One beneficiary highlighted the prestige associated with European funding and acknowledged the high budget for human resources. They also expressed the need for networking opportunities beyond technology and science, as their institution focuses on museums and cultural centres.
- Advancement and priorities: One beneficiary perceived the EU programs as more advanced compared to national programs, especially in terms of funding availability and alignment with EU priorities such as sustainability, digital innovation, and technology. They also noted that their cultural ministry's focus on internationalisation was relatively limited.

Key lessons learned and other important observations

- The EU funding call topics were generally aligned with the needs and interests of the beneficiaries, providing flexibility and openness. This flexibility fostered cooperation and communication among beneficiaries of different types and facilitated interdisciplinary collaboration.
- Beneficiaries appreciated the cooperative approach and stakeholder connections promoted by Horizon Europe, as they facilitated a comprehensive approach to conservation, preservation, and innovation in cultural heritage. The topics related to sustainability, social innovation, and

inclusion were particularly relevant, indicating a desire for multidisciplinary collaboration and new opportunities.

- EU funding played a significant role in stimulating beneficiaries to explore new research directions thematically and methodologically. The call topics acted as catalysts, influencing the beneficiaries' thematic focus, methodologies, and approaches. The importance of partnerships, their impact on research depth, and their potential for policy influence were also recognised.
- Beneficiaries universally referred to the complexity of EU calls and the need for expertise and resources to navigate them effectively. Challenges faced by small and medium enterprises (SMEs) in accessing funding and participating in consortia were highlighted. Communication, management, and coordination within diverse consortia were identified as additional challenges.
- Beneficiaries recognised the synergies and complementarities between Horizon Europe call topics and other funding opportunities at the EU or national level. The collaborative opportunities, societal impact, and funding support provided by EU programmes were appreciated. Some programme beneficiaries, such as Creative Europe, could be leveraged for project extension and impact expansion.
- EU funding programmes were seen to provide added value through collaborative opportunities, a global scope, and larger funding sums compared to national programmes. The limitations of national funding, the importance of complementarity between national and EU funding, and the prestige associated with European funding were also noted. The advanced nature of EU programmes and their alignment with EU priorities in areas such as sustainability and digital innovation were recognised.

Appendix 1: Calls

Call – Research and innovation on cultural heritage and CCIs – 2021

- HORIZON-CL2-2021-HERITAGE-01-01: Green technologies and materials for cultural heritage.
- HORIZON-CL2-2021-HERITAGE-01-02: New ways of participatory management and sustainable financing of museums and other cultural institutions.
- HORIZON-CL2-2021-HERITAGE-01-03: Cultural and creative industries as a driver of innovation and competitiveness.
- HORIZON-CL2-2021-HERITAGE-01-04: Preserving and enhancing cultural heritage with advanced digital technologies.

Call – Engagement with stakeholders

- HORIZON-CL2-2021-HERITAGE-02-01: Mobilising the network of National Contact Points in Cluster.
- HORIZON-CL2-2021-HERITAGE-02-02: Coordination of European cultural heritage research and innovation among Member States.

Call – Research and innovation on cultural heritage and CCIs – 2022

• HORIZON-CL2-2022-HERITAGE-01-01: Safeguarding endangered languages in Europe.

- HORIZON-CL2-2022-HERITAGE-01-02: Europe's cultural heritage and arts promoting our values at home and abroad.
- HORIZON-CL2-2022-HERITAGE-01-03: The role of perceptions, formed by traditions, values and beliefs, in shaping European societies and politics in the 21st century.
- HORIZON-CL2-2022-HERITAGE-01-04: Traditional crafts for the future: a new approach.
- HORIZON-CL2-2022-HERITAGE-01-05: Towards a competitive, fair and sustainable European music ecosystem.
- HORIZON-CL2-2022-HERITAGE-01-06: Increase the potential of the international competitiveness of the European filmmaking industry.
- HORIZON-CL2-2022-HERITAGE-01-07: Protection of artefacts and cultural goods from anthropogenic threats.
- HORIZON-CL2-2022-HERITAGE-01-08: Effects of climate change and natural hazards on cultural heritage and remediation.
- HORIZON-CL2-2022-HERITAGE-01-09: Games and culture shaping our society.
- HORIZON-CL2-2022-HERITAGE-01-10: The New European Bauhaus shaping a greener and fairer way of life in creative and inclusive societies through Architecture, Design and Arts.

Call – Research and innovation on cultural heritage and CCIs II – 2022

• HORIZON-CL-2-2022-HERITAGE-02-01: A culture and creativity-driven European innovation ecosystem – a collaborative platform.

Case Study No 9: Well-being and Tackling Inequalities

Executive Summary

This case study focuses on calls related to the theme of "Well-being and tackling inequalities" within Cluster 2 of the Horizon Europe programme. At this early stage of the programme, it is hardly possible to identify results and, thus, the effectiveness and efficiency of the relevant projects. Therefore, the case study concentrates on the question of the extent to which the target group has been reached and what their experiences have been so far. The target groups will be examined to see whether it has been possible to address more practice-oriented participants, such as trade unions and vocational training organisations. The results are based on a data analysis of successful and unsuccessful applicants and findings from interviews with beneficiaries.

In doing so, we demonstrated that the calls addressed a broader range of applicants compared to SSH-related calls in the predecessor programme. Moreover, interviews with beneficiaries showed a high level of satisfaction. Although the administrative hurdles are assessed as very high, especially for smaller organisations, beneficiaries state that the funding offers enormous added value. This added value is mainly linked to the transnational context of the funding programme, the amount and duration of funding and the cooperation within and between the projects. According to the

participants, the proposed topics met their needs and interests and also provided incentives for new research areas.

For the European Commission, the challenge will be to ensure a balance between the continuity of topics on the one hand (so that existing research strands can continue) and the consideration and inclusion of new research needs on the other in order to meet the goal of supporting the transformation of society through innovative research that is oriented towards or anticipates reality.

Introduction

Tackling inequalities and strengthening well-being are high priority issues for the EU.

This is most clearly reflected in the fact that the fight against inequalities is enshrined in the EU Treaties. Moreover, they are reflected in the European Pillar of Social Rights. Reducing inequality is rooted in the EU's commitments to promote and protect human rights, as the principles of non-discrimination and equality complement the principles of international human rights law.

Tackling inequalities is also one of the 17 Sustainable Development Goals (SDGs) to which the EU is fully subscribed. SDG 10 aims to reduce inequalities within and between countries based on income, gender, age, disability, sexual orientation, race, class, ethnicity, religion and opportunity by 2030. Empirical research also shows that income inequality is an obstacle to achieving many other Sustainable Development Goals. It has been shown that inequality slows down the fight against poverty (SDG1) and hinders working conditions and sustainable growth (SDG8), but inequality also hinders other struggles for peace, gender equality and protection of life on earth.⁷⁵

At the same time, the population generally supports the fight against inequalities and the creation of equal opportunities. According to a recent Eurobarometer, 88% of Europeans state that a social Europe is important to them personally, especially the aspects of equal opportunities and equal access to the labour market.⁷⁶

In general, inequality is an enormously diverse subject area. A relational concept refers to differences between individuals or groups and encompasses various dimensions. A distinction can be made between:

- Economic inequality (income, consumption or wealth).
- Social inequality (access to education or employment).
- Political inequality (decisions, participation, political resources).
- Environmental inequality (e.g., air or water pollution) and inequitable access to natural resources and other ecosystem services (e.g., land, parks and freshwater).³¹¹

³¹¹ https://international-partnerships.ec.europa.eu/policies/human-development/reducing-inequalities_en

In research, the topics of "inequality" and "well-being" were considered mostly separate from each other for a long time. However, according to experts in the field, this has changed considerably in the last five years. Accordingly, attention to health and well-being as cause of inequalities, i.e. as a conditioning factor, has increased strongly in research in recent years. Not least because of the pandemic, research on mental health issues and inequalities has increased, which can be explained primarily by the growing attention.

Within the framework of Horizon Europe, the European Commission is therefore addressing the topic of inequality and well-being in seven different calls. The diversity of topics in the calls also shows the broad scope of the topic.

As no results from the projects are expected at the time of writing the case study, the case study focusses on two aspects. First, the types of applicants and beneficiaries in the relevant calls will be examined within a quantitative data analysis framework. This is related to the European Commission's intention to increase the number of nonacademic partners in the relevant projects to avoid project results being too theoretical. In the field of tackling inequalities, actors who are aware of specific implementation requirements, i.e. civil society organisations, should therefore be addressed by the funding programme. Second, interviews with beneficiaries were conducted to find out to what extent the evaluation criteria (Relevance, Coherence, Efficiency, Effectiveness, EU Added Value) were met. A total of seven beneficiaries, one from each Call, were interviewed to cover the full scope of the topic. Another criterion for selecting the interview partners was the type of legal entity. Priority was given to representatives of organisations that are neither research institutions nor universities but rather practice-oriented actors. These include NGOs, trade unions and VET organisations. In addition, interviews were conducted with EC officials and external experts in the field.

Complementing the interviews, the survey we conducted on successful and unsuccessful applicants from cluster 2 will provide important insights. In cluster 2, 387 successful applicants and 805 unsuccessful applicants took part in the survey.

Key quantitative data

This case study focuses on the following relevant calls⁷⁷:

- HORIZON-CL2-2021-DEMOCRACY-01-02 Economic models and modern democracies
- HORIZON-CL2-2021-TRANSFORMATIONS-01-01 Estimates of irregular migrants in Europe - stakeholder network
- HORIZON-CL2-2021-TRANSFORMATIONS-01-02 Providing support in a changing world of work and social protection
- HORIZON-CL2-2021-TRANSFORMATIONS-01-03 Determining key drivers of inequality trends
- HORIZON-CL2-2021-TRANSFORMATIONS-01-04 Addressing poor learning outcomes in basic skills and early school leaving at national, regional and local level in Europe
- HORIZON-CL2-2021-TRANSFORMATIONS-01-05 Integration of emerging new technologies into education and training

 HORIZON-CL2-2021-TRANSFORMATIONS-01-06 - Towards a new normal? Employment and social impacts of changing supply chains and declining trade intensities

A total of 128 proposals were submitted to these calls, resulting in 21 projects being funded.

According to representatives of the European Commission, the aim of the calls was to address a broad spectrum of beneficiaries in order to avoid project results being too theoretical. Therefore, we analysed the legal types and profiles of the applicants (both successful and unsuccessful).

The data analysis showed that the 128 applications included a total of 1248 applicants⁷⁸ for the relevant calls. The 21 projects that were eventually funded included 232 beneficiaries.

The Figure below shows that of the 1248 applicants, a total of 640 are higher education institutes (51.3%), 216 are private enterprises (17.3%), 130 are research institutes (10.4%), and 68 applicants are public institutions (5.4%). 194 applicants are categorised as "others" (15.5%). Mostly, these organisations marked "others" are the relevant target group of our analysis. They include primarily civil society organisations such as NGOs, foundations and other organisations that are neither commercial nor public actors. Thus, they are an important enabler in implementing the results in practice because these actors have specific competencies in practical implementation, e.g., through existing networks.





Source: Compiled by the study team.

Among the successful applicants, the results vary to some extent. Of the total 232 beneficiaries, 135 are higher education institutes (58.2%), 28 private enterprises (12.1%), 31 research institutes (13.4%), 6 are public institutions (2.6%), and 32 are "others" (13.8%).



Figure 107. Share of successful applicants to the relevant calls under Horizon Europe – Cluster 2 by type



In other words, while the share of higher education institutes and research institutes is disproportionately higher than their respective share among all applicants, the reverse is true for private enterprises, public enterprises, as well as "others". Nonetheless, the difference (15.5% vs. 13.8%) is modest for the group that is most interesting to us for the purpose of this study.

The fact that this is an important target group is also evident when looking at the relevant calls for proposals. Several calls directly referred to the exploitation of results and the involvement of a wide network of stakeholders, including civil society actors.

Reflections on evaluation criteria (Effectiveness, relevance, coherence, efficiency & EU added value)

Effectiveness

"What type of actors have been involved in the proposals and projects? What is the share of civil society organisations among applicants and beneficiaries?"

"Has this share changed in relation to relevant calls within H2020?"

Since, at the time of writing the case study, it is not yet possible to make any statements about the results achieved by the projects, the effectiveness analysis focuses on the question of whether the desired target groups (in terms of beneficiaries) have been reached. According to the statements by European Commission representatives, an important goal was to expand the scope of participants. The aim was to counteract the risk that results from the projects remain too theoretical and only find limited application in practice. In order to avoid this, an attempt was made to increasingly address practice-oriented participants. These include, for example, trade unions or VET organisations. In general, the participation of such organisations is seen as very helpful in transferring findings from the projects into practical applications.

The analysis of the applicants and participants in the relevant calls shows the composition differentiated by legal entity type. As mentioned, the group which is of key interest to this case study are those marked as "others". Figures 106 and 107 showed that the share of "others" from the calls relevant to us is 15.5% among applicants and 13.8% among successful applicants. Both shares are slightly lower than the respective shares of "others" for the entirety of the Cluster 2 calls, which are 15.9% among all applicants and 15.6% among successful applicants, respectively. According to the survey, the percentage of civil organisations/NGOs in cluster 2 is 9.8% for successful applications and 11.2% for unsuccessful applications.

However, what is more important is how the mentioned shares compare to the numbers of "others" in the predecessor programme, Horizon 2020. For this, we benchmarked the numbers against the participation statistics in the programme part Societal Challenge 6, addressing the area of "Inclusive, innovative and reflective Societies". Unfortunately, it was not possible to benchmark the latter against a more specific programme part, as there was no destination corresponding to the theme of "Well-being and Tackling Inequalities". This is mainly due to the different internal structure of Societal Challenge 6 as compared to Cluster 2 of Horizon Europe. Hence, we had to take the entirety of Societal Challenge 6 as the nearest possible proxy benchmark.

The difference in the respective shares is quite remarkable: Looking at *all* applicants to Horizon 2020 SC6 calls, the share of "others" amounted to only 8.8%. Considering the 15.5% share (of 1248 applicants in the relevant calls) in Cluster 2, it means that there has been an increase in 6.7% percentage points. If the difference is not expressed in percentage points but in "percentage of percentage", there has been a 76.1% increase.³¹²

Looking at only *successful* applicants to Horizon 2020 SC6 calls, the share of "others" had amounted to 9.2%. Considering the 13.8% share in Cluster 2, it means that there has been an increase in 4.6% percentage points. If the difference is not expressed in percentage points but in "percentage of percentage", there has been a neat 50.0% increase.

Error! Reference source not found. 108 shows the shares of all applicants to *relevant* c alls under HE-Cluster 2, compared to *all* calls under HE-Cluster 2 and to *all* calls under H2020-SC6, differentiated by type. Figure 109 narrows the above selection to successful applicants only.

³¹² While the selection of calls is not fully comparable, as a subset of HE-Cluster 2 calls is compared to the full set of H2020-SC6 calls, it is reasonable to take the latter as the nearest possible proxy benchmark.





Source: Compiled by the study team.





Source: Compiled by the study team.

According to interviewees, these organisations labelled as "others" were able to add value in the respective consortia. This was done, for example, through specific expertise on labour market issues, but also through communicating the results. The

results, some of which are very complex, are thus "translated" and brought closer to a wider audience with the help of these organisations. However, these findings are based on individual anecdotes of project participants from interviews. A statement about effects of the target group expansion cannot be estimated at this stage.

Relevance

"How relevant are the call topics in view of the latest cultural, technological, social and/or economic developments? How well do they address stakeholders' needs?"

In assessing the relevance of the calls, it is essential to recognize that defining topics should encompass a variety of objectives, even if they don't always align with each other. First, the calls should allow the researchers to further develop and specialise based on their *current* research directions, in order to solve actual problems. Second, the calls should also stimulate and set incentives to explore *new* research themes. Third, they should have clear and practical societal relevance. Furthermore, considering that the time period between the definition of call topics and the end of the actual projects is at least five years, it is also important to define topics that are still relevant.

Against this background, understanding how a topic is created in the call is interesting. According to EC officials, this is a co-creational process. The so-called Cluster, the DGs involved in the respective Cluster, representatives of the Member States, and a wider group of stakeholders through Open Public Consultations (OPC) are involved in the topic identification process. In addition, experienced policy officers play an important role in bringing ideas together and defining topics. The process has been described as quite open and takes into account a wide range of different interests. The result is a list of proposed topics that both policy and research perspectives have influenced.

Interviews with beneficiaries suggest that this process resulted in calls that reconciled the above-mentioned objectives. All respondents confirmed that their interests and needs were addressed, but also that they were steered in new directions. According to the interviewees, the reason for this broadening of horizons was not only the proposed topics but also the cooperation in the consortia. In particular, the cooperation between research and practice has established further focal points. The exchange among different research institutions stimulated the application of new methodological approaches. The only minor criticism voiced by one of the respondents was that the prompt topics were a little too vague and that a slightly higher level of specification would be desirable.

Coherence

"Is there continuity of funded topics with respect to H2020?"

With regard to the question of the continuity of the topics between the H2020 and Horizon Europe calls, it must first be stated that such continuity is not an objective in itself. While it is good to support research topics over longer periods and thus create specific research communities and networks to better understand and solve societal problems, funders must also make sure to stimulate new areas of research and discovery. In order to support the latter, current developments, such as concrete migration crises, should be taken into account in the definition of new calls. According

to interviewees, both objectives were achieved. For example, one beneficiary explained that findings from the previous H2020 project were continued but with a more policy-oriented focus. In this context, it was helpful that the coordinator was again the same as in the H2020 project.

According to interview statements, the consortia that had been created in H2020 were often the starting point for reapplying for Horizon Europe. These were then expanded with partners with expertise in specific fields. In this process, new incentives (methodical and content-related) were created through these new partners. However, it was not only within the consortia that the exchange was perceived as fruitful, but also the exchange with other projects was highlighted by some interviewees. On the initiative of the project officers of REA, different projects from the same call were given the opportunity to be exchanged, which, according to statements, was very helpful. According to the interviews with beneficiaries, this also promoted the stimulation of new directions, e.g. in the methodological approach.

"How well do the call topics align (in terms of synergies or complementarities) with other funding (or other policy instruments) at EU and/or national level?"

In its calls for proposals, the Commission is trying to make more references to national and international research programmes and to create synergies due to the scarcity of funds. This is a challenge, however, because how the Member States design their funding programmes is up to them and can, at best, be influenced indirectly by the European Commission. While some of the interviewed beneficiaries observed synergies with national funding and also used them, others limited themselves to European funding, and others again used national calls that were thematically open.

Independently of the synergies and complementarities of funding programmes per se, interviewed beneficiaries confirmed that elements of the findings from EU projects were also applied in the context of nationally funded projects and vice versa. Often, knowledge gained in national funding projects serves as the basis for application decisions in Horizon Europe.

Efficiency

"What are the challenges encountered by beneficiaries and has there been an improvement with respect to H2020?"

Interviews with beneficiaries suggest that the application process requirements are perceived as an enormous challenge, especially for smaller institutions. As one beneficiary stated, "the level of administration and detail was a shock". It should be noted that this impression is only partially confirmed when looking at the survey. Accordingly, successful applicants from Cluster 2 are largely satisfied with the HEU application process and are only occasionally critical, e.g., with the evaluation process's transparency. Unsuccessful applicants from Cluster 2, on the other hand, criticise that the effort required was not in proportion to the chances of obtaining Horizon Europe funding, organisations not used to write research funding applications usually depend on specialised support. This can be provided internally by their departments or by more experienced consortium partners. According to the survey, most of the support came from internal company departments or the consortium, but almost 22% of the respondents also used external consulting services, which were usually paid for. In other words, the chances of success depend significantly on the experience in the consortia and is thus not particularly "newcomers-friendly".

Furthermore, the demands are high in the application process and in the course of the projects. This starts with the identification of the appropriate funding programme but also includes the specifics of the individual calls and the proposal templates. While, according to the survey, most of these requirements meet with the satisfaction of the (successful) applicants, some requirements, such as the level of detail of the feedback provided in the evaluation report, are seen more critically. In the interviews, some respondents described the fact that planning milestones and deliverables to be indicated years in advance is very challenging. In this respect, the respondents would like to see a little more flexibility. The lack of flexibility is confirmed by the survey. According to the survey, EC lacks flexibility with regard to changes in the consortium and in adapting the project objectives to changing circumstances.

EU added value

"Does the transnational nature of the projects funded through the calls allow for issues/aspects to be addressed that could not be covered in the same way by national projects?"

During the interviews, we also asked whether Horizon Europe projects offer added value compared to national funding. All respondents answered this question affirmatively. All interviewees confirmed that the transnational character of the Framework Programme offers enormous benefits. Especially since issues such as migration, education and growing inequalities are not purely national issues but topics that occur across national borders, partners in consortia learn from other partners and thus exchange knowledge on best practices across borders. As stated by one expert: "International perspective is not helpful; it's crucial."

Furthermore, according to the interviewees, the financial aspects also add enormous value compared to national funding programmes, which are usually budgeted much more narrowly. The very good financial resources combined with the high degree of personal responsibility offer the beneficiaries enormous freedom in their project work. Some respondents also positively emphasised the long time horizon of Horizon Europe compared to national funding, which makes long-term planning possible.

On the other hand, respondents also pointed out that transnational characters pose enormous challenges. The large consortia require a high degree of coordination, and in particular, the collection and harmonisation of cross-border statistics is an enormous challenge.

Key lessons learned and other important observations

Several key lessons have emerged from the analysis that are relevant to the programme's future development.

First of all, it should be mentioned that the process of drafting the call topics seems to have worked very well. It not only managed to address the needs of the applicants but also stimulated the respondents to research new directions and new methods. To be fair, it must be pointed out that there is a selection bias because the interviewees were restricted to successful programme participants. Nonetheless, there is a good reason to argue that this process should therefore be maintained.

Another key takeaway is that the participants appreciate continuity despite adjustments. It has been confirmed in the interviews with beneficiaries that long-term

cooperation in consortia is particularly fruitful. This is important since many issues in the field of inequality are long-term issues that cannot be solved in the short term and thus require research and funding over a long period of time.

According to statements by the beneficiaries, the transnational character also plays an important role in funding within the framework of Horizon Europe. Since topics such as migration and growing inequality are not limited to national borders, they are particularly important to be studied in a transnational context.

Last but not least, it should be noted that the relevant calls have succeeded in broadening the range of applicants. Our analysis has shown that the diversity of applicants has increased compared to H2020. Whether this also achieves the desired effect of better translating project results into practice cannot be determined at this stage but should be part of the following evaluation. In order to attract even more (and potentially smaller and less experienced) organisations, the EC should consider lowering the administrative hurdles somewhat.

Appendix 1: Calls

Relevant Calls: Total 21 Projects

HORIZON-CL2-2021-DEMOCRACY-01-02: Economic models and modern democracies

- 10 proposals
- 3 projects: DemoTrans 101059288, INCA 101061653, REBALANCE 101061342

HORIZON-CL2-2021-TRANSFORMATIONS-01-01: Estimates of irregular migrants in Europe - stakeholder network

- 3 proposals
- 1 project MIrreM (101061314)

HORIZON-CL2-2021-TRANSFORMATIONS-01-02: Providing support in a changing world of work and social protection

- 12 proposals
- 3 projects: TransEuroWorkS 101061198, WeLaR, 101061388 rEUsilience 101060410

HORIZON-CL2-2021-TRANSFORMATIONS-01-03: Determining key drivers of inequality trends

- 14 proposals
- 3 projects: MapIneq 101061645, EXIT 101061122, ESSPIN 101061104

HORIZON-CL2-2021-TRANSFORMATIONS-01-04: Addressing poor learning outcomes in basic skills and early school leaving at national, regional and local level in Europe

• 15 proposals

- 3 projects: CLEAR 101061155, SCIREARLY 101061288, LETS CARE 101059425
- HORIZON-CL2-2021-TRANSFORMATIONS-01-05: Integration of emerging new technologies into education and training
 - 68 proposals
 - 5 projects: Exten.D.T.2 (101060231), i-MASTER 101060107, e-DIPLOMA 101061424, augMENTOR 101061509, EMPOWER 101060918
- HORIZON-CL2-2021-TRANSFORMATIONS-01-06: Towards a new normal? Employment and social impacts of changing supply chains and declining trade intensities
 - 6 proposals
 - 3 projects: ReSChape 101061729, RETHINK-GSC 101061123, TWIN SEEDS 101056793.

Case Study No 10: Assessing the societal impacts of security research in addressing stakeholders' needs in the areas of Fighting Crime and Terrorism, Border Management, Resilient Infrastructure, and Disaster-Resilient Society

Executive Summary

This case study assesses the societal impacts of security research funded under Cluster 3 (CL3), "Civil security for society" of Horizon Europe, in addressing stakeholders' needs in the thematic areas (Destinations) of Fighting Crime and Terrorism (FCT), Border Management (BM), Resilient Infrastructure (INFRA), and Disaster-Resilient Society (DRS). The aim is to analyse how security research has supported the development of security solutions (new technologies, solutions and knowledge) meeting stakeholders' needs.

The mandatory eligibility criteria of including security practitioners in consortia have been in force in all the thematic areas addressed. Furthermore, the high TRL target levels of CL3 Work Programme 2021-2022 calls have enforced stakeholder engagement since they indicate the necessity of user involvement in testing and demonstrating activities that take place in a relevant or operational environment.

Public bodies represent the public sector practitioners and end users in the security domain either directly or indirectly. In the following, the shares of public bodies in the CL3 actions of Horizon Europe funded in 2021-2022 are compared to the SC7 actions of H2020:

- **FCT actions**: the share of public bodies has remained on the same level both in terms of numbers and assigned EC contribution
- **BM actions**: the share of public bodies has remained on the same level in terms of numbers, but their share of assigned EC contribution has decreased
- **INFRA actions**: the share of public bodies has decreased both in terms of numbers and assigned EC contribution

 DRS actions: the share of public bodies has decreased both in terms of numbers and assigned EC contribution

According to the Horizon Europe beneficiary survey results, stakeholders not only participate in the CL3 actions as partners but also play a role in the governance structures of actions (e.g., acting as work package leaders). This is particularly common in the FCT actions funded in 2021.

Beneficiaries of all the thematic areas consider that relevant stakeholder groups and their needs were addressed adequately in the 2021 call topics of the CL3 Work Programme. In a similar vein, the eligibility criteria for compulsory participation of end users from different Member States is seen as beneficial for stakeholder engagement. However, the beneficiaries suggest expanding the eligible stakeholder groups. Beneficiaries' views regarding the impact of project size (amount of funding) or duration on stakeholder involvement were mixed, in general. Some saw no impact, while others considered a large-scale project necessary for stakeholder involvement and commitment.

The success factors related to interaction with citizens and stakeholder organisations representing citizens or communities:

- Transparent and inclusive stakeholder engagement processes;
- Effective communication strategies to bridge the gap between experts and the public;
- Incorporation of diverse perspectives and values in decision-making;
- Demonstrating tangible benefits and positive impacts of security technologies, including AI-based technologies.

Introduction

This case study assesses the societal impacts of security research funded under Cluster 3 (CL3) "Civil security for society" of Horizon Europe in addressing stakeholders' needs in the thematic areas of Fighting Crime and Terrorism (FCT)³¹³, Border Management (BM)³¹⁴, Resilient Infrastructure (INFRA)³¹⁵, and Disaster-Resilient Society (DRS)³¹⁶. The aim is to analyse how security research has supported the development of security solutions (new technologies, solutions and knowledge) addressing stakeholders' needs. By stakeholders, we refer to end users and policy makers in the security domain, including citizens and stakeholder organisations representing citizens or communities, as well.

In particular, we address evaluation question RV10: To what extent have securityrelated research and innovation activities funded under Horizon Europe met stakeholders' needs? Special attention is paid to the question of how well the call topics of the CL3 Work Programme 2021-2022 have corresponded to the actual needs and interests of stakeholders. We also address whether the size of actions in terms of funding available or their duration has had an impact on the ability to meet

³¹³ Equivalent to CL3 Destination on 'better protection of the EU and its citizens against crime and terrorism'.

³¹⁴ Equivalent to CL3 Destination on 'effective management of EU external borders'.

³¹⁵ Equivalent to CL3 Destination on 'resilient infrastructure'.

³¹⁶ Equivalent to CL3 Destination on 'disaster-resilient society for Europe'.

stakeholders' needs in R&I activities. The role of stakeholders in the governance structures of actions is considered, as well.

Public bodies represent end users and practitioners in the security domain either directly or indirectly (e.g., ministries). We analyse the share of public bodies in the CL3 actions of Horizon Europe funded in 2021-2022 in terms of numbers and assigned EC contribution. These Figures are compared to security research funded under the Societal Challenge 7 (SC7) of H2020. Additionally, we also analyse how security research funded under CL3 deals with the barriers and success factors related to interaction with citizens and stakeholder organisations representing citizens or communities.

This case study mainly focuses on the evaluation questions of relevance, while the evaluation questions on coherence are addressed in the parallel case study 11, "Assessing the societal impacts of security research on cross-border cooperation between security practitioners and relevant authorities". Both case studies are based on four methodological approaches:

- 1. Document analysis (e.g., Work Programmes and policy documents)
- Analysis of beneficiary and policy officer interview data (27 beneficiaries representing twelve FCT, BM, INFRA, DRS and SSRI actions, which were funded in 2021, were interviewed during May-September 2023 for this case study and parallel case study 11 on assessing the societal impacts of security research on cross-border cooperation)
- 3. Analysis of CORDA data
- 4. Analysis of the results of the Horizon Europe beneficiary survey 2023 led by an Evaluation study on "Excellent Science in the European Framework Programmes for Research and Innovation."

The actions analysed in this case study belong to CL3, which forms the third cluster under Pillar 2 "Global Challenges and European Industrial Competitiveness" of Horizon Europe. Similarly to its H2020 predecessor, SC7, CL3 aims for 1) better protection of the EU and its citizens against crime and terrorism (FCT); 2) effective management of EU external borders (BM); 3) resilient infrastructure (INFRA); 4) increased cybersecurity (CS); 5) disaster-resilient society for Europe (DRS); 6) strengthened security research and innovation (SSRI). Currently, there are 83 actions funded under the Cluster 3 Work Programme 2021-2022 with 1596 participants and a funding volume of EUR 413.7 million (See Appendix 1).

Next, the stakeholder involvement in the thematic areas of FCT, BM, INFRA and DRS is addressed one by one. This is followed by consideration of barriers and success factors related to interaction with citizens and organisations representing citizens or communities. Finally, reflections on evaluation criteria and key lessons learned are presented and discussed.

Outcomes/Results

Stakeholder Engagement in Fighting Crime and Terrorism

The thematic area of Fighting Crime and Terrorism (FCT) of Cluster 3 was addressed in the Work Programme 2021-2022 of Civil Security for Society with 5 RIA, 13 IA and 1 CSA calls (see Appendix 2). All the calls included a formal requirement for the inclusion of practitioners in a consortium. The inclusion of Law Enforcement Authorities (LEAs) was required in all the calls. In addition, forensic institutes, civil society organisations, first responders and border guards were required to be included as beneficiaries in the majority of the calls. At least three different EU Member States or Associated Countries had to present in a consortium, as well. Overall, the eligibility criteria were similar to the FCT calls of Societal Challenge 7 (SC7) of H2020.³¹⁷

The TRL target of the FCT calls 2021-2022 varied from 5 to 8 (see Appendix 2). The typical target TRL target range was 6-7. In contrast, the FCT calls of SC7 of H2020 also included the TRL target of 4 (validated in the lab), which is no longer targeted in the FCT calls 2021-2022.³¹⁸ This means that all the technologies and solutions developed by the actions funded under the FCT calls 2021-2022 have to be either validated or demonstrated in a relevant environment, thus indicating the necessity of user involvement in testing activities.

In the Figure below, we present the participation of beneficiaries by numbers and assigned EC contributions in the actions funded under the FCT calls 2021-2022. Special attention should be paid to the share of public bodies (PUB) since they represent the public sector practitioners in the security domain either directly or indirectly (e.g., ministries). In comparison to the FCT actions of SC7, the share of public bodies is on the same (and relatively high) level in the actions funded under the FCT calls 2021-2022, both in terms of numbers and EC contribution.³¹⁹

³¹⁷ Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 267. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=. 318 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 267. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part= 319 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 267. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part= 319 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 268. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=.


Figure 110. Participation in FCT 2021-2022³²⁰

Source: Compiled by the study team using its own calculations and CORDA data.

In the Horizon Europe beneficiary survey conducted in May-July 2023, Cluster 3 respondents were asked about the role of stakeholders (civil society representatives and/or governmental institutions) in their project's execution. Regarding the actions funded under the FCT calls, 9 respondents reported that stakeholders act as work package leaders in their actions, while 1 respondent reported that a stakeholder is the coordinator of the action (see the Figure below). This implies that stakeholders not only participate in the FCT actions but also play a role in the governance structures of actions.

³²⁰ Total number of participants analysed: 400. Total amount of EC contribution analysed: EUR 82.0 million. Note: REC = research organizations, PUB = public bodies, PRC = private sector, HES = higher education institutions, OTH = other participants. For the details of participation analysis, see Annex 1.



Figure 111. Role of stakeholders in FCT (n=36).³²¹

Source: Compiled by the study team using results of Horizon Europe beneficiary survey 2023.

The FCT beneficiaries interviewed in May-September 2023 saw that relevant stakeholder groups and their needs were addressed adequately in the FCT 2021 call topics. However, the beneficiaries made suggestions to widen the scope of stakeholders to include NGOs (non-governmental organizations) and NPOs (non-profit organizations) in addition to policy makers and security practitioners. In relation to criminal justice and rehabilitation, it was also suggested that offenders could be considered as a stakeholder group in some contexts. It was noted that this could be done without prioritizing their interests over those of victims or the justice system.

Beneficiaries' views regarding the impact of project size (amount of funding) or duration on stakeholder involvement were mixed. Some saw no impact, while others saw that a large-scale project (both resource- and time-wise) is necessary for stakeholder involvement and commitment in the case of LEAs.

The eligibility criteria for compulsory participation of security practitioners (end users) were seen as beneficial by the FCT beneficiaries. In general, they were seen to lead to active engagement of the end users who can bring versatile perspectives and experiences to the action. It was noted, however, that end user representatives often change during the lifecycle of action since persons move into other positions inside the public bodies. This creates difficulties in ensuring professional end user contributions supporting innovation uptake throughout the action lifecycle. A personnel change in an end user organisation can decrease the level of professionalism in project work as the new replacements can be junior and less experienced colleagues.

Stakeholder engagement in Border Management

The thematic area of Border Management (BM) of Cluster 3 was addressed in the Work Programme 2021-2022 of Civil Security for Society with 3 RIA, 6 IA and 1 CSA

³²¹ Answers given to the survey question "What role do civil society representatives and/or governmental institutions play in your project's execution?" 36 respondents are beneficiaries who represent actions funded under the FCT calls 2021. Source: Horizon Europe beneficiary survey 2023 led by Evaluation study on "Excellent Science in the European Framework Programmes for Research and Innovation".

calls (see Appendix 2). All the calls included a formal requirement for the inclusion of practitioners in a consortium. The inclusion of Border/Coast Guard Authorities or Customs Authorities was required in all the calls. In addition, Police Authorities were required to be included as beneficiaries in one call (HORIZON-CL3-2022-BM-01-02). Similarly to the FCT calls addressed earlier, at least three different EU Member States or Associated Countries had to present in a consortium. In comparison to the BES calls of SC7 of H2020, the eligibility criteria were more or less the same.³²²

The TRL target of the BM calls 2021-2022 varied from 4 to 8 (see Appendix 2). The typical target TRL target range was 7-8, which implies that most technologies and solutions are to be demonstrated in the operational environment of border management. Overall, the TRL targets were similar to the BES calls of SC7 of H2020.³²³

In the Figure below, we present the participation of beneficiaries by numbers and assigned EC contributions in the actions funded under the BM calls 2021-2022. In comparison to the BES actions of SC7, the share of public bodies (PUB) is on the same level in terms of numbers, while the share of assigned EC contribution of public bodies has decreased.³²⁴

³²² Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 267. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=. 323 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 268. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=. 324 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 268. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=. 324 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 268. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=.



Figure 112. Participation in BM 2021-2022³²⁵

Source: Compiled by the study team using its own calculations and CORDA data.

As noted earlier, Cluster 3 respondents were asked about the role of stakeholders (civil society representatives and/or governmental institutions) in their project's execution in the Horizon Europe beneficiary survey. Regarding the actions funded under the BM calls, 3 respondents reported that stakeholders act as work package leaders in their actions (see the Figure below). Although the number of respondents is small (11), this implies that stakeholders play at least some role in the governance structures of the BM actions.

³²⁵ Total number of participants analysed: 248. Total amount of EC contribution analysed: EUR 63.2 million. Note: REC = research organizations, PUB = public bodies, PRC = private sector, HES = higher education institutions, OTH = other participants. For the details of participation analysis, see Annex 1.



Figure 113. Role of stakeholders in BM (n=12)³²⁶

Source: Compiled by the study team using results of Horizon Europe beneficiary survey 2023.

The BM beneficiaries interviewed in May-September 2023 considered that relevant stakeholder groups and their needs were addressed adequately in the BM 2021 call topics. It was noted that some stakeholder groups who are not present in the consortium could be partially involved in project activities through stakeholder forums or similar project measures. This is particularly useful in the case of stakeholder groups whose involvement and inputs are needed only occasionally.

The BM beneficiaries reported that the impact of project size (amount of funding) is significant for stakeholder involvement in some cases. Potential stakeholder partners with a smaller budget share can be discouraged by the administrative complexity and time needed to ensure compliance during the application phase. It has happened that a potential partner has refused to participate in the consortium as the return on investment (research against administrative work) was considered too low.

The BM beneficiaries did not present views on the impact of project duration on stakeholder involvement. Neither did they comment on the eligibility criteria for compulsory participation of security practitioners. It was noted, however, that meeting the eligibility criteria did not cause challenges.

³²⁶ Answers given to the survey question "What role do civil society representatives and/or governmental institutions play in your project's execution?" 12 respondents are beneficiaries who represent actions funded under the BM calls 2021. Source: Horizon Europe beneficiary survey 2023 led by Evaluation study on "Excellent Science in the European Framework Programmes for Research and Innovation".

Stakeholder Engagement in Resilient Infrastructure

The thematic area of Resilient Infrastructure (INFRA) of Cluster 3 was addressed in the Work Programme 2021-2022 of Civil Security for Society with 1 RIA and 3 IA calls (see Appendix 2). Similar to the FCT and BM calls addressed earlier, all the INFRA calls included a formal requirement for the inclusion of practitioners in a consortium. The inclusion of operators of critical infrastructure was required in case of two calls. Government entities responsible for security, organisations dealing with research on infectious diseases, and local or regional government authorities were required to participate in separate INFRA calls, as well. At least two or three different EU Member States or Associated Countries had to present in a consortium. In comparison to the INFRA calls of SC7 of H2020, the eligibility criteria were similar.³²⁷

The TRL target of the INFRA calls 2021-2022 varied from 4 to 7. The TRL target range of 6-7 was set for three calls (all IAs) implying that technologies and solutions are to be either validated or demonstrated in a relevant environment of critical infrastructure protection. In general, the TRL targets were similar to the INFRA calls of SC7 of H2020.³²⁸

In the Figure below, we present the participation of beneficiaries by numbers and assigned EC contribution in the actions funded under the INFRA calls 2021-2022. In comparison to the INFRA actions of SC7, the share of public bodies (PUB) is on the lower level both in terms of numbers and assigned EC contribution. This is partially explained by the increased shares of research organisations (REC) and the private sector (PRCf).³²⁹

³²⁷ Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 265. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=. 328 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 265. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=. 329 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 266. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=. 329 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 266. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=.



Figure 114. Participation in INFRA 2021-2022³³⁰

Source: Compiled by the study team using its own calculations and CORDA data.

As noted earlier, Cluster 3 respondents were asked about the role of stakeholders (civil society representatives and/or governmental institutions) in their project's execution in the Horizon Europe beneficiary survey. Regarding the actions funded under the INFRA calls, 2 respondents reported that stakeholders act as work package leaders in their actions, while one respondent reported that a stakeholder is the coordinator of the action (see the Figure below). Although the number of respondents is small (10), this implies that stakeholders play a role in the governance structures of the INFRA actions.

³³⁰ Total number of participants analysed: 118. Total amount of EC contribution analysed: EUR 29.9 million. Note: REC = research organizations, PUB = public bodies, PRC = private sector, HES = higher education institutions, OTH = other participants. For the details of participation analysis, see Annex 1.



Figure 115. Role of stakeholders in INFRA (n=10)³³¹

Source: Compiled by the study team using results of Horizon Europe beneficiary survey 2023.

The INFRA beneficiaries interviewed in May-September 2023 considered that relevant stakeholder groups and their needs were addressed appropriately in the INFRA 2021 call topics. Concerning security practitioners, it was seen that they may become relevant recipients of the innovations developed during the actions with different practical applications.

The INFRA beneficiaries saw that the project size (amount of funding) and the number of partners are directly related to the capacity to involve stakeholders in project activities. Collaborative workshops were mentioned as a key means of stakeholder interaction. To reach relevant stakeholders for workshops and similar activities, the contact network was seen as a fundamental precondition: the more partners are involved in the action, the more stakeholders can be potentially contacted. Furthermore, the more budget and duration the action has, the more time can be allocated to these activities and the more profound and complex topics can be addressed together with stakeholders.

The eligibility criteria for compulsory participation of end users from different Member States was seen as beneficial for stakeholder engagement by the INFRA beneficiaries. However, more flexibility is called for in terms of stakeholder definition. It was suggested that the involvement of EU institutions, such as Frontex and Europol, in project activities could be helpful for achieving more ambitious project objectives even though they cannot be beneficiaries.

³³¹ Answers given to the survey question "What role do civil society representatives and/or governmental institutions play in your project's execution?" 10 respondents are beneficiaries who represent actions funded under the INFRA calls 2021. Source: Horizon Europe beneficiary survey 2023 led by Evaluation study on "Excellent Science in the European Framework Programmes for Research and Innovation".

Stakeholder Engagement in Disaster-Resilient Society

The thematic area of Disaster-Resilient Society (DRS) of Cluster 3 was addressed in the Work Programme 2021-2022 of Civil Security for Society with 5 RIA, 8 IA and 1 CSA calls (see Appendix 2). Similar to the other thematic areas addressed earlier, all the DRS calls included a formal requirement for the inclusion of practitioners in a consortium. The inclusion of first/second responders was required in eight DRS calls. The participation of local/regional authorities was required in six DRS calls while the presence of organisations representing citizens/local communities was required in four DRS calls. In most cases, at least two or three different EU Member States or Associated Countries had to present in a consortium (three DRS calls did not specify geographical eligibility criteria). In comparison to the DRS calls of SC7 of H2020, the eligibility criteria have remained similar.³³²

The TRL target of the DRS calls 2021-2022 varied from 4 to 8 (see Appendix 2). Seven DRS calls did not specify TRL targets. The typical TRL target range was 6-8 (five calls), which means that technologies and solutions are to be demonstrated in a relevant environment regarding first/second responders and other practitioners. Overall, the TRL targets were similar to the DRS calls of SC7 of H2020.³³³

In the Figure below, we present the participation of beneficiaries by numbers and assigned EC contribution in the actions funded under the DRS calls 2021-2022. In comparison to the DRS actions of SC7, the share of public bodies (PUB) is on the lower level both in terms of numbers and assigned EC contribution. In contrast, the shares of all other types of participants have remained the same or increased (both in terms of numbers and assigned EC contribution).³³⁴

³³² Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 266. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=. 333 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 266. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=. 334 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 266. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=. 334 Cf. European Commission, Directorate-General for Research and Innovation, Stančiauskas, V., Kazlauskaitė, D., Zharkalliu, K. et al. (2023). Evaluation study of the European framework programmes for research and innovation for a resilient Europe – Final report – Phase 1. Annexes, p. 267. Available: https://op.europa.eu/o/opportal-service/downloadhandler?identifier=e3f2a4e0-012d-11ee-87ec-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=.



Figure 116. Participation in DRS 2021-2022³³⁵

Source: Compiled by the study team using its own calculations and CORDA data.

As has been noted earlier, Cluster 3 respondents were asked about the role of stakeholders (civil society representatives and/or governmental institutions) in their project's execution in the Horizon Europe beneficiary survey. Regarding the actions funded under the DRS calls, 3 respondents reported that stakeholders act as work package leaders in their actions (see the Figure below). This implies that stakeholders play at least some role in the governance structures of the DRS actions.

³³⁵ Total number of participants analysed: 322. Total amount of EC contribution analysed: EUR 83.4 million. Note: REC = research organizations, PUB = public bodies, PRC = private sector, HES = higher education institutions, OTH = other participants. For the details of participation analysis, see Annex 1.



Figure 117. Role of stakeholders in DRS (n=27)³³⁶

Source: Compiled by the study team using results of Horizon Europe beneficiary survey 2023.

The DRS beneficiaries interviewed in May-September 2023 considered that relevant stakeholder groups and their needs were addressed adequately in the DRS 2021 call topics. According to the DRS beneficiaries, the key stakeholder groups are security practitioners, cities and public institutions, among others.

Regarding the impact of project size (amount of funding) or duration on stakeholder involvement, the DRS beneficiaries expressed mixed views. The amount of funding and duration did not affect the number of stakeholders while consortia were being formed according to some beneficiaries. Other beneficiaries saw, however, that the project duration of three years limits stakeholder involvement. The action has to guide and steer stakeholders by showing them design ideas to comment on or providing them with options to choose from in order to deliver a solution within three years.

The eligibility criteria for compulsory participation of end users from different Member States was considered as beneficial for stakeholder engagement by the DRS beneficiaries. It was noted, however, that if the participating countries do not share a land border, the scope for operational cross-border cooperation between end users will be limited in some cases.

Perceived barriers and critical success factors

This section study provides an analysis of how security research funded under Cluster 3 deals with the barriers and success factors related to interaction with citizens and stakeholder organisations representing citizens or communities. While the participation of the latter is a compulsory requirement in the eligibility criteria of four DRS calls of Cluster 3 Work Programme 2021-2022, citizens, in general, form an important stakeholder group for all Cluster 3 actions. The rationale for this lies in Regulation 2021/695 on the Horizon Europe Framework Programme for Research and

³³⁶ Answers given to the survey question "What role do civil society representatives and/or governmental institutions play in your project's execution?" 27 respondents are beneficiaries who represent actions funded under the DRS calls 2021. Source: Horizon Europe beneficiary survey 2023 led by Evaluation study on "Excellent Science in the European Framework Programmes for Research and Innovation"

Innovation, which emphasizes the need to engage citizens and civil society in R&I while addressing their concerns, needs and expectations.³³⁷ Moreover, interacting with citizens and creating public trust in security technologies and solutions are required for the successful adoption and acceptance of security innovations in society, that is, fostering innovation uptake. The analysis below relies on the interview data of beneficiaries representing twelve ongoing FCT, BM, INFRA, DRS and SSRI actions (funded in 2021).

Perceived barriers

Lack of public awareness and understanding of security technologies

The lack of public awareness and understanding of security technologies refers to a barrier that hinders the adoption and acceptance of these technologies within society. It represents a gap in knowledge and comprehension among the general public regarding the purpose, functioning, benefits, risks, and ethical considerations associated with security technologies, including AI-based technologies. Addressing this barrier requires concerted efforts to improve public awareness and understanding. Public awareness campaigns, educational initiatives, and knowledge-sharing platforms were understood to play a crucial role in disseminating accurate and accessible information about security technologies. These initiatives should aim to bridge the knowledge gap, demystify complex concepts, and provide real-world examples of how these technologies can positively impact society.

Concerns regarding privacy and data protection

Concerns regarding privacy and data protection represent a significant barrier to the adoption and acceptance of security, including AI-based technologies. These concerns arise from the potential risks associated with the collection, use, and storage of personal data in the context of these technologies. Addressing these concerns requires robust privacy and data protection measures. The sampled ongoing actions have prioritized data minimization, ensuring that only necessary and relevant data is collected and processed. Implementing strong secure storage practices is also helping protect personal data from unauthorized access. Additionally, promoting transparency and providing clear information about data handling practices and the purpose of data collection is helping alleviate privacy concerns.

Perception of security and AI technologies as invasive or threatening to personal freedom

One of the primary concerns expressed across the actions is the potential for increased surveillance and monitoring. Security technologies, especially AI-based technologies, involve the collection and analysis of vast amounts of data, which can include personal information. This raises fears about the erosion of privacy and the potential misuse or abuse of this data by authorities or other entities. Individuals may worry that their actions, behaviours, and private lives are monitored, leading to a sense of constant scrutiny and loss of personal freedom. Addressing these concerns requires a robust framework of ethical considerations and safeguards. Therefore, the ongoing actions sampled for the case study prioritize transparency in data collection and usage, providing clear information about the purpose, scope, and limitations of data gathering.

³³⁷ https://eur-lex.europa.eu/eli/reg/2021/695/oj

Implementing privacy-enhancing technologies is also acknowledged to help protect individual privacy and alleviate concerns about surveillance.

Perceived critical success factors

Transparent and inclusive stakeholder engagement processes

Transparency in stakeholder engagement processes means providing clear and accessible information about the action's objectives, methodologies, data handling practices, and intended outcomes. It ensures that stakeholders have a comprehensive understanding of the action and can contribute meaningfully. Transparency also includes sharing updates, findings, and lessons learned, allowing stakeholders to stay informed and provide feedback at various stages.

Inclusivity is essential to ensure that diverse perspectives, knowledge, and experiences are considered. It involves actively seeking input from a wide range of stakeholders who may be affected by or have expertise relevant to the project. Inclusive stakeholder engagement processes should prioritize representation, inclusivity, and equitable participation, ensuring that marginalized voices and underrepresented groups have the opportunity to contribute.

For instance, in **SAFE CITIES**³³⁸, civil security organizations and local authorities - conceived as end users - are involved in the design and validation of a simulation platform and a security assessment methodology, which will lead to recommendations of actions for public space uses, so that potential risks associated with their use are effectively identified and mitigated.

Effective communication strategies to bridge the gap between experts and the public

A key challenge experienced by ongoing actions is translating technical jargon and complex information into language that is understandable and relatable to the general public. Effective communication strategies involve breaking down complex concepts into simpler terms, avoiding technical jargon, and using relatable examples or analogies to convey ideas. This helps bridge the gap between experts and the public, ensuring that information is accessible and easily digestible.

Utilizing diverse communication channels and formats is also crucial to reach a wider audience. This includes traditional media, social media platforms, public events, workshops, and educational materials. By using a combination of written, visual, and interactive mediums, information can be disseminated in a way that resonates with different audiences and learning styles. Furthermore, effective communication strategies emphasize the societal implications and ethical considerations associated with security technologies, including Al-based technologies. They go beyond technical aspects and highlight the potential benefits, risks, and safeguards to address public concerns. This helps foster informed public discourse, encourages critical thinking, and enables individuals to make more informed decisions and contribute to the responsible development and deployment of these technologies.

³³⁸ https://cordis.europa.eu/project/id/101073945

Incorporation of diverse perspectives and values in decision-making

Incorporating diverse values in decision-making ensures that the outcomes of security research projects align with the needs, priorities, and aspirations of diverse communities. It recognizes that different stakeholders may have distinct cultural, ethical, and moral frameworks that influence their perspectives on security technologies, including Al-based technologies. By considering these diverse values, decision-making processes can be more inclusive and equitable.

Across the actions analysed in the case study, the incorporation of diverse perspectives and values enhances the legitimacy and acceptance of the project outcomes. It is broadly agreed upon that when stakeholders see their perspectives and values taken into account, this fosters a sense of ownership and trust in the decision-making processes. It helps to build a more robust and inclusive decision-making framework that reflects the concerns and aspirations of the wider society.

To further incorporate diverse perspectives and values effectively, stakeholder engagement processes should be designed to be more inclusive and participatory. A good example is offered by **C2IMPRESS**³³⁹, which identifies as a citizen-action project. One of the main functions of the action is to involve public organisations, private citizens, and civil partnerships, emphasizing their active participation and merging their diverse responsibilities in the crisis management domain. Case studies, workshops, meetings and open dialogue are used to assess and identify societal needs and ethical considerations. This will be operationalised in the action through demonstrators across four countries.

Demonstrating tangible benefits and positive impacts of security technologies

Demonstrating tangible benefits and positive impacts of security technologies, including AI-based technologies, through pilots, cases and experiments is a common critical success factor across the actions analysed. It involves providing evidence of how these technologies can effectively address security challenges while delivering real-world benefits and positive societal impacts.

Tangible benefits can include improvements in security, efficiency, accuracy, and effectiveness in various domains such as crime prevention, threat detection, disaster response, and public safety. For example, AI-powered surveillance systems may enhance the ability to detect and respond to security threats more quickly and accurately. Demonstrating how these technologies can mitigate risks, enhance public safety, and safeguard individuals and communities can help build confidence and support. **ODYSSEUS³⁴⁰** is focused on the development of an ethically sound platform enabling non-stop border control checks using a combination of portable unobtrusive screening technology, drone-assisted image processing, and AI-based data analytics.

Furthermore, showcasing positive impacts beyond security is crucial. This includes emphasizing how security and related AI technologies can contribute to broader societal goals such as economic growth, sustainability, and social well-being. For instance, AI applications in postal transportation security can lead to improved transportation efficiency and decreased environmental impact. For example,

³³⁹ https://cordis.europa.eu/project/id/101074004

³⁴⁰ https://cordis.europa.eu/project/id/101073910

PARSEC³⁴¹ is developing postal/ parcel scanning solutions which have an increasing degree of filtering. Benefits are generated for both transporters and border authorities. Transporters focus on lawfully doing their job whilst border authorities focus on protecting society. The discovery of illegal substances stands as a key indicator of impact, as does avoiding disturbing the handling of packages for smoother operations.

Reflections on evaluation criteria

Relevance

Similar to the calls of Societal Challenge 7 (SC7) of H2020, the mandatory eligibility criteria of including security practitioners or other relevant stakeholders as partners in consortia was maintained in the FCT, BM, INFRA and DRS calls of Cluster 3 Work Programme 2021-2022.³⁴² The typical TRL target level of these calls was 6-8, which means that most technologies and solutions are to be demonstrated in relevant/operational environment, thus, indicating the necessity of user involvement in testing activities.

Public bodies represent an important participant group in Cluster 3 actions since they represent the public sector practitioners in the security domain either directly or indirectly. In comparison to the FCT actions of SC7, the share of public bodies has remained on the same level in the actions funded under the FCT calls 2021-2022. In the actions funded under the BM calls 2021-2022, the share of public bodies has remained on the same level in terms of numbers, though their share of assigned EC contribution has decreased in comparison to the BES actions of SC7. Regarding the actions funded under the INFRA and DRS calls 2021-2022, the share of public bodies has decreased both in terms of numbers and assigned EC contribution in comparison to the INFRA and DRS actions of SC7.

Based on the results of the Horizon Europe beneficiary survey, there are stakeholders (including public bodies) that act as work package leaders in the FCT, BM, INFRA and DRS actions funded in 2021. This implies that stakeholders not only participate in the Cluster 3 actions as partners but also play a role in the governance structures of actions. Based on the survey results, the role of stakeholders as work package leaders is particularly common in the FCT actions.

The FCT, BM, INFRA and DRS beneficiaries interviewed saw that relevant stakeholder groups and their needs were addressed adequately in the 2021 call topics of the Cluster 3 Work Programme. In a similar vein, the eligibility criteria for compulsory participation of end users from different Member States was seen as beneficial for stakeholder engagement in general. However, the beneficiaries suggested expanding the eligible stakeholder groups to include, for instance, non-governmental organizations and EU institutions (Frontex and Europol). It was also noted that end user representatives often change during the lifecycle of action since persons move into other positions inside the public bodies. This creates difficulties in ensuring

³⁴¹ https://cordis.europa.eu/project/id/101073963

³⁴² Horizon Europe Work Programme 2021-2022: 6. Civil Security for Society. Available: https://ec.europa.eu/info/fundingtenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-6-civil-security-for-society_horizon-2021-2022_en.pdf. Horizon Europe Work Programme 2023-2024: 6. Civil Security for Society, Available at: https://ec.europa.eu/info/fundingtenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-6-civil-security-for-society_horizon-2023-2024_en.pdf.

professional end user contributions supporting innovation uptake throughout the action lifecycle.

Beneficiaries' views regarding the impact of project size (amount of funding) or duration on stakeholder involvement were mixed, in general. Some saw no impact, while others considered that a large-scale project (both resource- and time-wise) is necessary for stakeholder involvement and commitment.

Coherence

The evaluation questions of coherence (CH8³⁴³, in particular) are addressed in the parallel case study 11 "Assessing the societal impacts of security research on cross-border cooperation between security practitioners and relevant authorities".

Efficiency

Regarding the efficiency question on which enablers/barriers exist for security-related projects for the further development of an end-product or service after the end of a project life-cycle (EFF9), the beneficiaries of Cluster 3 see that the compulsory participation of end users from different Member States leads to a significant exchange of information between them and will be an enabling factor to improve innovation uptake.

Effectiveness

The beneficiaries of Cluster 3 have faced challenges regarding end user engagement (EFC14). End user representatives often change during the lifecycle of action since persons move into other positions inside the public bodies. This creates difficulties in ensuring professional end user contributions supporting innovation uptake throughout the action lifecycle. A personnel change in an end user organisation can decrease the level of professionalism in project work as the new replacements can be junior and less experienced colleagues.

EU added value

The evaluation question of EU added value (EAV3³⁴⁴) is addressed in the parallel case study 11 "Assessing the societal impacts of security research on cross-border cooperation between security practitioners and relevant authorities".

Key lessons learned and other important observations

The mandatory eligibility criteria of including security practitioners in consortia have been in force in all the thematic areas addressed. Furthermore, the high TRL target levels of CL3 Work Programme 2021-2022 calls have enforced stakeholder

³⁴³ CH8: How coherent have the security-related research and innovation activities funded under Horizon Europe been with the Justice Programme, the Asylum, Migration and Integration Fund, the Internal Security Fund, the European Defence Fund and the EU Civil Protection Mechanism?

³⁴⁴ EAV3: What was the EU added value of participating to the a security-related research and innovation activity funded by the Framework Programme for project beneficiaries such as first responders / end users / public authorities / SMEs?

engagement since they indicate the necessity of user involvement in testing and demonstrating activities that take place in a relevant or operational environment.

Public bodies represent the public sector practitioners and end users in the security domain either directly or indirectly. In the following, the shares of public bodies in the CL3 actions of Horizon Europe funded in 2021-2022 are compared to the SC7 actions of H2020:

- **FCT actions**: the share of public bodies has remained on the same level both in terms of numbers and assigned EC contribution
- **BM actions**: the share of public bodies has remained on the same level in terms of numbers, but their share of assigned EC contribution has decreased
- **INFRA actions**: the share of public bodies has decreased both in terms of numbers and assigned EC contribution
- **DRS actions**: the share of public bodies has decreased both in terms of numbers and assigned EC contribution

Based on the results of the Horizon Europe beneficiary survey, stakeholders not only participate in the Cluster 3 actions as partners but also play a role in the governance structures of actions. This is particularly common in the FCT actions funded in 2021.

Based on the analysis of beneficiary interview data, beneficiaries saw that relevant stakeholder groups and their needs were addressed adequately in the 2021 call topics of the Cluster 3 Work Programme. In a similar vein, the eligibility criteria for compulsory participation of end users from different Member States was seen as beneficial for stakeholder engagement. However, the beneficiaries suggested expanding the eligible stakeholder groups. Beneficiaries' views regarding the impact of project size (amount of funding) or duration on stakeholder involvement were mixed, in general. Some saw no impact while others considered that a large-scale project is necessary for stakeholder involvement and commitment.

The barriers and success factors related to interaction with citizens and stakeholder organisations representing citizens or communities are presented below.

Barriers

- Undeveloped public awareness and understanding of security technologies, including AI-based technologies
- Concerns regarding privacy and data protection
- Perception of security technologies, including AI-based technologies, as threatening personal freedom

Success factors

- Transparent and inclusive stakeholder engagement processes
- Effective communication strategies to bridge the gap between experts and the public
- Incorporation of diverse perspectives and values in decision-making
- Demonstrating tangible benefits and positive impacts of security technologies, including AI-based technologies

Appendix 1 PARTICIPATION ANALYSIS

Participation analysis is based on the CORDA data and our own calculations. The thematic areas of Cluster 3 analysed:

- FCT (call id: HORIZON-CL3-2021-FCT-01 and HORIZON-CL3-2022-FCT-01);
- BM (call id: HORIZON-CL3-2021-BM-01 and HORIZON-CL3-2022-BM-01);
- INFRA (call id: HORIZON-CL3-2021-INFRA-01 and HORIZON-CL3-2022-INFRA-01);
- DRS (call id: HORIZON-CL3-2021-DRS-01 and HORIZON-CL3-2022-DRS-01);
- CS (call id: HORIZON-CL3-2021-CS-01 and HORIZON-CL3-2022-CS-01);
- SSRI (call id: HORIZON-CL3-2021-SSRI-01 and HORIZON-CL3-2022-SSRI-01).



Figure 118. Participation in Cluster 3 in total³⁴⁵

Source: Compiled by the study team.

³⁴⁵ Total number of participants analysed: 1596. Total amount of EC contribution analysed: EUR 413.7 million. Note: REC = research organizations, PUB = public bodies, PRC = private sector, HES = higher education institutions, OTH = other participants.

Appendix 2. Eligibility criteria of FCT, BM, INFRA and DRS calls of CLUSTER 3 2021-2022

Fighting Crime and Terrorism (FCT)

Topic id	TRL	eligibility criteria			
		Amount	Organisation type	Geographical coverage	
HORIZON- CL3-2021- FCT-01-01 (IA)	6-7	At least 3	Police Authorities	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-02 (RIA)	5-6	At least 3	Police Authorities	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-03 (IA)	6-7	At least 3	Police Authorities	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-04 (IA)	7-8	At least 3	Police Authorities	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-05 (IA)	6-7	At least 4 (2+2)	Police Authorities and Forensic Institutes	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-06 (IA)	6-7	At least 4 (2+2)	Police Authorities and Civil Society Organisations	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-07 (IA)	6-7	At least 4 (2+2)	Police Authorities and First Responder organisations	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-08 (IA)	5-6	At least 4 (2+2)	Police Authorities and Border Guards Authorities	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-09 (IA)	6-7	At least 4 (2+2)	Police Authorities and Border Guards Authorities	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-10 (IA)	6-7	At least 4 (2+2)	Police Authorities and Border Guards Authorities	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-11 (RIA)	N/A	At least 4 (2+2)	Police Authorities and Civil Society Organisations	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- FCT-01-12 (RIA)	5-6	At least 3	Police Authorities	From at least three different EU Member States or Associated Countries	

HORIZON- CL3-2022- FCT-01-01 (IA)	7-8	At least 4 (2+2)	Police Authorities and Forensic Institutes	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- FCT-01-02 (RIA)	N/A	At least 4 (2+2)	Police Authorities and Forensic Institutes	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- FCT-01-03 (RIA)	N/A	At least 3	Police Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- FCT-01-04 (CSA)	N/A	At least 3	Police Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- FCT-01-05 (IA)	6-7	At least 4 (2+2)	Police Authorities and Border Guards Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- FCT-01-06 (IA)	6-7	At least 4 (2+2)	Police Authorities and Border Guards Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- FCT-01-07 (IA)	6-7	At least 4 (2+2)	Police Authorities and Border Guards Authorities	From at least three different EU Member States or Associated Countries

Source: Compiled by the study team.

Border Management (BM)

Topic id	TRL	eligibility criteria		
		Amount	Organisation type	Goographical covorago
		Amount	Organisation type	Geographical coverage
HORIZON- CL3-2021- BM-01-01 (IA)	7-8	At least 3	Border/Coast Guard Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2021- BM-01-02 (CSA)	N/A	At least 4 (2+2)	Border/Coast Guard Authorities and Customs Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2021- BM-01-03 (IA)	7-8	At least 3	Border Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2021- BM-01-04 (RIA)	4-6	At least 4 (2+2)	Customs Authorities and Police Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2021- BM-01-05 (IA)	7-8	At least 3	Customs Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- BM-01-01 (RIA)	4-6	At least 3	Border/Coast Guard Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- BM-01-02 (IA)	7-8	At least 4 (2+2)	Border/Coast Guard Authorities and Police Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- BM-01-03 (IA)	7-8	At least 3	Customs Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- BM-01-04 (RIA)	5-7	At least 4 (2+2)	Border/Coast Guard Authorities and Customs Authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- BM-01-05 (IA)	5-7	At least 4 (2+2)	Border/Coast Guard Authorities and Customs Authorities	From at least three different EU Member States or Associated Countries

Source: Compiled by the study team.

Resilient Infrastructure (INFRA)

topic id	TRL	eligibility criteria			
		Amount	Organisation type	Geographical coverage	
HORIZON- CL3-2021- INFRA-01- 01 (IA)	6-7	At least 3	Government entities responsible for security	From at least three different EU Member States or Associated Countries	
HORIZON- CL3-2021- INFRA-01- 02 (IA)	6-7	At least 2 (1+1)	Operator of critical infrastructure and Organisation dealing with research on infectious diseases	From at least two different EU Member States or Associated Countries	
HORIZON- CL3-2022- INFRA-01- 01 (RIA)	4-5	At least 2	Local or regional government authorities	From at least two different EU Member States or Associated Countries	
HORIZON- CL3-2022- INFRA-01- 02 (IA)	6-7	At least 2	Operators of critical infrastructure	From at least two different EU Member States or Associated Countries	

Source: Compiled by the study team.

Disaster-Resilient	Society	(DRS)
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Topic id	TRL	eligibility criteria		
		Amount	Organisation type	Geographical coverage
HORIZON- CL3-2021- DRS-01- 01 (RIA)	N/A	At least 3	Organisations representing citizens or local communities, practitioners (first and/or second responders), and local or regional authorities and private sector	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2021- DRS-01- 02 (IA)	N/A	At least 3	Organisations representing citizens or local communities, practitioners (first and/or second responders), and local or regional authorities and private sector	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2021- DRS-01- 03 (RIA)	N/A	N/A	Local or regional communities and authorities, and Representatives of scientific areas that are related to disaster risk management, societal and historical aspects	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2021- DRS-01- 04 (CSA)	N/A	At least 2	National standardisation organisations and representatives of scientific stakeholders involved in standardisation-related research and end users (both practitioners and policy-makers) in the areas of risk management of natural hazards and CBRN-E	N/A
HORIZON- CL3-2021- DRS-01- 05 (IA)	6-8	At least 3	First responders' organisations or agencies and representatives of local or regional authorities in charge of managing sanitary crises	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- DRS-01- 01 (IA)	N/A	At least 4	Organisations representing citizens or communities; Organisations representing practitioners (first and/or second responders); Local or regional authorities;	N/A

			Private sector entities	
HORIZON- CL3-2022- DRS-01- 02 (RIA)	4-5	N/A	Representatives of scientific areas that are relevant to this topic; Representatives of stakeholders (both practitioners and policy-makers)	N/A
HORIZON- CL3-2022- DRS-01- 03 (IA)	6-8	At least 5	Accredited measurement institutes/laboratories in charge of delivering data to risk management decision-making authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- DRS-01- 04 (RIA)	N/A	At least 4 (2+2)	Organisations representing citizens or communities, and Representatives of societal sciences (psychology, history)	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- DRS-01- 05 (IA)	6-8	N/A	Representatives of scientific areas that are relevant for this topic; Practitioners (first and second responder); Representatives of local or regional management authorities	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- DRS-01- 06 (IA)	5-6	At least 2	Representatives of the financial sector and of insurance companies	From at least two different EU Member States or Associated Countries
HORIZON- CL3-2022- DRS-01- 07 (RIA)	N/A	At least 3	First responders' organisations or agencies	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- DRS-01- 08 (IA)	6-8	At least 3	First responders' organisations or agencies	From at least three different EU Member States or Associated Countries
HORIZON- CL3-2022- DRS-01- 09 (IA)	6-8	At least 3	First responders' organisations or agencies	From at least three different EU Member States or Associated Countries

Source: Compiled by the study team.

Case Study No 11: Assessing the societal impacts of security research on cross-border cooperation between security practitioners and relevant authorities

Executive Summary

Cross-border cooperation between different communities, including practitioners and policy makers, is at the core of research and innovation within the security domain. Security is a common, shared responsibility with associated security challenges exceeding national and EU external borders calling for international cooperation between Member States and countries outside the Union area. The security challenges are primarily transnational, whether looking at their origin, drivers or effective ways to address them. More intense collaboration involving law enforcement, judicial and other public authorities, as well as EU institutions and agencies, is thus needed for building understanding and exchange to develop common solutions.

The main aim of this case study is to assess the societal impacts of Horizon Europe security research in improving cross-border cooperation between security practitioners and relevant authorities, going beyond the action's expected outcomes and results. The case study examines whether cross-border cooperation within actions enables better address of security challenges. Together with cross-border cooperation-related questions, this case study contemplates data sharing issues and the Better Regulation Guidelines (BRG) evaluation criteria. The case study focuses on four thematic and one horizontal area of security research (i.e., Destinations) funded under Cluster 3 of Horizon Europe (CL3 - Civil Security for Society). The areas addressed:

- Better protection of the EU and its citizens against crime and terrorism (FCT);
- Effective management of EU external borders (BM);
- Resilient infrastructure (INFRA);
- Disaster-resilient Society for Europe (DRS); and
- Strengthened security research and innovation (SSRI, horizontal).

The results of this case study are based on four methodological approaches: 1) document analysis; 2) qualitative analysis of beneficiary and policy officer interview data; 3) analysis of CORDA and other EC monitoring data; and 4) analysis of the results of the Horizon Europe beneficiary survey 2023 led by Evaluation study on "Excellent Science in the European Framework Programmes for Research and Innovation". Beneficiary interviewees represent actions from all the thematic areas addressed.

The results show that transnational security challenges are best solved under European frameworks of research cooperation instead of nationally funded initiatives. Gaining a comprehensive understanding of complex security challenges is difficult to achieve at the national level, as the research problems typically require the involvement of numerous stakeholders from different Member States and Third Countries. Undertaking similar projects under national funding schemes would result in tailormade solutions to individual Member States, not considering various aspects of different organisations in other countries. While local technology development does take place within Member States, EU-funded actions are important as the specific research topics relate to the entire EU with various regulative frameworks, policy documents and so forth. Considering the time, resources, and expertise available in each Member State, national projects would be rather limited in their cross-national impacts, findings, and outcomes. EU funding also positively contributes to creating diverse consortia, and similar cooperation patterns would not be possible in national settings.

The cross-border collaboration activities have enabled CL3 actions to address stakeholder needs by the following means better:

 Creation of new knowledge clusters and working groups combining European and global experiences gained in different countries and the latest developments made by the industry and the research community. For instance, SUNRISE action created a new cluster of societal resilience within the area of pandemic-specific vital services. Previously, there was low or limited cross-border collaboration on societal resilience against pandemics in the Member States.

- Facilitation of organisational and in-person interaction, communication and dialogue between stakeholders and strengthening public-private collaboration.
- Organisation of engaging piloting activities. For instance, SUNRISE action hosted informative field events in complex critical infrastructure production facilities to raise awareness and provide tangible evidence on the impact of key risks to the physical infrastructure.
- Establishment of a common culture for disaster preparedness and security. For instance, SAFE-CITIES action developed an interactive platform enabling the simulation of complex scenarios. Simulations support the achievement of a common preparedness culture through regular revision of business continuity plans by testing.
- **Building trust between practitioners** facilitating the development of common solutions for shared challenges.

Introduction

Cross-border cooperation³⁴⁶ between different communities, including practitioners and policy makers, is at the core of research and innovation within the security domain. This is reflected in the Security Union Strategy of the European Commission (2020)³⁴⁷ highlighting security as a common, shared responsibility with associated security challenges exceeding national and EU external borders calling for internal and international cooperation between Member States and countries outside the Union area. The security challenges are primarily transnational, whether looking at their origin, drivers, and effective ways for authorities to address them. More intense collaboration involving law enforcement, judicial and other public authorities, and with EU institutions and agencies is needed 'to build the understanding and exchange needed for common solutions'.348 Regarding societal resilience, adaptation and disaster management, the transboundary impacts of climate risks and their management require strengthened scientific and practitioner-level cooperation and dialogue.³⁴⁹ On the higher security agenda, stronger political and security agency for the EU is difficult to achieve without joint action as put forward in the Strategic Compass for Security and Defence of the Council of the European Union (2022)³⁵⁰. Technological or other innovations developed through collaborative efforts play a critical role.

Cluster 3 - Civil Security for Society (CL3) forms the third cluster under Pillar 2 - Global Challenges and European Industrial Competitiveness of the Horizon Europe focusing on security research and innovation. Similar to its H2020

³⁴⁶ Regulation (EU) No 2021/695 of the European Parliament and of the Council on Horizon Europe establishes that the Horizon Europe framework programme 'should strengthen cooperation between European Partnerships and private and/or public sector partners at international level, including by joining up R&I programmes and cross-border investment in R&I bringing mutual benefits to people and businesses while ensuring that the Union can uphold its interests in strategic areas' (recital 38). Moreover, the regulation emphasizes a focus on 'objectives and activities that cannot be effectively realised by Member States alone, but in cooperation' (Article 3(1)).

³⁴⁷ COM(2020) 605 final

³⁴⁸ Ibid.

³⁴⁹ COM(2021) 82 final

³⁵⁰ https://data.consilium.europa.eu/doc/document/ST-7371-2022-INIT/en/pdf

predecessor, Societal Challenge 7 - Secure societies - Protecting freedom and security of Europe and its citizens (SC7), Cluster 3 is divided into six destinations with the aims of 1) better protection of the EU and its citizens against crime and terrorism (FCT); 2) effective management of EU external borders (BM); 3) resilient infrastructure (INFRA); 4) increased cybersecurity (CS); 5) disaster-resilient society for Europe (DRS); and 6) strengthened security research and innovation (SSRI). Compared to H2020, a new thematic area was introduced (SSRI) representing a horizontal approach towards serving all expected impacts of Cluster 3.

The main aim of this case study is to assess the societal impacts of Horizon Europe security research in improving cross-border cooperation between security practitioners and relevant authorities, going beyond the action's expected outcomes and results. The case study examines whether cross-border cooperation within actions enables better address of security challenges. The focus is on four thematic areas (FCT, BM, INFRA and DRS) and one horizontal area (SSRI) of security research funded under Cluster 3. Cyber Security is excluded from the assessment, as the thematic area is addressed in more detail in a separate case study of the Resilient Europe evaluation study (CS12). At the time of the current evaluation, two Cluster 3 work programmes have been published (2021-2022³⁵¹ and 2023-2024³⁵²). Together with cross-border cooperation-related questions, this case study contemplates data sharing issues and the Better Regulation Guidelines (BRG) evaluation criteria. Especially the following evaluation questions are addressed:

- RV10: To what extent have security-related research and innovation activities funded under Horizon Europe met stakeholders' needs?
- CH8: How coherent have the security-related research and innovation activities funded under Horizon Europe been with the Justice Programme, the Asylum, Migration and Integration Fund, the Internal Security Fund, the Border Management and Visa Instrument (BMVI) the European Defence Fund, the Digital Europe Programme and the EU Civil Protection Mechanism?

The case study results are based on four methodological approaches: document analysis; qualitative analysis of beneficiary and policy officer interview data; analysis of eCORDA and other EC monitoring data; and analysis of the results of the Horizon Europe beneficiary survey 2023 led by Evaluation study on "Excellent Science in the European Framework Programmes for Research and Innovation". 27 beneficiaries representing twelve FCT, BM, INFRA, DRS and SSRI actions (funded in 2021) were interviewed during May-September 2023 for this case study and parallel case study 10 on assessing the societal impacts of security research in addressing stakeholders' needs (see Appendix 1).

Outcomes/results

Figure below presents a country breakdown that summarises the overall geographical participation patterns of Cluster 3 at the aggregate level. The country breakdown shows the share of participants by numbers and the assigned EC contribution. The

³⁵¹ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-6-civil-security-for-society_horizon-2021-2022_en.pdf

³⁵² https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-6-civil-security-for-society_horizon-2023-2024_en.pdf

target group consists of 1596 participants of 83 actions funded under Cluster 3 in 2021 and 2022 with a total amount of EC contribution of EUR 413.7 million.





PARTICIPATING ASSOCIATED COUNTRIES: ALB, ARM, BIH, GBR, GEO, ISL, ISR, MDA, MKD, NOR, SRB, TUR, UKR, XKX

PARTICIPATING THIRD COUNTRIES: AUS, CHE, EGY, ETH, JPN, KOR, MAR, THA, USA

Source: Compiled by the study team using its own calculations and CORDA data.

The above Figure illustrates that the highest participation in CL3 comes from EU-14 Member States (i.e., Austria, Belgium, Denmark, Finland, France, Germany, Greece, Republic of Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, and Sweden). The compound share of Third Countries and Associated Countries arrives close to that of EU-13 (i.e., Bulgaria, Croatia, Cyprus, Czechia, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, and Slovenia) with slightly over 4% difference. In general, the level of participation and the level of EC contribution seem to correlate, except in the case of Third Countries that rely on national funding sources.

The Work Programmes 2021-2022 and 2023-2024 of Cluster 3 encourage collaboration with Third Countries, especially developing countries, in case of many call topics (FCT, DRS and INFRA).³⁵³ The Work Programme 2023-2024 has a mandatory requirement for the inclusion of non-associated Third Countries as partners in one call topic (HORIZON-CL3-2023-DRS-01-04).

CL3 respondents of the Horizon Europe beneficiary survey reported challenges associated particularly with the participation of partners coming from the UK. There was a long uncertainty and unclarity about the status of UK partners, which created different negative impacts, such as financial risks for actions, partner exclusion from project proposals, or fear within a consortium of generating ineligible proposals.

³⁵³ Legal entities established in China are fully ruled out from any Cluster 3 Innovation Actions.

Fighting crime and terrorism

Fighting crime and terrorism (FCT) is addressed in the CL3 WP 2021-2022 and WP 2023-2024 with 15 RIA, 17 IA and 1 CSA calls. Figure 120 summarises the geographical participation patterns of actions funded under the FCT calls 2021-2022.

Compared to the overall Figures of Cluster 3, the level of EU-14 participation is slightly lower. In contrast, EU-13 participation is higher, while Third Countries (Switzerland) and Associated Countries are close to the overall Figures of Cluster 3. With regards to EC contributions, Third Countries and Associated Countries receive limited contributions. Compared to Horizon 2020, the level of participation has remained similar to that of SC7 with no significant changes met in any country category.



Figure 120. Country breakdown of the participants of FCT (n=400)³⁵⁴

PARTICIPATING ASSOCIATED COUNTRIES: ALB, BIH, GBR, ISR, MDA, MKD, NOR, SRB, XKX

PARTICIPATING THIRD COUNTRY: CHE

Source: Compiled by the study team using its own calculations and CORDA data.

The results of the beneficiary interview data suggest that FCT actions do improve cross-border cooperation between security practitioners and relevant authorities. The interviewees perceive the undertaking of similar projects within national government schemes as extremely difficult with limited resources available to fund such initiatives. Also, the societal importance of security projects might be nationally undervalued, and the expertise in solving European or transnational security challenges is not considered available within Member States to the extent required. The mandatory participation of practitioners from different Member States is seen to lead to significant information exchange between them, and it is considered an effective means for active engagement of end users. In the case of projects aiming at formulating policy recommendations, it might be appropriate also to require mandatory participation from relevant ministries and their policy officers as cross-border cooperation can be influenced by political factors that may not align with the eligibility conditions.

³⁵⁴ Total number of participants analysed: 400. Total amount of EC contribution analysed: EUR 82.0 million.

EU-funded research can support Member State practitioners to better understand efficient and effective cooperation mechanisms between new organisational units that have been recently set up because of new regulatory requirements (e.g., national Passenger Information Units collecting, processing, and retaining on flight passenger data³⁵⁵). Overall, a project exclusively funded by a national entity is likely to be tailored to the specific needs and requirements of an individual Member State, severely limiting the potential for broader application in other Member States. The end user beneficiaries interviewed see the involvement of numerous stakeholders at the EU level as imperative for addressing transboundary security challenges.

An important challenge to cross-border cooperation is brought by the nature of end users as public bodies where the officers or personnel have their roles frequently changed. This means that the involvement of end users much depends on the specific person involved, and, when this person is moved to another role, it may happen that the replacement is not at all committed or simply not aware of collaborative projects. This can compromise or limit the overall cross-border cooperation. Besides, public bodies are often short in staff and may not have dedicated resources to allocate on the project. This means that effective cross-border cooperation between end users most of the time depends, again, on the specific persons working on collaborative projects within the organization. There are only limited ways of effectively improving the situation.

Border management

Border management – effective management of EU external borders – is addressed in the CL3 WP 2021-2022 and WP 2023-2024 with 5 RIA, 8 IA and 1 CSA calls. Figure 121 summarises geographical participation patterns of BM. The data analysis addresses 12 BM actions funded under Cluster 3 in 2021 and 2022.



Figure 121. Country breakdown of the participants of BM (n=248)³⁵⁶

PARTICIPATING ASSOCIATED COUNTRIES: ALB, GBR, ISR, MDA, NOR, SRB

PARTICIPATING THIRD COUNTRY: CHE

Source: Compiled by the study team using its own calculations and CORDA data.

The geographical distribution of participations in Border management is similar to the programme level of Cluster 3. Compared to the BM actions of SC7 of Horizon 2020, the level of participation has changed with a 6.7% increase in EU-14, a 2.8% decrease in EU-13 and a slight decrease in Associated Countries and Third Country participations.

The BM beneficiaries interviewed see that EU funding in the area of border management brings coherence into the activities of public administrations. The actions form a so-called learning cycle in which each partner enriches shared knowledge through their own work, everyone having their own domain of contribution. BM actions support stakeholders in addressing transnational security challenges as the actions also include partners from European countries not eligible for EU funding. These partners have been able to secure national funding for their own activities. Cross-organisational cooperation within actions is also built through trust relationships, something requiring significant rebuilding effort in case of personnel changes. It is also mentioned that public procurement tenders mostly focus on highly mature equipment or other products. Thus, EU funding is important for introducing new solutions in which law enforcement authorities may not have previous experience or cannot rely on proven results.

Resilient infrastructure

Resilient infrastructure is addressed in the CL3 WP 2021-2022 and WP 2023-2024 with 2 RIA and 7 IA calls. Figure 122 summarises INFRA's geographical participation patterns. The data analysis addresses 4 INFRA actions under Cluster 3 in 2021 and 2022.

The geographical distribution of participations in Resilient infrastructure is significantly different to the programme level of Cluster 3. The share of EU-13 is close to twice as

³⁵⁶ Total number of participants analysed: 248. Total amount of EC contribution analysed: EUR 63.2 million.

high in Resilient infrastructure than at the programme level. This results in lower participations in all other categories with Third Country and Associated Country participations being less than half of the programme level. As explained in a discussion with DG HOME representatives, the high EU-13 participation is likely to be linked to the preparatory process of the Critical Entities Resilience Directive (CER)³⁵⁷, in which EU-13 actively participated. The CER process was assessed to increase EU-13's interest also towards the Horizon Europe calls on critical infrastructure resilience. This is also visible when comparing CL3 against SC7, showing that there has been a large increase in the number of participations of EU-13 countries (+11.7%) while the number of participations.



Figure 122. Country breakdown of the participants of INFRA (n=118)³⁵⁸

PARTICIPATING ASSOCIATED COUNTRIES: GBR, ISR, NOR, SRB

Source: Compiled by the study team using its own calculations and CORDA data.

Beneficiaries interviewed see that cross-border cooperation between critical infrastructure providers, including regional governments and public authorities tends to be low. Therefore, EU-funded INFRA actions form an important cross-sectoral and cross-border communication and collaboration platform for these practitioners. Within the context of critical infrastructure protection, establishing collaboration between the stakeholders is considered highly costly and time-consuming. For example, a consortium addressed in interviews consists of over 40 partners representing different sectors and coming from 15 countries. It would be difficult to organise similar cooperation without EU support. The beneficiaries report that without EC contribution the stakeholders would not devote their time to such activities or perceive them as a priority, even though these might turn out crucial in the future.

Disaster-resilient society

Disaster-resilient society – A disaster-resilient society for Europe – is addressed in the CL3 WP 2021-2022 and WP 2023-2024 with 14 RIA, 10 IA and 1 CSA calls. Figure

³⁵⁷ The CER Directive (Directive (EU) 2022/2557) entered into force on 16 January 2023.

³⁵⁸ Total number of participants analysed: 118. Total amount of EC contribution analysed: EUR 29.9 million.

123 summarises the geographical participation patterns of DRS. The data analysis addresses 18 DRS actions under Cluster 3 in 2021 and 2022.

The geographical distribution of participations in Disaster-resilient infrastructure differs from the programme level in all country categories. The shares of EU-14 and EU-13 are lower while the shares of Third Countries and Associated Countries are higher than those of the programme level. Additionally, the variety of Associated Country participants (8 countries) and Third Country participants (9 countries) is broad compared to the other thematic areas. Only FCT has a higher number of individual Associated Countries participating (9 countries). The geographical participation patterns of DRS align with CL3 Work Programme objectives highlighting the transnational dimension of different natural and man-made hazards and their drivers. To meet these challenges, international cooperation is strongly encouraged.

Compared to Horizon 2020 (the DRS calls of SC7), the level of participation has slightly changed with a 3.1% and a 3.2% decrease in EU-14 and EU-13 participations respectively. There has been a significant increase in Third Country participation while Associated Country participation has remained close to the same.



Figure 123. Country breakdown of the participants of DRS (n=322)³⁵⁹

PARTICIPATING ASSOCIATED COUNTRIES: ARM, GBR, GEO, ISL, ISR, NOR, TUR, UKR

PARTICIPATING THIRD COUNTRIES: AUS, CHE, EGY, ETH, JPN, KOR, MAR, THA, USA

Source: Compiled by the study team using its own calculations and CORDA data.

The beneficiary interview data confirms that multinational cooperation has been required to find solutions to European and transnational security challenges in the context of disaster management. Applying for national funding is considered an insufficient way to support project frameworks building upon cross-border knowledge transfer and information exchange between various partners. The mandatory participation of practitioners in consortia is considered to direct partners to collaborate with different organisations from various countries. These eligibility conditions efficiently broaden the scope of the actions' societal impacts towards different

³⁵⁹ Total number of participants analysed: 322. Total amount of EC contribution analysed: EUR 83.4 million.

geographies. In some cases, action's beneficiaries do not share a land border and the scope for operational cross-border cooperation might be limited.

Cross-border cooperation is challenged by the availability of practitioners (e.g., project work conducted outside working hours and not being paid for). Public organizations often lack additional resources to collaborate and actively participate in project activities. Language can be a practical problem in project fieldwork when translations are required because performing local translations is a time-consuming process.

The actions aim to be stakeholder-driven and guided by their expectations and requirements. However, the short-term nature of the actions means that the elicitation of needs cannot start with a blank sheet. As solutions need to be delivered within three years, too much time cannot be spent on exploring the problems in a collaborative manner with stakeholders as it would take too long to develop a concept model to be used in the design. This forces actions to steer stakeholders heavily in order to be able to deliver a solution within the duration of the action. Instead of a blank sheet, the actions present design ideas to stakeholders to comment on or provide them with options to choose between. Therefore, the solutions might not be as stakeholder-driven as actions would like them to be.

Strengthened security research and innovation

Destination on 'strengthened security research and innovation' (SSRI) represents a horizontal approach designed to serve equally to all security domains and their expected impacts of Cluster 3. SSRI is addressed in the CL3 WP 2021-2022 and WP 2023-2024 with 3 RIA, 6 CSA and 2 PCP calls. Figure 124 summarises the geographical participation patterns of SSRI. The target group consists of 9 funded actions under the SSRI calls of Cluster 3 in 2021 and 2022.

The geographical distribution of participations of SSRI aligns with the programme level of CL3 concerning EU-14 and EU-13 countries. With regards to Associated Countries, their share of 11.7% is close to the CL3 average. There are no Third Country participants in SSRI actions. As SSRI is horizontal and covers several security domains, we do not address the thematic characteristics of cross-border collaboration here as we did in previous sections.



Figure 124. Country breakdown of the participants of SSRI (n=120)³⁶⁰

PARTICIPATING ASSOCIATED COUNTRIES: ALB, GBR, ISL, ISR, NOR, TUR

Source: Compiled by the study team using own calculations and CORDA data.

Perceived barriers and critical success factors

Data sharing is a key precondition for facilitating and ensuring cross-border cooperation between security practitioners and other relevant authorities within Cluster 3 actions. In this section, we examine how security research funded under Cluster 3 overcomes potential barriers to data sharing. Data sensitivity may create barriers to collaboration within actions and across the research community at large, thus hindering progress towards impact and creating synergies. Handling sensitive information or results varies between thematic areas, and this is reflected in the specific conditions, namely eligibility conditions defined for each topic³⁶¹.

Barriers

Based on the interview data analysis, Cluster 3 thematic areas and actions within the same thematic area differ in the potential challenges they might have experienced in data sharing. Most challenges seem to be associated with FCT and BM, although some interviewed beneficiaries in these thematic areas report no issues in data sharing so far, while others consider it as a major challenge. Notwithstanding, similar data-sharing challenges seem to be present in the whole of Cluster 3, particularly in actions relating to border management and surveillance. If examining the special conditions established in Cluster 3 Work Programmes, classified background or security-sensitive results may also be associated with INFRA topics and part of the DRS topics. Nevertheless, in our interviews, none of the DRS, INFRA and SSRI beneficiaries claimed to process EUCI information, imposing specific requirements for

³⁶⁰ Total number of participants analysed: 120. Total amount of EC contribution analysed: EUR 15.1 million.

³⁶¹ The eligibility conditions may establish that "some activities, resulting from this topic, may involve using classified background and/or producing of security sensitive results (EUCI and SEN)". For example, in Cluster 3 Work Programme for 2021-2022, all topics under FCT, BM and INFRA refer to such eligibility conditions.

actions and thus making data sharing more unyielding and controlled³⁶². Interviewed SSRI beneficiaries did not identify any data-sharing challenges affecting the action.

With regard to data sharing challenges, the nature of specific research data may limit or hinder access to real data for research work and validation of project results (e.g., including sensitive personal data of persons, such as passenger data). FCT beneficiaries note that most of the time, the question is more on data availability than data sharing, and certain kinds of data might be considered more difficult to exchange between beneficiaries, such as video streams from public or semi-public spaces. Based on the beneficiaries' previous experience, access to such data is possible, but the process to achieve this is time-consuming.

Similarly, BM beneficiaries maintain that the bureaucracy associated with the sharing of sensitive data and its overall administration is time-consuming as it also requires a lot of negotiation between research partners, coming from different countries with different rules. Due to this, it may take several months before data can be exchanged in practice. Ideally, beneficiaries would be provided with new, uniform rules and clear, ready-made forms to use when referring to specific regulations or directives on data sharing. Currently, many negotiation processes in this area start from scratch.

Success factors

Cluster 3 actions implement various methods to mitigate potential data sharing challenges ranging from the collection or generation of the research data itself to different measures for ensuring safe and secure sharing in support of the technical development, testing and validation of the results. Post-project access to data is also important for beneficiaries.

With regards to AI-based solutions, one means is to use **synthetic data**³⁶³ to train the developed models. FCT beneficiaries describe that in cases where less granular data is available (e.g., on people flows or crowding levels at railway stations), aggregated data could be used to reconstruct required datasets to a needed level of detail. Once simulations have been completed, an internal validation with end users could be conducted to ensure that the synthetic datasets qualitatively resemble real data and do not negatively affect the effectiveness, or the accuracy of the outputs generated by the developed tools. Another FCT action reports that they have approached a relevant EU agency, **eu-LISA** (*the European Union Agency for the Operational Management of Large-Scale IT Systems in the Area of Freedom, Security and Justice*), to receive suitable datasets for AI model training.

Overall, data sharing inside the actions is facilitated by standard contractual agreements, such as **the Grant Agreement** and **the Consortium Agreement**³⁶⁴, and other agreements between beneficiaries that depend on the type of data needed for processing. If an action is dealing for example with aggregated data, a **Non-**

363Synthetic data refers to "artificial data that is generated from original data and a model that is trained to reproduce the characteristics and structure of the original data." https://edps.europa.eu/press-publications/publications/techsonar/syntheticdata en

³⁶²See e.g., EC (2021) Classification of information in Horizon Europe projects. https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/classification-of-information-in-he-projects_he_en.pdf

³⁶⁴Often, Horizon Europe projects implement the DESCA model Consortium Argeement. The model is similar to the preceding H2020 programme. https://www.desca-agreement.eu/desca-model-consortium-agreement/
Disclosure Agreement (NDA) could be sufficient. An NDA might also be relevant in project-to-project collaboration if other than public information is shared.

In contrast, sharing sensitive data, such as emergency response measures for public spaces, requires more stringent access control. In practice, this may mean the usage of private servers or clouds with a username and password. The aim is to ensure that no one outside the consortium has access such data. Another way is to set up **a sandbox**³⁶⁵ for test data sharing. The objective of the sandbox is to form a secure environment in which end users could provide, for example, their actual real data. A BM action investigates the possibility to use **dataspaces**³⁶⁶ for data sharing. Overall, **specific protected repositories** are a commonly used method to distribute also other relevant information and materials to project partners³⁶⁷.

As general best practices for data sharing, the following are highlighted:

- Ensure data openness and accessibility through open-access publications or appropriate data-sharing platforms;
- Establish clear guidelines, protocols, and agreements among project partners for sharing sensitive data securely, including
 - o rules on how datasets are characterized and documented;
 - o creation of a catalogue of datasets;
 - o rules on data sharing and data storage in shared workspaces;
 - o definition of criteria for identifying who has access to the data;
 - promotion of collaboration and knowledge exchange among stakeholders to enhance data-sharing practices.

Reflections on evaluation criteria

Relevance

The cross-border collaboration activities have enabled CL3 actions to better address stakeholder needs in the following ways for example:

Create new knowledge clusters and working groups combining European and global experiences gained in different countries, including raising awareness

³⁶⁵According to the Computer Security Resource Center of the U.S. National Institute of Standards and Technology (NIST), a sandbox refers to "a system that allows an untrusted application to run in a highly controlled environment where the application's permissions are restricted to an essential set of computer permissions. In particular, an application in a sandbox is usually restricted from accessing the file system or the network. A widely used example of applications running inside a sandbox is a Java applet." https://csrc.nist.gov/glossary/term/sandbox

³⁶⁶A dataspace " refers to a type of data relationship between trusted partners who adhere to the same high level standards and guidelines in relation to data storage and sharing within one or many vertical ecosystems." https://gaia-x.eu/what-is-gaia-x/deliverables/data-spaces/

³⁶⁷Other solutions for research data sharing are discussed e.g., in Sharma, A., Nilsen, T.B., Johansen, S., Johansen, D., Johansen, H.D. (2022). Designing a service for compliant sharing of sensitive research data. In: Luo, B., Mosbah, M., Cuppens, F., Ben Othmane, L., Cuppens, N., Kallel, S. (eds) Risks and Security of Internet and Systems. CRiSIS 2021. Lecture Notes in Computer Science, vol 13204. Springer, Cham. https://doi.org/10.1007/978-3-031-02067-4_10

of local cultures and communities and the latest developments made by the industry and the research community.

- SUNRISE action created a new cluster of societal resilience within the area of pandemic-specific vital services. Previously, there were low or limited cross-border collaboration on societal resilience against pandemics in the Member States.
- C2IMPRESS action implemented a novel 'place and people' centred framework to develop tools risk and resilience assessment. The framework provided better understanding and public awareness to multi-hazard risks, associated multidimensional impacts, vulnerabilities, and resilience of extreme weather events.
- Facilitating organisational and in-person interaction, communication and dialogue between stakeholders and the strengthening of public-private collaboration.
- Organising engaging pilots that go beyond only providing information about project activities and outputs.
 - SUNRISE action hosted informative field events in complex critical infrastructure production facilities to raise awareness and provide tangible evidence on the impact of key risks to the physical infrastructure.
- Establishing common cultures for disaster preparedness and security.
 - SAFE-CITIES action developed an interactive platform enabling the simulation of complex scenarios. Simulations support the achievement of a common preparedness culture through regular revision of business continuity plans by testing.
- Building trust that facilitates the development of common solutions for shared challenges.

Cluster 3 activities support the implementation of various European and international policy frameworks. In July 2020, the European Commission introduced a new EU **Security Union Strategy**³⁶⁸ delineating tools and measures to be developed for ensuring the security of the physical and digital environment of European societies for the period 2020 to 2025. The strategy builds upon previous work of the European Parliament (e.g., the Special Committee on Terrorism), the European Council (e.g., priorities endorsed between 2015-2019) and the European Commission (e.g., European Agenda on Security 2015-2020³⁶⁹). The Security Union Strategy recognises four EU-level priority actions – a future-proof security environment, tackling evolving threats, protecting Europeans from terrorism and organised crime and a strong European security ecosystem. Interconnected with the Security Union Strategy, Cluster 3 destinations particularly contribute to fulfilling **EU Strategy to tackle organised crime**³⁷⁰, **EU Strategy on Combatting Trafficking in Human Beings**³⁷¹, **EU strategy for a more effective fight against child sexual abuse**³⁷², **EU Action**

- 369 COM(2016) 230 final
- 370 COM(2021) 170 final
- 371 COM(2021) 171 final

³⁶⁸ COM(2020) 605 final

³⁷² COM(2020) 607 final

Plan on firearms trafficking³⁷³, **EU Maritime Security Strategy** and associated Action Plan³⁷⁴, **EU's Cybersecurity Strategy for the Digital Decade**³⁷⁵ and **Directive (EU) 2022/2557 on the resilience of critical entities**. Cluster 3 activities also relate to the **Counter-Terrorism Agenda for the EU**³⁷⁶ aimed at improving EU's response to threats posed by terrorism and violent extremism; the **New Pact on Migration and Asylum**³⁷⁷ enhancing EU migration processes and the governance of migration and border policies; and the **Strategy towards a fully functioning and resilient Schengen area**³⁷⁸ supporting the enhancement of modern and effective management of EU's external borders.

The first pillar of the Security Union Strategy aligns with **EU Strategy on Adaptation to Climate Change**³⁷⁹ and **EU Disaster Risk Reduction policies** (e.g., **Union Civil Protection Mechanism**³⁸⁰) emphasizing the increasing interdependencies of disruptions affecting multiple critical infrastructures simultaneously or in cascade. As stressed within the EU Adaptation Strategy (2021), there is an urgent need to develop societal resilience and disaster preparedness against various climate change impacts caused by more frequent and more severe weather extremes. Globally, for example, the **Sendai Framework for Disaster Risk Reduction**³⁸¹ adopted on March 18, 2015, delineates four priority areas: understanding disaster risk; strengthening disaster risk governance to manage disaster risk; investing in disaster reduction for resilience and; enhancing disaster preparedness for effective response, and to "Build Back Better" in recovery, rehabilitation and reconstruction.

According to the Security Union Strategy, 'innovation should be seen as a strategic tool to counter current threats and to anticipate both future risks and opportunities. Innovative technologies can bring new tools to help law enforcement and other security actors.' Moreover, 'EU research, innovation and technological development offer the opportunity to take the security dimension into account as these technologies and their application are developed.' As put forward in the EU Adaptation, including the cost of adaptation, its benefits and distributional effects. Understanding the interrelationships of climate hazards between socio-economic vulnerabilities and inequalities also require further research. Finally, 'There is increasing demand to translate the wealth of climate information available into customised, user-friendly tools'.

Coherence

Cluster 3 Work Programmes establish that actions should find synergies with other EU funding instruments in the context of final development, market uptake and deployment of relevant research results. As noted also in the Security Union Strategy, '*The Commission's proposals for Horizon Europe, the Internal Security Fund, the*

³⁷³ COM/2020/608 final

³⁷⁴ Latest strategy update 2023, see JOIN(2023) 8 final.

³⁷⁵ JOIN(2020) 18 final

³⁷⁶ COM(2020) 795 final

³⁷⁷ COM(2020) 609 final

³⁷⁸ COM(2021) 277 final

³⁷⁹ COM(2021) 82 final

³⁸⁰https://civil-protection-humanitarian-aid.ec.europa.eu/what/civil-protection/eu-civil-protection-mechanism_en

³⁸¹https://www.preventionweb.net/files/43291_sendaiframeworkfordrren.pdf?_gl=1*1x1axwd*_ga*MTY0ODkyNDM3Ni4xNjk 1Nzk0MDU2*_ga_D8G5WXP6YM*MTY5NTc5NDI2OC4xLjAuMTY5NTc5NDI3Mi4wLjAuMA..

Integrated Border Management Fund, the EUInvest Programme, the European Regional Development Fund and the Digital Europe Programme will all support the development and deployment of innovative security technologies and solutions along the security value chain.' Table 117 summarises the interrelations of the funding instruments to the Cluster 3 thematic areas as indicated in the CL3 WPs for 2021-2022 and 2023-2024. As a cross-sectional thematic area, SSRI could be understood as indirectly connected to most of the other EU funding instruments.

According to the interview data, beneficiaries found some synergies between Cluster 3 and other EU funding instruments. However, as the actions are in their early phases, concrete exploitation plans regarding other funding instruments are still in a forming stage. SSRI beneficiaries comment on not seeing a direct connection with other instruments. Instead, the actual impact might come through when the results of SSRI actions are utilised by other CL3 actions seeking funding opportunities of other EU instruments.

 Table 117. Synergies between other EU funding instruments and CL3 thematic areas.

EU funding instrument	Thematic area
Internal Security Fund (ISF)	FCT
Digital Europe Programme (DIGITAL)	FCT, CS
Integrated Border Management Fund (IBMF), consisting of the Border Management and Visa Instrument (BMVI) and the Customs Control Equipment Instrument	ВМ
European Defence Fund (EDF) and its precursor programmes (e.g., Preparatory Action on Defence Research)	BM
Cohesion policy, particularly through the European Regional Development Fund (ERDF)	INFRA, DRS
Union Civil Protection Mechanism (UCPM)	DRS

Source: Compiled by the study team based on CL3 WP 2021-2022 and WP 2023-2024.

The interviewed beneficiaries for example identify **the Internal Security Fund** as a synergic funding instrument, however, its full benefits are difficult to estimate at the current implementation stage of the actions. In contrast, the actions see a close relation to what relevant EU agencies, such as **eu-LISA**, currently develop or implement (e.g., the Entry-Exit System or the European Travel Information and Authorisation System). The results of ongoing Horizon Europe actions could become subsets of such platforms or systems. The connection with ISF may also be seen as more indirect and reflected through actions' practical collaboration with EU agencies and other EU bodies, such as **Frontex** (*the European Border and Coast Guard Agency*), **Europol** (*European Union Agency for Law Enforcement Cooperation*), **CEPOL** (*European Union Agency for Law Enforcement Training*) and **DG HOME** (*Directorate-General for Migration and Home Affairs*).

Additionally, **the Innovation Lab of Europol**³⁸² is recognised as providing good opportunities for beneficiaries to have their solutions tested by law enforcement authorities. Moreover, the potential is seen in ISF funding and innovative public procurement. However, exploitation opportunities depend on the success of the project

³⁸²https://www.europol.europa.eu/operations-services-and-innovation/innovation-lab

results. Beneficiaries also describe having previous background in ISF projects addressing similar topics as to those addressed within Cluster 3, and ongoing collaboration between the Horizon Europe actions and ISF-funded projects is taking place. This is supported by the fact that approximately 70% of the beneficiaries (76 out of 109) funded under the ISF Work Programme 2021-2022 participate in the Cluster 3 actions (based on the analysis of EC monitoring data).

In addition to ISF, the beneficiaries identify the **Union Civil Protection Mechanism** as offering exploitation opportunities at later project stages. Exploring national funding schemes is also mentioned, but the actual potential depends on the country and the identified, specific funding instrument. Beneficiaries see room for improvement and coherence between CL3 activities and other instruments in terms of collaboration and alignment of objectives. Together with the EU Civil Protection Mechanism, **Interreg Central Europe** (a European Union funding programme supporting transnational cooperation) is mentioned as a previous background to partner-level collaboration.

The Cluster 3 Work Programmes encourage successful proposals to actively cooperate with other EC-chaired or -funded initiatives in relevant domains. Beneficiaries in different thematic areas report strong interaction with other Horizon Europe actions having overlapping interests and topics. A good collaboration atmosphere is present among experts focusing on similar topics within and outside the limits of single thematic areas. A lot of clustering activities, collaboration, and exchange of experiences take place not only between project partners but also between actions and EC representatives. Approximately one-fourth of CL3 respondents to the Horizon Europe beneficiary survey report some planned activities with other Cluster 3 actions.

Beneficiaries also highlight the importance of **CERIS** (*Community of European Research and Innovation for Security*) as a forum for coordinating collaboration between EU-funded CL3 actions. Beneficiaries have actively participated in different CERIS events since the launch of their actions. It is, however, commented that for newcomers in civil security research, a significant effort is required to build connections into and integrate with relevant stakeholder communities, networks, and EU agencies, such as CERIS or Europol. A concrete example of a joint event mentioned by several beneficiaries is the **Projects to Policy Seminar**³⁸³, organised by **DG HOME** and **REA** (*the European Research Executive Agency*) in June 2023. Overall, beneficiaries see collaboration in Horizon Europe to be more intense compared to earlier funding programmes.

Efficiency

The beneficiaries of Cluster 3 see that the compulsory participation of end users from different Member States leads to a significant exchange of information between them and will be an enabling factor to improve innovation uptake (evaluation criteria EFF9). However, more flexibility is called for in eligibility criteria so that the end user requirement can be met in multiple ways, e.g., by restricting the share of EU-14 countries in the consortia.

³⁸³https://home-affairs.ec.europa.eu/whats-new/events/projects-policy-seminar-2023-06-14_en

Effectiveness

Based on the analysis of Work Programmes 2021-2022 and 2023-2024 of Cluster 3, the call topics of Cluster 3 create multiple links to key EU security policies (evaluation criteria EFC13). Destination of Border Management addresses objectives identified by the Security Union Strategy and the border management and security dimensions of the New Pact on Migration and Asylum. Destination of Resilient Infrastructure creates links to the Security Union Strategy by aiming at supporting the protection of European infrastructures to face the challenges of growing interconnectivity and emerging and complex threats. Destination of Increased Cybersecurity contributes to the implementation of the digital and privacy policy of the Union, the EU Cybersecurity Act, and the EU Cybersecurity Strategy.

EU added value

Based on the analysis of interview data, beneficiaries stress the importance of European-funded research compared to nationally funded initiatives. At the national level, implementing similar projects is considered demanding, because the research problems require the involvement of numerous stakeholders at the EU level to gain a comprehensive understanding on transnational security challenges. Undertaking similar projects under national funding schemes would result in tailormade solutions to individual Member States, not considering various aspects of different organisations in other countries. While local technology development happens in Member States, EU-funded actions are important as the specific research topics address the entire EU with regulative frameworks, policy documents and so forth. Considering the time, resources, and expertise available in each Member State, national projects would be rather limited in their cross-national impacts, findings and outcomes. EU funding also positively contributes to creating diverse consortia, and similar cooperation would not be possible in national settings.

If projects would not receive EU funding, other funding sources would generally be sought. However, national funding would not often serve as the most preferred alternative, as it is considered less efficient and even dysfunctional. Additionally, making a proposal to another funding instrument might impact the project's approach or concept so that only a part of the originally proposed solution could be included in a new proposal. Overall, the European dimension would be lost in a national project, and any partnerships, targets, and ways to reach them should be completely restructured. Additionally, EU-funded actions are valued as they open doors in terms of trust. An action receiving European funding is perceived as trustworthy and relevant.

Beneficiaries see it as more economically effective that the EU funds civil security research than wait for businesses to develop new technologies with their own resources. If considering public tenders relating to Cluster 3 topics, it would be impossible to create similar consortia for submitting joint offers to the open tenders. Bringing in all valuable academic partnerships, the private sector, and public authorities, while aligning them for the same objectives, illustrates the benefits of the European funding mechanisms.

Key lessons learned and other important observations

Achieving sustainable practitioner engagement in project activities during implementation remains as a challenge in civil security research as identified also in the evaluations addressing the preceding Horizon 2020 programme. Stakeholder

engagement, translating into cross-border cooperation as well, is vulnerable to person risks caused by staff changes or limited availability of human resources for project work. These challenges apply to all beneficiaries regardless of organisational type, but as Cluster 3 primarily conducts applied research with (obligatory) close involvement of practitioners, their role in actions is heavily underlined.

It is important for Cluster 3 actions to demonstrate synergies with different EU funding programmes already at the proposal stage. Beneficiary organisations also actively participate in projects funded through other programmes. However, it seems to be challenging for Cluster 3 beneficiaries to further specify the benefits of other EU funding instruments and concretize related exploitation plans in the first implementation year. The beneficiaries recognise the key instruments and how they relate to Cluster 3 actions, but performing detailed assessments on their actual potential is not yet topical. The project results, whose success is yet unknown, also heavily drive this process.

Cluster 3 actions actively cooperate with one another and across thematic areas, connecting with relevant EU agencies and EU bodies working on the project's topics as well. With regards to other Horizon Europe clusters or other funding programmes, collaboration is more limited. However, identifying and selecting most relevant international events, activities and collaboration forums to project goals and participating physically or virtually in them is demanding and time-consuming.

Other observations relating to programme-level comparisons between H2020 and Horizon Europe

According to the analysis of interview data, beneficiaries see no major differences between the H2020 and Horizon Europe programmes from an administrative perspective. In terms of proposal development, the processes and requirements seem more straightforward in Horizon Europe than in H2020. Proposals need to define more measurable impacts, and overall, the application process seems now more competitive. The importance of ethics is more underlined in the current programme in comparison to H2020. Additionally, there is a stronger emphasis on applying the results into the field and raising the Technology Readiness Levels (TRL) in ways that are more concrete, more tangible and more quantifiable from a business perspective.

Compared to H2020, the shorter application length implemented in Horizon Europe requires more concise descriptions. This can sometimes be challenging. As the consortia are described only at the high-level, reviewers might not well understand for example the expertise of the consortium. Templates used in H2020 proposals included more detailed information about partners and individuals participating in the research activities. This information is not submitted as extensively anymore. A change in certain financial conditions between the H2020 and Horizon Europe programmes has caused issues with some organisations previously operating on a different basis (e.g., personnel costs have now to be calculated in daily rates, not hourly rates like in H2020).

With regard to data sharing, beneficiaries report challenges associated with the definition of the classification levels for project deliverables. As the practices differ between calls and societal challenges/clusters of H2020 and HE programmes, there has been a misunderstanding in the proper definition of deliverables and research work. During implementation, actions have had to declassify deliverables (e.g., from EU Restricted to Sensitive), which is perceived as a significant challenge hindering or

limiting practical end user involvement in project activities. The full process of declassifying the deliverables may take almost a year.

DRS beneficiaries mention a lesson learned from an H2020 SC5 (Societal Challenges 5 -Climate action, Environment, Resource Efficiency and Raw Materials) action concluded in May 2022, noting that more support and guidance could be offered to actions in finding new funding opportunities for taking the project results to a higher TRL level (from TRL 5-6 to TRL 9 for example). Although, certain EU initiatives in this area exist, such as **EIC Accelerator** or **Horizon Results Booster**³⁸⁴, their eligibility requirements may be too strict or their recommendations not specific enough for many actions to benefit from them (e.g., an applicant must be an SME).

Appendix 1

FUNDED CL3 ACTIONS FROM THE FIRST CALL OF WORK PROGRAMME 2021-2022 (EXCLUDING CYBER SECURITY - CS).

FIGHTING CRIME AND TERRORISM		No. of actions: 15			
Торіс	Action	Type of action	Торіс	Action	Type of action
FCT-01-01 FCT-01-02 FCT-01-03 FCT-01-03 FCT-01-04 FCT-01-05 FCT-01-06 FCT-01-06	TENACITY POLIIICE VIGILANT FERMI LAGO TENSOR ISEDA IMPROVE	IA RIA IA IA IA IA IA	FCT01-07 FCT01-08 FCT01-09 FCT01-09 FCT01-10 FCT01-11 FCT01-12	SAFE-CITIES RITHMS PERIVALLON EMERITUS Ceasefire 2PS EITHOS	ia Ria Ia Ia Ria Ria
BORDER MANAGEMENT		No. of actions: 7			
Торіс	Action	Type of action	Торіс	Action	Type of action
BM-01-01 BM-01-01 BM-01-03 BM-01-03	EURMARS I-SEAMORE FLEXI-cross ODYSSEUS	IA IA IA IA	BM01-04 BM01-04 BM01-05	PARSEC iFLOWS MELCHIOR-Z	RIA RIA IA
RESILIENT INFRASTRUCTURE		No. of actions: 2			
Торіс	Action	Type of action	Торіс	Action	Type of action
INFRA-01- 01	ATLANTIS	IA	INFRA01-02	SUNRISE	IA
DISASTER-RESILIENT SOCIETY		No. of actions: 9			
Торіс	Action	Type of action	Торіс	Action	Type of action
DRS-01-01 DRS-01-01 DRS-01-02 DRS-01-02	C2IMPRESS PANTHEON The HuT DIRECTED	RIA RIA IA IA	DRS-01-03 DRS-01-04 DRS-01-05 DRS-01-05	MEDiate PEERS ONELAB MOBILISE	RIA CSA IA IA

³⁸⁴ https://eic.ec.europa.eu/eic-funding-opportunities/eic-accelerator_en

DRS-01-03	PARATUS	RIA			
		No. of actions: 4			
RESEARCH					
Торіс	Action	Type of action	Торіс	Action	Type of action
SSRI-01-01 SSRI-01-02	MultiRATE EU-CIP	RIA CSA	SSRI-01-03 SSRI-01-05	SEREN5 TRANSCEND	CSA RIA

Source: Compiled by the study team.

Case Study No 12: AI in cybersecurity: Building European competencies and synergies on AI and machine learning

Executive Summary

This case study addresses the evaluation questions on meeting stakeholder needs and reinforcing EU autonomy in the security domain by analysing how the cybersecurity research funded under Cluster 3 of Horizon Europe has contributed to building European competencies and synergies on Artificial Intelligence (AI) and machine learning. The analysis builds on desk research, analysis of CORDA data, and thematic interviews with 18 beneficiaries of six actions contributing to the application of AI and machine learning in cybersecurity.

According to **the participation analysis**, the shares of participating organisations (research organizations, public bodies, firms, etc.) have remained the same in terms of numbers and the EC contribution in the cybersecurity research funded under Cluster 3 in comparison to the cybersecurity research funded under Societal Challenge 7 (SC7) of H2020. When analysing the country breakdown of participating organisations, the latest CORDA data (2022) shows that the geographical distribution of participating organisations on the aggregate level is similar to the cybersecurity research funded under SC7 of H2020.

Regarding **the application of AI in cybersecurity**, beneficiaries emphasize that the increasing importance of AI technology in cybersecurity is driven by the need to increase the efficiency of cyber defence through automation. AI and machine learning technologies can substantially improve and enhance human labour. However, the full realisation of the potential of AI technologies in the field of cybersecurity is hampered by multiple barriers. Barriers include the scarcity of suitable and publicly available datasets for cybersecurity solutions and training, as well as issues concerning regulation and societal trust vis-à-vis emerging technologies.

All beneficiaries interviewed agreed that the potential of **EU added value** for cybersecurity actions is substantial. EU funding was seen as a critical component for ambitious actions that aim for global impact. The actions in our sample would not exist in their current transnational form without EU funding. Moreover, in terms of project management, it was noted that collaborating with other EU actions is an important factor in ensuring that the action won't produce isolated initiatives or duplicated results. However, the fragmented nature of different EU programmes was seen as a barrier to collaboration between different actions. Similarly, the rigid nature of project management requirements for EU funding was seen to consume too much time and resources while lacking agility.

Based on the analysis of interview data, the critical success factors of project management are the following conditions:

- Interoperable collaboration within the action and with other projects
- Clear division of labour within the action
- Availability of public cybersecurity datasets

Likewise, **the critical success factors of stakeholder engagement** cover the following conditions:

- The ability to involve committed partners from the whole cybersecurity value chain
- Ensuring acceptance by aligning end user needs and project objectives
- Acquiring early adopters for use cases
- Skilled communication, interaction, and dissemination activities vis-à-vis stakeholders

Regarding **barriers**, project management challenges include the lack of exploitation plans for research results, inflexible project management practices, and fragmentation of project activities. On the other hand, the challenges of stakeholder engagement stem from the stakeholders' lack of trust in Al-based solutions, immaturity of Al regulation, cybersecurity market fragmentation, and communication deficits.

Introduction

The focus of this case study is on the thematic area of **Increased Cybersecurity** (CS) of the Cluster 3 Work Programme 2021-2022 (Civil Security for Society) of Horizon Europe. This thematic area is formed by the cybersecurity research funded under the CS calls of the Work Programme in 2021-2022 (Destination on 'increased cybersecurity').³⁸⁵ Increased Cybersecurity aims to support the achievement of the EU's strategic objectives in cybersecurity, including strengthening EU cybersecurity capacities and sovereignty; enhancing the resilience of digital infrastructures and systems; and improving the security of software, hardware, and supply chain.³⁸⁶

The expected impacts of Increased Cybersecurity concern the creation of pathways towards technological sovereignty, secure online environments, robust digital infrastructures, and improved capabilities in digital technologies. The cybersecurity research and innovation activities should contribute to the implementation of cybersecurity and digital policies of the EU such as the NIS Directive³⁸⁷, the EU

³⁸⁵ Horizon Europe, Cluster 3 Work Programme 2023-2024 https://ec.europa.eu/info/funding-

tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-6-civil-security-for-society_horizon-2023-2024_en.pdf 386 Horizon Europe, Cluster 3 Work Programme 2021-2022 https://ec.europa.eu/info/funding-

tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-6-civil-security-for-society_horizon-2021-2022_en.pdf 387 Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (NIS Directive).

Cybersecurity Act³⁸⁸, The EU Cybersecurity Strategy³⁸⁹, and the GDPR³⁹⁰. Furthermore, the aim of Increased Cybersecurity is to build on the results of Horizon 2020 and align research activities with the objectives of the Cybersecurity Competence Centre and Network of National Coordination Centres.³⁹¹

This case study addresses the evaluation questions on meeting stakeholder needs and reinforcing EU autonomy in the security domain by analysing *how the cybersecurity research funded under Cluster 3 has contributed to building European competencies and synergies on Artificial Intelligence (AI) and machine learning.* The methods of this case study build on desk research, analysis of CORDA data, and thematic interviews with beneficiaries. The emphasis of the analysis is on interview data.

The evaluation criteria of the analysis include the dimensions of relevance, coherence, and EU added value. Especially the following evaluation questions are addressed:

- To what extent have security-related research and innovation activities funded under Horizon Europe met stakeholders' needs?
- To what extent did the research and innovation security-related activities funded under Horizon Europe build synergies and complement activities of other relevant programmes, such as Horizon 2020 ICT-LEIT, CEF and the Digital Europe Programme?
- To what extent did Horizon Europe actions contribute to building or reinforcing EU autonomy in key strategic areas?

Thematic interviews were conducted with 18 beneficiaries during the spring and summer of 2023. The interviewees included project coordinators, managers, and partners who work as scientists, developers, designers, university professors, and personnel of large companies and start-ups. They represented six actions that started in the second half of 2022 under the thematic area of Increased Cybersecurity:³⁹²

• AI4CYBER (Trustworthy Artificial Intelligence for Cybersecurity Reinforcement and System Resilience) aims to provide an Ecosystem

³⁸⁸ Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act).

³⁸⁹ Joint Communication to the European Parliament and the Council The EU's Cybersecurity Strategy for the Digital Decade JOIN/2020/18 final.

³⁹⁰ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

³⁹¹ Regulation (EU) 2021/887 of the European Parliament and of the Council of 20 May 2021 establishing the European Cybersecurity Industrial, Technology and Research Competence Centre and the Network of National Coordination Centres. 392 The CS calls covered: HORIZON-CL3-2021-CS-01-01: Dynamic business continuity and recovery methodologies based on models and prediction for multi-level Cybersecurity; HORIZON-CL3-2021-CS-01-02: Improved security in open-source and open-specification hardware for connected devices; HORIZON-CL3-2021-CS-01-03: AI for cybersecurity reinforcement; HORIZON-CL3-2021-CS-01-04: Scalable privacy-preserving technologies for cross-border federated computation in Europe involving personal data.

Framework for future cybersecurity services, combating AI-powered cyberattacks in energy, banking, and healthcare sectors.³⁹³

- **CROSSCON** (*Cross-platform Open Security Stack for Connected Devices*) tackles the challenge of the current fragmented IoT landscape and how to ensure security and interoperability in it³⁹⁴.
- **DYNABIC** (*Dynamic business continuity of critical infrastructures on top of adaptive multi-level cybersecurity*) is focused on enhancing critical service resilience through Al-based defensive solutions by developing a framework for real-time assessment and mitigation of business continuity risks³⁹⁵.
- HARPOCRATES (Federated Data Sharing and Analysis for Social Utility) is developing digitally blind evaluation systems using cryptographic schemes to eliminate proxies, preserving privacy while enabling comprehensive data analytics³⁹⁶.
- **KINAITICS** (*Cyber-kinetic attacks using Artificial Intelligence*) seeks to explore new attack opportunities with the introduction of AI-based control and perceptive systems, in addition to the new methodologies that incorporate human factors and subsequent uncertainties³⁹⁷.
- **TRUMPET** (*TRUstworthy Multi-site Privacy Enhancing Technologies*) will create a scalable platform that improves data privacy and allows researchers to run AI studies on European datasets, a platform which will be tested and improved through eHealth use cases³⁹⁸.

Next, the participation analysis of the thematic area of Increased Cybersecurity is presented for the years 2021 and 2022. This is followed by a discussion on AI in cybersecurity. The analysis of the interview data is presented in the following sections on outcomes and critical success factors & barriers. In the end, this study is wrapped up by reflecting on evaluation criteria and key lessons learned based on the analysis of interview data.

Participation analysis

The participation analysis of the thematic area of Increased Cybersecurity for the year 2021 (covering the actions funded under the CS calls of 2021) is presented in Figure 125. The shares of participating organisations in terms of numbers and the EC contribution are close to the figures of the cybersecurity research funded under Societal Challenge 7 (SC7) of H2020. The share of private sector (PRC) is considerably high both in terms of numbers (57%) and the EC contribution (56%), which is again similar to the cybersecurity research funded under the SC7 of H2020. The country breakdown of the participants shows that the participants coming from the EU-14 countries form the largest group with a share of 84.1%. This is a significantly

³⁹³ https://cordis.europa.eu/project/id/101070450
394 https://cordis.europa.eu/project/id/101070537
395 https://cordis.europa.eu/project/id/101070455
396 https://cordis.europa.eu/project/id/101069535
397 https://cordis.europa.eu/project/id/101070176
398 https://cordis.europa.eu/project/id/101070038

higher figure than in the cybersecurity research funded under the SC7 of H2020 $(72.7\%).^{399}$





Source: compiled by the study team using own calculations and CORDA data.

When focussing on the participation in the thematic area of Increased Cybersecurity in the year 2022 (covering the actions funded under the CS calls of 2022), it can be noted that the shares of participating organisations remain essentially on the same level in terms of numbers (Figure 126). There is, however, a change in the EC contribution of the private sector (PRC) that is reduced to 47% (56% in 2021). The country breakdown shows some changes, as well. The share of participants coming from the EU-14 countries is reduced to 76.8% (84.1% in 2021) while the shares of participants coming from the EU-13 countries, Associated Countries and Third Countries have slightly increased. In turn, these figures come close to the figures of the cybersecurity research funded under the SC7 of H2020.⁴⁰¹

³⁹⁹ For the participation analysis of the cybersecurity research funded under SC7 of H2020, see Evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe. Final Report Phase 1 – Annexes, p. 269. Available: https://op.europa.eu/en/publication-detail/-/publication/e3f2a4e0-012d-11ee-87ec-01aa75ed71a1/language-en/format-PDF/source-search.

⁴⁰⁰ Total number of participants analysed: 207. Note: REC = research organizations, PUB = public bodies, PRC = private sector, HES = higher education institutions, OTH = other participants. For the details of participation analysis, see Annex 1.

⁴⁰¹ Evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe. Final Report Phase 1 – Annexes, p. 269. Available: https://op.europa.eu/en/publication-detail/-/publication/e3f2a4e0-012d-11ee-87ec-01aa75ed71a1/language-en/format-PDF/source-search.



Figure 126. Participation in the thematic area of increased cybersecurity in 2022⁴⁰²

Source: compiled by the study team using own calculations and CORDA data.

Al in cybersecurity

Technologies and systems based on Artificial Intelligence (AI) are fundamentally important to cybersecurity. As the digital landscape continues to expand and cyber threats become increasingly sophisticated, the reliance on traditional security measures alone has proven to be inadequate. The emergence of AI technologies has provided powerful tools to enhance cybersecurity defences, enabling real-time detection and response to cyber threats. Machine learning algorithms can analyse vast amounts of data, identify patterns, and detect anomalies that may indicate malicious activities. AI-powered systems can automate cyber threat intelligence gathering, incident response, and vulnerability assessments, enabling faster and more effective cyber defence. Indeed, the need to automate various functions because of the vast scale and volume of heterogeneous data of the cyber realm is identified as a major driver of the application of AI in cybersecurity. Without automated algorithms, it is increasingly difficult to detect and deter various anomalies and zero-day attacks.⁴⁰³

Conversely, a key barrier to the application of AI in cybersecurity has been the lack of publicly available cybersecurity datasets and a lack of training data for machine learning algorithms. Particularly cybersecurity data is often considered too sensitive and confidential to be shared outside the organizations. Another barrier to the application of AI is the lack of benchmarks, which creates difficulties in the creation of

⁴⁰² Total number of participations analysed: 181. Note: REC = research organizations, PUB = public bodies, PRC = private sector, HES = higher education institutions, OTH = other participants. For the details of participation analysis, see Annex 1. 403 For more information on the application of AI in cybersecurity, see ENISA (2023). Artificial Intelligence and Cybersecurity Research. ENISA Research and Innovation Brief. Available: https://www.enisa.europa.eu/publications/artificial-intelligence-and-cybersecurity-research.

standardized tools. Moreover, AI and cybersecurity are separate and distinct fields which makes it difficult to find experts who have know-how in both areas.⁴⁰⁴

In terms of AI legislation, the EU is seeking to regulate a complex and challenging field. Regulatory efforts are complicated by the fact that technological development is advancing faster than legislation can keep up. Similarly, the need to provide training data for machine learning is challenged by the imperative to simultaneously ensure data privacy. Indeed, the key ethical issue in the field of digital technologies is the conflict between data needs and user rights. Regulation plays a key role in trying to find suitable trade-offs for a compromise between efficient data utilization and privacy guarantees. Moreover, it is important to note that the application of AI in cybersecurity is shaped by EU regulation even though the two are not always directly linked.⁴⁰⁵

At the global level, the United States is widely considered to be leading the state of the art both in AI and cybersecurity. The European field of AI application in cybersecurity is diverse and fragmented into many sub-segments. In terms of cybersecurity, there are many different research actors and vendors in Europe, with many smaller companies and start-ups playing a major role. In terms of major companies, some of the notable organizations on the European level include Leonardo⁴⁰⁶, Thales⁴⁰⁷, and ATOS⁴⁰⁸. The EU is also a major funder of AI and cybersecurity R&D, but the collaboration between different actions and initiatives remains limited despite efforts for more cooperation. In short, the field of AI in cybersecurity is characterized by multiple smaller initiatives while coordination is lacking.⁴⁰⁹

Outcomes/results

This section is based on the analysis of interview data of six actions in the thematic area of Increased Cybersecurity. In terms of the project outputs, it is difficult to assess the results and effects of the actions, let alone their effectiveness, because the actions are still in their early stages (they started in the second half of 2022). Nonetheless, the project activities can be analysed with respect to the objectives of the respective actions and the goals of the thematic area of Increased Cybersecurity. The main guiding question of our analysis is to examine how the cybersecurity research funded under Horizon Europe contributes towards building European competencies on AI and machine learning-based solutions.

The **AI4CYBER** action focuses specifically on the R&D of AI and machine learningbased cybersecurity solutions (KERs) to ensure the resilient management of critical infrastructure systems and services by building tools to support system developers and operators to effectively manage AI-powered cyberattacks. The objective is to

⁴⁰⁴ ENISA (2023). Artificial Intelligence and Cybersecurity Research. ENISA Research and Innovation Brief. Available: https://www.enisa.europa.eu/publications/artificial-intelligence-and-cybersecurity-research.

⁴⁰⁵ For more information on the EU regulatory processes on AI, including the incoming EU AI Act, see

https://www.europarl.europa.eu/news/en/headlines/society/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence.

⁴⁰⁶ https://cybersecurity.leonardo.com/en/home

⁴⁰⁷ https://www.thalesgroup.com/en/cyber-security

⁴⁰⁸ https://atos.net/en/solutions/cyber-security/cybersecurity-services

⁴⁰⁹ Cf. ENISA (2023). Artificial Intelligence and Cybersecurity Research. ENISA Research and Innovation Brief. Available: https://www.enisa.europa.eu/publications/artificial-intelligence-and-cybersecurity-research.

deliver AI-driven security testing services that better facilitate the work of the experts by improved identification of flaws and automated code fixing. As a part of this objective, AI4CYBER further analyses how to defend against the malicious use of AI technology for cyberattacks. The insights arising from this research, such as cyber threat intelligence, will help to define the competencies and capabilities that are needed for the improvement of cybersecurity preparedness in Europe. In practice, R&D is conducted in various use cases, which will provide competence building for the 13 beneficiaries of AI4CYBER action. In terms of stakeholders, the focus of the action is on the energy, banking, and health sectors, which form the context for the scenarios that are utilized to validate project output. The scenarios will focus on the issue of how to detect and mitigate AI-powered attacks as well as on how to increase the resilience and robustness of relevant systems against these intrusions. Importantly, the project activities involve the building of a community of experts around relevant cybersecurityrelated EU actions, which will also help the integration of the project outcomes into other cybersecurity solutions and tools. Finally, in terms of cybersecurity R&D, AI4CYBER is working towards the better public availability of cybersecurity datasets and the trustworthiness of applied AI techniques, for example through workshops⁴¹⁰.

The DYNABIC action focuses on reinforcing the resilience of critical services and infrastructure against cascading cyber-physical disruptions by adopting AI-based defensive solutions and methods for business continuity risk management. More specifically, DYNABIC aims to investigate the utilization of Digital Twins (DT) for cybersecurity purposes. DYNABIC aims to deliver socio-technical methods, models, and tools for resilience management. These include a framework that will help predict, guantitively assess, and mitigate real-time business continuity risks and their potential cascading effects. In terms of stakeholders, DYNABIC collaborates with transport, telecommunication, and healthcare professionals, which helps to validate the project framework. An important component in these activities is the utilization and leveraging of AI technology for cyber resilience. For example, the Digital Twin components, such as the RISK4BC and SOAR4B, leverage AI technology. Despite these efforts, DYNABIC is hampered by the same problem as the AI4CYBER action. The Digital Twins for cybersecurity require datasets from which the characteristics of the use-case can be extracted, but there is a general lack of publicly available cybersecurity datasets. The reason for this is the often sensitive and confidential nature of cybersecurity data which is usually not shared outside the organization. Another reason is that not all use-case owners record enough relevant or appropriate cybersecurity data to begin with. These problems tend to hamper R&D efforts. Nonetheless, despite these difficulties, DYNABIC seeks to build a community of experts around the action to develop AI-based cybersecurity solutions and to ensure that project outcomes are in line with the principles of trustworthy Al⁴¹¹. Importantly, DYNABIC has already contributed to the CER directive by providing insights on the relationship between cybersecurity and smart grids by presenting its use cases for relevant actors.

The **KINAITICS** action focuses on investigating the novel opportunities and potential impacts provided by various AI-powered tools in the interconnected cyber-physical world. KINAITICS will develop an innovative spectrum of tools and methodologies against various threats such as cyber and chemical attacks. Specifically, KINAITICS plans to create seven tools and a cyber-defence platform during the action. According to their estimations, these tools will "significantly improve systems robustness,

⁴¹⁰ PRECINT Conference

⁴¹¹ Task 1.4 and Task 6.3

resilience and response, and will help Europe save 3-4 billion € yearly by 2030"⁴¹². Moreover, KINAITICS emphasizes the importance of legal and ethical expertise by providing an analysis of the regulation of big data for the purpose of providing guidelines for EU policy actions. In short, the approach of KINAITICS covers a broad spectrum of tools and methodologies from behavioural monitoring and human factors to more traditional cybersecurity tools with a specific focus on promoting collaboration between AI and cybersecurity fields. To promote these efforts, the KINAITICS researchers participated in a panel discussion in June between different projects covering the topic of AI and cybersecurity.

The aim of the **CROSSCON** action is to develop platform solutions to protect machine learning models that power the Internet of Things (IoT). The IoT consists of a fragmented landscape of different devices and hardware platforms which creates difficulties for cyber defence. Therefore, CROSSCON investigates how machine learning models can be better secured on IoT devices' hardware platforms. In short, CROSSCON will design an "open and flexible, and highly portable vendor-independent IoT security stack that can run across different edge devices and multiple hardware platforms".⁴¹³ CROSSCON aims for technological readiness level (TRL) 4 and focuses on open-source hardware. As such, the action is not directly related to Albased cybersecurity competencies but, nonetheless, seeks to develop European competencies in the field of machine learning by generating insights on how to run trusted services using machine learning models stored on IoT devices. This provides complementary knowledge towards the building of European AI and machine learning competencies.

The **TRUMPET** action focuses on secure federated AI learning methods to improve data privacy. The specific objective of TRUMPET is to "research and develop novel privacy enhancement methods for federated learning, and to deliver a highly scalable federated AI service platform for researchers that will enable AI-powered studies of siloed, multi-site, cross-domain, cross border European datasets with privacy guaranteed that exceed the requirements of GDPR"414. Together with the EU-funded action FLUTE, TRUMPET is working on the broad issues of regulatory acceptance, organizational change, and technology development. These objectives also involve activities to better understand the advantages and risks of AI-based systems in cybersecurity. The TRUMPET platform will be piloted, demonstrated, and validated in two specific eHealth use cases in European cancer hospitals. Nonetheless, the focus of TRUMPET is on fundamental research and use cases that can be widely applied in multiple fields beyond the healthcare sector by demonstrating their scalability. These activities involve the development of a privacy metric tool that will be developed with EU data protection authorities for the purpose of measuring the level of privacy associated with an AI solution.

The goal of the **HARPOCRATES** is to build privacy-preserving machine learning models and cryptographic schemes for "digitally blind evaluation systems designed to eliminate proxies". This objective originates from the fact that the utilization of large volumes of user data for the purposes of statistical analysis and subsequent personalization has increased the risk of the loss of privacy. These processes are often inexact and biased and they utilize unfair proxies based on geography, gender, and

⁴¹² https://cordis.europa.eu/project/id/101070176

⁴¹³ https://cordis.europa.eu/project/id/101070537

⁴¹⁴ https://cordis.europa.eu/project/id/101070038

race. HARPOCRATES aims for more fair and unbiased utilization of data for ethically sound decision-making. In terms of stakeholders, HARPOCRATES works with local authorities and healthcare professionals in data-sharing scenarios.

Critical Success Factors and Perceived Barriers

In this section, we analyse the success factors and critical barriers as perceived by the interviewed beneficiaries. While each of the actions concerned had a variety of unique success factors and barriers, many of the issues were shared by beneficiaries. At the end of this section, the common success factors and critical barriers are divided into two Tables concerning **project management** and **stakeholder engagement**.

Success Factors

In terms of stakeholder engagement, the beneficiaries emphasized the importance of having committed partners from the whole cybersecurity value chain, from manufacturing to end users. Notably, the ability to demonstrate the practical utility of research was seen as a crucial success factor for acquiring a variety of early adopters from the entire cybersecurity value chain. Working with a diverse set of stakeholders from the start was perceived as a crucial step towards the identification of end user needs, which in turn helps to create realistic use cases that pave the way to results that are in demand by end users and accepted by societal stakeholders. In short, the objectives of the action should be in alignment with end user needs and market demand. Indeed, the creation of an interactive community of stakeholders and practitioners that can help to transition use cases to business cases was seen as another success factor. Crucially, in this type of community, the end users are not only involved in mere piloting and validation activities but also in business planning.

In terms of project management, the importance of establishing a clear division of labour within the action was emphasized by the beneficiaries. The coordinator should ensure that all the partners understand the objectives of the action as well as their roles and responsibilities in the process of achieving those goals. Ideally, the division of labour would include a clear agreement on intellectual property and exploitation of research results, whereby a champion company would lead the commercial exploitation of research, while universities and RTOs would focus on generating scientific impact through high-quality scientific publications. Moreover, in terms of project management, it was noted that collaborating with other EU actions is an important factor in ensuring that the action won't produce isolated initiatives or duplicated results. The action should be designed in a collaborative and coherent manner from the outset to ensure interoperability and compatibility of the research results with project partners as well as with other EU actions.

In terms of cybersecurity-specific success criteria, the pressing need for publicly available cybersecurity datasets was emphasised by the beneficiaries as a key enabler or even a pre-condition of high-quality and high-impact research. Finally, the ability to disseminate and communicate the research results to the stakeholders and broader society was seen as an important success factor. Having ambitious goals can help to produce high-quality research and visibility for the project activities.

Barriers

In terms of project management, the difficulty of commercializing research results was identified as the major barrier hindering the impact of cybersecurity research. Despite

high-quality capabilities and expertise in cybersecurity, the valorisation of scientific research into commercial products and services was seen as an enduring key challenge for EU actions and for European research in general. According to the beneficiaries, one reason for this situation is the structurally fragmented nature of the cybersecurity market in Europe.

Another barrier related to project management was seen as originating from the rigidness of EU requirements. Some of the beneficiaries argued that too much time and resources are being spent on activities related to the project management requirements established by the EU. Similarly, the project management process of Horizon Europe was not seen as flexible enough to provide the ability to respond to the fast pace of technology development. This lack of agility could lead to situations where some research results are already outdated before they are published. It was argued that in order for the actions to become stepping-stones for future endeavours, the research results should be shared as early as possible.

Thirdly, if the division of labour between the beneficiaries is not clear, the implementation of the project actions can become very difficult to perform as partners tend to start deviating from the agreed objectives. The risk is that project actions become fragmented, which creates a barrier to the interoperability and compatibility between partners and their activities. This is often further exacerbated by the fragmented nature of different EU programmes, which was seen as a barrier to collaboration between different projects.

In terms of stakeholder engagement, the barriers related to the societal impact of Albased cybersecurity solutions were seen to originate from the immaturity of Al regulation and the end users' lack of trust in Al technology in general. The barriers to the commercialisation of cybersecurity research were related to the substantial resources required for the successful promotion of research results. The successful commercialization of research results requires communication and exploitation skills such as market analysis, which do not belong to the core abilities of most researchers. Therefore, some beneficiaries felt that they did not have enough resources or the skills to successfully market their research results for commercial purposes. Finally, a potential barrier lies in the technical challenge of replicating cybersecurity scenarios in the real world.

management Common Success Factors Common Barriers

Table 118. Critical success factors and perceived barriers regarding project

Common Success Factors	Common Barriers
Interoperable collaboration within the action and with other projects	Challenges in the commercial exploitation of results
Clear division of labour within the action	Lack of flexibility in project management
Availability of public cybersecurity datasets	Fragmentation of project activities

Source: Compiled by the study team based on the analysis of interview data.

Table 119. Critical success factors and perceived barriers regarding stakeholder & societal engagement

Common Success Factors	Common Barriers
The ability to involve committed partners from the whole cybersecurity value chain	Lack of trust for AI-based solutions
Ensuring acceptance by aligning end user needs and project objectives	Immaturity of AI regulation
Acquiring early adopters for use cases	Cybersecurity market fragmentation
Skilled communication, interaction, and dissemination activities vis-à-vis stakeholders	Poor scientific communication, interaction, and dissemination activities vis-à-vis stakeholders

Source: Compiled by the study team based on the analysis of interview data.

Reflections on evaluation criteria

In this section, we reflect on the evaluation criteria based on the analysis of beneficiary interviews.

Relevance

The AI4CYBER and DYNABIC actions have identified relevant stakeholder needs by analysing different use cases. Stakeholders of these actions include healthcare, telecommunications, energy, transport, and banking professionals. In practice, end user needs were derived from document analysis and meetings with the stakeholders. In both actions, the end users and different cybersecurity experts participated in defining key performance indicators, extracting system requirements, and evaluating and validating solutions and components.

In the TRUMPET action, stakeholders mainly consist of clinical partners in hospitals and their medical research groups. Stakeholders include two clinical partners, three RTOs, one university and three SMEs. End user needs and project requirements were identified by involving the partners in the design of the use cases and relevant methods through co-creation meetings. The stakeholders provided data and helped the technical partners come up with relevant technologies. In HARPOCRATES the mapping and identification of the needs of the stakeholders was conducted through an interaction between universities and end user partners to understand their practical needs and create responses to this demand. Stakeholders include local law enforcement authorities and health professionals. By emphasizing functionality and practical applicability, end user needs in HARPOCRATES are located between the research-oriented needs of the universities and the market-oriented SMEs.

In CROSSCON, the focus is on hardware-related stakeholders, such as application vendors who are a part of the Internet of Things (IoT) value chain. The substantial size and diversity of the IoT supply chain present a challenge. This requires use case providers to interact with all the relevant parties within the supply chain and help to organise the elicitation of requirements and the validation criteria of the IoT security stack. In KINAITICS the stakeholders and end users are partners in the different work packages.

Coherence

The DYNABIC action builds on the cyber resilience research done by EU-actions PRAETORIAN and PRECINT in addition to having plans to collaborate with EU-action SUNRISE. The Al4Cyber action has held a presentation in the ELECTRON project workshop and plans to collaborate with the EU-actions ENCRYPT and ATLANTIS. The Al4Cyber and DYNABIC participate in the CyberEPESand the ECSCIclusters. Both actions have also been participated in at a conference organised by the PRECINT action in addition to a STAM workshop within the ARES conference.

The CROSSCON action has thus far established collaborations with six actions, three/four of which are from the same call⁴¹⁵. CROSSCON has organised joint workshops with CERTIFY in Berlin and with ENCRYPT in Italy. These collaborations aim to integrate and further develop components such as software from previous EU actions. The KINAITICS action has cooperative connections to EU-actions STARLIGHT and ENCRYPT, which focus on working with AI and cyber issues in the context of LEAs. KINAITICS has also established cooperative collaboration with an EDF-funded project called AINCEPTION.

The TRUMPET action is still in its early stages, but there are plans to collaborate with other actions from the same call to develop synergies, particularly for the dissemination phase. TRUMPET also has links to earlier cybersecurity calls since it was designed to build on the EU-action SPARTA. By design, TRUMPET is also meant to provide a basis for another future EU action. The HARPOCRATES action is similarly still in its early days. Nonetheless, they have plans to work with the EU-action MOSAICROWN on protecting private, sensitive, and confidential information.

The added value of the EU

All beneficiaries agreed that the potential of EU added value for cybersecurity actions is substantial. EU funding was seen as a critical component for ambitious actions that aim for global impact. To put it concisely, the actions in our sample would not exist in their current transnational form without EU funding.

First, EU funding is particularly helpful in the sense that it brings together a diverse set of nationalities and partners into international and transnational interactions that would not otherwise happen. In the process, EU funding enables the amalgamation of a multitude of perspectives as well as the creation of cross-sectoral collaborations. A European-wide consortium can create a more complete technological solution by combining different competitive advantages and perspectives that can facilitate totally new ideas, solutions, and innovations.

Second, EU funding allows the beneficiaries to innovate, explore, and scale various cybersecurity solutions. This funding is particularly important for concepts and ideas in an early developmental phase with a low technology readiness level (TRL). Moreover, EU funding is often the logical "next step" after national funding because it can help pick up and further develop innovations that national institutions have initially funded.

⁴¹⁵ The name of projects of which CROSSCON collaborates are listed in the project official website.

Third, EU funding is also crucial for addressing European deficiencies in hardware, such as semiconductors, on the continental level. These issues relate to the broader question of open strategic autonomy, which is best addressed on the EU level. In practical terms, developing AI-based cybersecurity intelligence, tools, and solutions on the EU level can help to ensure a more resilient critical infrastructure in Europe.

Key lessons learned and other important observations

During the interviews, beneficiaries emphasized that the increasing importance of AI technology in cybersecurity is driven by the recognized need to increase the efficiency of cyber defence through automation. AI and machine learning technologies can substantially improve and enhance human labour with AI. Despite these widely recognised trends, the full realization of AI technologies' potential in cybersecurity is hampered by multiple barriers. These include the scarcity of suitable and publicly available datasets for cybersecurity solutions, training, and issues with regulation and societal trust vis-à-vis emerging technologies.

Regarding R&D activities in the cybersecurity domain, Europe's enduring difficulty is obtaining high-quality cybersecurity and machine learning datasets for research and training purposes. This was seen both as a challenge and a concern by beneficiaries. Another key lesson on research activities relates to the challenges of creating a generic cybersecurity solution since each end user context is unique. Therefore, all cybersecurity tools must be tailored to a specific context, and their components must be customised accordingly, which takes substantial effort.

In terms of lessons learned regarding project management, beneficiaries emphasised the need for forward-looking planning in combination with a clear division of labour and organization of work between partners. The coordinator together with the main partners responsible for the scientific state of the art, should establish an approach for each partner to follow. This approach would outline the achievement of key objectives, relevant methods, as well as roles and responsibilities for each partner.

Beneficiaries also emphasized that the project planning and the creation of the consortium from the idea phase onwards should be based on a meritocracy of expertise instead of just established networks and partners. Moreover, the preparation phase should include a thorough analysis of EU policies, market demand and relevant end user needs. One beneficiary argued that consortia are too often built on existing partnerships and previous collaborations instead of being guided by the requirements of end users and selecting partners based on expertise and capability.

The increasing size and diversity of project consortia further highlight the role of communication channels and underlying communication skills and tools. Beneficiaries also pointed out the importance of having some in-person meetings in order for the partners to acquaint themselves with each other on a more personal level. This helps to enable more substantive and productive remote work and meetings. In short, the consortium should possess diverse expertise among its partners and stakeholders and good communication tools to facilitate their interaction.

Table 120. Key lessons learned

Main Lessons Learned

Successful actions require planning based on meritocratic know-how, end user needs, and a clear division of labour between the partners.

The increasing size and diversity of consortia create the need for high-quality communication skills for fruitful interactions between partners.

The development of cybersecurity solutions requires increasing efforts to customise solutions to a specific end user context.

Source: Compiled by the study team based on the analysis of interview data.

Appendix 1: Participation analysis

Participation analysis is based on the CORDA data and our own calculations. The main characteristics of Destination on 'increased cybersecurity' (CS) under the Horizon Europe Work Programme 2021-2022 Civil Security for Society⁴¹⁶ analysed in the study:

Increased Cybersecurity 2021:

- 16 actions
- 207 participating organisations
- Total net EC contribution: 69 285 540,76 €
- Call topics:
 - HORIZON-CL3-2021-CS-01-01 (RIA): Dynamic business continuity and recovery methodologies based on models and prediction for multi-level Cybersecurity
 - HORIZON-CL3-2021-CS-01-02 (RIA): Improved security in opensource and open-specification hardware for connected devices
 - HORIZON-CL3-2021-CS-01-03 (RIA): AI for cybersecurity reinforcement
 - HORIZON-CL3-2021-CS-01-04 (RIA): Scalable privacy-preserving technologies for cross-border federated computation in Europe involving personal data

Increased Cybersecurity 2022:

- 14 actions
- 181 participating organisations
- Total net EC contribution: 70 767 671,02 €
- Call topics:

⁴¹⁶ Horizon Europe Work Programme 2021-2022: 6. Civil Security for Society. Available: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-6-civil-security-for-society_horizon-2021-2022_en.pdf.

- HORIZON-CL3-2022-CS-01-01 (IA): Improved monitoring of threats, intrusion detection and response in complex and heterogeneous digital systems and infrastructures;
- HORIZON-CL3-2022-CS-01-02 (RIA): Trustworthy methodologies, tools and data security "by design" for dynamic testing of potentially vulnerable, insecure hardware and software components;
- HORIZON-CL3-2022-CS-01-03 (IA): Transition towards Quantum-Resistant Cryptography;
- HORIZON-CL3-2022-CS-01-04 (IA): Development and validation of processes and tools used for agile certification of ICT products, ICT services and ICT processes.

Figure 127. Participation in the thematic area of increased cybersecurity in 2021-2022 in total⁴¹⁷



Source: Compiled by the study team using own calculations and CORDA data.

Case Study No 13: The new Transforming Health and Care Systems partnership – Learnings from previous partnerships and early experience

Executive Summary

The new Transforming Health and Care Systems (THCS) partnership was established in 2023. The partnership was shaped by the input from initiatives such as TO-REACH

⁴¹⁷ Total number of participants analysed: 388. Note: REC = research organizations, PUB = public bodies, PRC = private sector, HES = higher education institutions, OTH = other participants. For the details of participation analysis, see Annex 1.

and the Active and Assisted Living (AAL) programme. In particular, TO-REACH played a significant role in informing THCS as it was initiated to help prepare the THCS proposal. In general, stakeholders express satisfaction with the set-up and focus of THCS. The Strategic Research and Innovation Agenda (SRIA) is seen as comprehensive, covering both theoretical and practical aspects of system transformation, and stakeholders believe it has the potential to make a significant impact on health and care systems. Some see the financial arrangements underpinning THCS as a potential constraint.

The membership of THCS is viewed as comprehensive and promising, with involvement from partners outside the European Union seen as advantageous. The combination of different types of organisations brings together diverse communities and enhances cooperation. Challenges include aligning different foci and managing the varying experiences of member organizations.

Overall, stakeholders are optimistic about the potential of THCS to bring a new perspective to transforming health and care systems. They see it as an opportunity to address previously unexplored research fields, build a strong community for health system transformation, shape healthcare agendas, and inform policy. Transparency within the partnership is rated positive, but there may be challenges in including new members.

In conclusion, THCS has the potential to make a significant impact on health and care systems across Europe, but its success will depend on effective implementation, addressing financing challenges, and maintaining transparency and inclusivity within the partnership.

Introduction

Background

The Transforming Health and Care Systems (THCS) partnership is a co-funded European partnership that was established in 2023 under the framework of the Horizon Europe programme (based on a programme co-fund action)⁴¹⁸ and will run until 2030. The European Commission's (EC) co-financing rate of the partnership is 30% for all eligible costs that the participating organisations produce.⁴¹⁹ Members of the partnerships are ministries, research funding and research-performing organisations from the EU and Horizon Europe-Associated Countries. In addition, members from outside of the EU can participate at their own costs, i.e., without receiving co-funding.⁴²⁰

The partnership addresses urgent needs as health and care systems across Europe are facing similar challenges and need to transform to meet the needs of the future.

⁴¹⁸ See the CORDIS entry of THCS for more information regarding the placement of the partnership in the Horizon Europe framework: https://cordis.europa.eu/project/id/101095654. The difference between co-funded European partnerships and co-programmed or institutionalised partnerships is explained in Article 10 of the Horizon Europe Regulation (EU/2021/695).

⁴¹⁹ The remaining 70% must be borne by the organisations themselves.

⁴²⁰ See https://www.thcspartnership.eu/thcs/thcs-at-a-glance.kl

The COVID-19 pandemic has further increased the challenges faced by health and care systems and strongly highlighted the existing shortcomings.⁴²¹

Health and care systems in the EU vary significantly across its 27 member states (e.g. concerning public and/or private models, historical backgrounds, political factors, etc.) Despite the challenges of harmonization, the diversity of EU health and care systems allows for sharing best practices and learning from other countries' experiences. Sharing knowledge between countries and their health systems is vital. It enables the identification of common challenges and the learning from successful strategies, and it fosters collaboration and innovation. It promotes a global perspective, helping countries work together to improve healthcare access, quality, and affordability. Ultimately, knowledge sharing enhances the collective capacity to address health challenges and improve population well-being.

Bearing the different starting positions in mind, THCS seeks to bring stakeholders together, foster collaboration, coordinate research and innovation efforts, and facilitate the digital transformation of healthcare services. The partnership aims to create sustainable, efficient, inclusive, and high-quality health and care systems that are accessible to all.⁴²² It focuses on generating new knowledge and evidence and, co-designing innovative solutions and supporting their transfer and scaling across countries and regions. Capacity building is also a key aspect of THCS's objectives.

Looking at the different documents, it should be noted that THCS is contributing to several EU priorities, outlined in the 'Communication on effective, accessible and resilient health systems' (COM(2014) 215 final), the 'Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society' (COM(2018) 233 final) and shares some objectives with the EU4Health Programme (COM(2020) 405 final). Furthermore, THCS acknowledges in its Strategic Research and Innovation Agenda (SRIA) different reports of the EU on health and care that further illustrate that THCS's objectives and priorities are in line with the needs and challenges recorded at the EU level. Those are in particular the 'Health at a Glance: Europe' reports⁴²³, the 'Companion Report of the State of Health in the EU'⁴²⁴ and the report on 'Assessing the Resilience of Health Systems in Europe: an overview of the theory, current practice and strategies for improvement'.⁴²⁵

In addition, the partnership's SRIA outlines which synergies are sought with other European initiatives, such as the EU4Health programme or the Digital Europe Programme.⁴²⁶ THCS aims to avoid duplications by actively searching for synergies and ensuring coherence between the partnership and other Horizon Europe initiatives.

⁴²¹ THCS (2023) Call for transnational proposals 2023 - 'Healthcare of the Future'. Available:

https://www.thcspartnership.eu/kdocs/2076654/call_text_version_1.1_5th_of_april_2023.pdf.

⁴²² See https://cordis.europa.eu/project/id/101095654

⁴²³ See https://ec.europa.eu/health/state/glance_en

⁴²⁴ See https://ec.europa.eu/health/state/companion_report_en.

⁴²⁵ See https://health.ec.europa.eu/system/files/2021-10/2020_resilience_en_0.pdf.

⁴²⁶ The full list of programmes/initiatives can be viewed in the SRIA.

THCS: Objectives and working method

THCS aims to improve people's health by transforming health and care systems towards more high-quality, accessible, sustainable, efficient, resilient, and inclusive services. The partnership seeks to catalyse this transformation through an open and supportive partnership, working together to stimulate research, innovation, and policy implementation. It is unique in this field as it is the first large-scale partnership addressing the transformation of Europe's health and care system. THCS aims to provide evidence for policymakers and become an effective knowledge broker. The partnership has five specific objectives, namely:

- Increase funding opportunities and strengthen the research and innovation community;
- Fill knowledge gaps;
- Increase the ability to implement innovation;
- Intensify cooperation among countries and regions and beyond health and care sectors;
- Increase stakeholder involvement and capacity building.

Collaboration among researchers, innovators, enterprises, administrations, and society will be crucial in achieving these objectives through a co-creation approach. THCS brings together 64 consortium partners from 26 countries in total (Figure 128). EU-Member States, as well as Horizon Europe-Associated Countries, are included in the partnership. Partners are countries from across Europe, and organisations from Iceland, Israel and Norway are part of Horizon Europe associated non-EU partners. Additionally, organisations from non-associated Third Countries can join, as partners from the UK, US and Switzerland have done. The coordination of THCS lies within the Ministry of Health of Italy.



Figure 128. Number of THCS member organisations per country

Source: Prognos (2023), own illustration, based on TCHS' information: <u>https://www.thcspartnership.</u> eu/thcs/partners/partners.kl.

The expected outcomes of the partnership include enhanced collaborative research among European researchers, leading to the development of evidence-based strategies and policies for transforming healthcare systems. Health and care providers and professionals are expected to implement innovative care delivery methods, while authorities and stakeholders will make efficient investments in health and care systems. The partnership aims to foster stronger local and regional stakeholder ecosystems, facilitating the uptake of successful innovations. Another aim is to improve citizens' and professionals' digital and health literacy. Additionally, countries will cooperate more effectively, utilising context-specific knowledge and evidence to enhance the resilience of their health and care systems in anticipation of future needs and crises.⁴²⁷

The partnership resources are based on the multi-annual co-funding model under Horizon Europe. The EU co-funding rate, as mentioned above, is 30% and applies to different activities. In order to realise the co-funding approach, participants must make financial commitments. The internal allocation of the co-funding by the EC depends on the activities pursued.⁴²⁸ However, 75% of the partnership's funding will be available

⁴²⁷ THCS's intervention logic is illustrated in the annex.

⁴²⁸ For example, the EU contribution for the coordinator is the highest (with around EUR 16 million) among partners.

for funding research and innovation (i.e., through calls for proposals). The following activities are implemented and co-financed:⁴²⁹

- Research and innovation funding (through calls for proposals): The calls will address different stages and categories of R&I concerning the transformation of health and care systems.
- Support Actions: The actions can take different forms, for example, addressing cross-project cooperation, increasing networking or raising awareness. Research activities can be additionally carried out by THCS's research-performing organisations.
- Governance of the partnership: The governance structure should manage and coordinate THCS on a strategic and operational level.
- Efforts for national coordination: This includes the mobilisation of relevant national stakeholders/actors and activities to ensure the translation of knowledge.

Bearing in mind the different objectives, envisaged outcomes and activities, the partnership follows a pillar structure that is organised in different work packages (WPs). The pillars are meant to illustrate the approach taken by THCS to transform health and care systems (bringing evidence into policy, funding research and innovation, and supporting transferability). The member organisations are represented in the different WPs based on their area of expertise. A differentiation is made between the research funding agencies and research performing organisations: The latter is not involved in any preparation regarding the joint transnational calls to ensure their possible participation in calls.

The governance of the partnership is divided into a strategic and an operational level.⁴³⁰ At the strategic level, the General Assembly is the ultimate decision-making body in which all partners are represented. Each country is granted one voting right, although it might be represented by more than one partner. Third parties have no voting rights.⁴³¹ The EC has an observer status, also without voting rights. In addition to the Assembly, the Governing Board is the mandated decision-making body. It is responsible, amongst other things, for the implementation of the SRIA and the annual work plan and for taking strategic directions. The Board will liaise with the National Mirror Groups (national stakeholders reflecting the health and care systems' specificities) and the Advisory Boards (consisting of experts and stakeholders of health and care systems, supply (companies, insurers, investors) and demand side (citizens, (in)formal health and care), academia and governments). Additionally, the Coordinating Body will manage the partnership overall. On an operational level, the Operational Team will be responsible for the daily work and perform the actual work. It consists of the work package leaders, and therefore, it executes and manages the implementation of the WPs.

⁴²⁹ Drafting Group THCS (2020) Draft proposal for a European Partnership under Horizon Europe Transforming health and care systems. 9 June 2020. Available: https://research-and-innovation.ec.europa.eu/system/files/2020-06/ec_rtd_hepartnerships-health-system-transform.pdf.

⁴³⁰ See the partnership's draft proposal for more information.

⁴³¹ Third parties are organisations that are affiliated or legally linked to a participant but did not sign the grant agreement.

Figure 129. Programme structure THCS



Source: THCS (2023) THCS at a glance. Available: https://www.thcspartnership.eu/thcs/thcs-at-a-glance.kl.

Methodological approach

The case study focuses on two sets of questions:

- To what extent does the THCS partnership build on the experience of previous programmes (e.g., AAL, JPI MYBL, EIP AHA, TO-REACH)⁴³², and how have key learnings from these programmes been used to inform the new partnership?
- What is the perspective of partners from member states on the new partnership? To what extent are they satisfied with the development of the partnership to date? To what extent does the partnership involve countries across the EU (especially from Eastern Europe)? How does the partnership tally/overlap/create synergies with existing national programmes?

Given the short existence of the THCS partnership, the case study will focus on selected evaluation questions only. Effectiveness and efficiency are criteria that cannot be answered as the first call for proposals of the partnership has only been published recently, and consequently, no projects have started yet. However, it is possible to examine the criteria of 'relevance', 'coherence' and 'EU added value'. The following questions will be addressed:

• **Relevance**: To what extent have the objectives of the partnerships been and are still relevant regarding the challenges and needs addressed in this area by the Framework Programme?

⁴³² Active and Assisted Living Programme (AAL), Joint Programming Initiative More Years Better Lives (JPI MYBL), European Innovation Partnership on Active and Healthy Aging (EIP AHA), Transfer of Organisational innovations for Resilient, Effective, Eequitable, Accessible, sustainable and Comprehensive Health Services and Systems (TO-REACH).

- **Coherence**: How is the level of coherence among partnerships and between partnerships and the Framework Programme activities in this area?
- **EU Added Value**: What is the value resulting from partnerships in this area that is additional to the value that could result from interventions carried out at the regional or national level?

To address the evaluation criteria, the case study mainly draws on insights gained from an interview programme with THCS stakeholders. In total, 13 stakeholders were interviewed (in 11 interviews): 1 interviewee representing the EC, 2 the coordination team, 4 were leads of work packages, and 6 were additional member organisations, held between February and May 2023 (see Table in sources). Given the short period of existence of THCS, no project data could be analysed. In addition, the essential programme documents were reviewed (first and foremost, the Strategic Research and Innovation Agenda). However, the number of documents available is still limited, given the recent start of the partnership.

Inclusion of previous experiences

This section addresses the first question of how far previous experiences were built upon and learnings were included. For this purpose, it will discuss each initiative separately and analyse its influence. Many of the interviewed stakeholders were already involved in at least one preceding initiative. For them, this previous involvement was among the main reasons for joining the new partnership. Several of the preceding initiatives already collaborated with each other. As outlined in the draft proposal for THCS, the experience of collaboration led stakeholders to aim for a combination of approaches in THCS, namely 'evidence-based research for policymakers, targeted in particular by TO-REACH and JPI MYBL is coupled with the innovation drive of the AAL programme in health and care service delivery through public and private enterprises/entities and EIP on AHA's focus on integrating learning into regional ecosystems.'433 Due to this interweaving in different initiatives, it was pointed out that it is difficult to identify which development can be attributed to an initiative. Often, long-term developments are a 'learning journey'. Moreover, the interviews revealed that the set-up of THCS was much informed by preceding initiatives (see below for more information), but due to the different structures and foci of the other initiatives, not all learnings could and were envisaged to be included in the new partnership.

There was agreement among interviewees that it is important that the partnership combines the experiences from different initiatives because this is crucial for success: it brings different perspectives and areas of expertise together and broadens the geographical representation. This will also be beneficial for the calls for proposals (having a variety of partners and contributions).

As outlined in the SRIA, 4 initiatives, in particular, have influenced the development of the new partnership by providing a foundation of consolidated knowledge and experience.⁴³⁴ The TO-REACH Coordination and Support Action (CSA) has informed the strategic research agenda and conceptual framework for service and policy

⁴³³ Drafting Group THCS (2020) Draft proposal for a European Partnership under Horizon Europe Transforming health and care systems. 9 June 2020. Available: https://research-and-innovation.ec.europa.eu/system/files/2020-06/ec_rtd_he-partnerships-health-system-transform.pdf.

⁴³⁴ In addition, several other initiaves/programmes influenced the development of THCS, as outlined in the SRIA.

innovations in health systems. The AAL programme gained expertise in end user involvement, co-creation, and ecosystem development. The EIP on AHA brought together stakeholders across health policy areas to address societal challenges related to ageing and innovation. The JPI MYBL enhanced coordination and collaboration in demographic change research. These initiatives have shown reciprocities in addressing the entire research and innovation value chain and involving various sectors of health and care systems. The new partnership builds upon their achievements and insights while offering a distinct and unique approach to health and care system change. In the following sections, the analysis of information from interview partners will focus on TO-REACH and AAL.

TO-REACH

TO-REACH was the main initiative informing the THCS partnership.⁴³⁵ TO-REACH was a CSA funded by Horizon 2020 with a consortium of governmental and funding organisations, along with research institutes. It aimed to improve health services and systems by encouraging mutual learning from different care models, laying the basis for a future joint research programme (namely the current THCS partnership), and establishing collaboration among funding organisations to address health system challenges and priorities.⁴³⁶

Considering the launch of the new partnership, it can be stated that THCS is addressing a research gap. This gap was identified by the work of TO-REACH, which also identified the need to have a European programme.⁴³⁷ The expectations of countries towards a partnership on health and care systems research are all well-reflected in THCS's structure and aims – contributing to the partnership's relevance.

Moreover, in 2013, an article published in the Lancet underlined that too little research on health systems was conducted in Europe.⁴³⁸ In particular, it was argued that the focus of the European Union in the framework programme was on biomedical research and innovation. Therefore, the article's authors pushed for the inclusion of health systems research into the Horizon 2020 programme. The idea was to build a strong strategic research agenda to strengthen health system development, which was achieved. However, during TO-REACH the partners realised that it was not possible to further build a joint research programme based on this agenda. The Strategic Research Agenda of TO-REACH informed the Strategic Research and Innovation Agenda of THCS. For some of the activities, the link with TO-REACH is strongly recognisable. For example, work package 4 includes the development of a methodological and assessment framework, which echoes the types of activities carried out in TO-REACH (e.g., mapping information about research needs and future directions of research).

⁴³⁵ TO-REACH (2021) TO-REACH Final Conference 'Implementing and transferring innovations across health systems'. Conference Report.

⁴³⁶ See https://cordis.europa.eu/project/id/733274.

⁴³⁷ See amongst others: TO-REACH (2020) Report on the consensus from Member States on the future Joint Research Programme at EU level in the field of health systems and health services research. Available:

https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5e0640474&appId=PPGMS.

⁴³⁸ Walshe, Kieran, Martin McKee, Mark McCarthy, Peter Groenewegen, Johan Hansen, Josep Figueras, Walter Ricciardi (2013) Health systems and policy research in Europe: Horizon 2020. Comment in The Lancet (382:9893), pp. 668-669. DOI: https://doi.org/10.1016/S0140-6736(12)62195-3.

There is also some **continuity** of participants. Many members of THCS were already involved in TO-REACH. The coordination of the partnership has also been done by the same organisation. This continuation ensures that previous learnings from TO-REACH are further exploited.

AAL

The AAL programme was a partnership between the EC and selected member states running from 2008 to 2021. It aimed to foster innovative products, services and systems to support people to age well and enable them to continue living at home. Although the AAL programme ended in 2021, several projects of AAL are still ongoing. There are some experiences from AAL that were mentioned by interviewees as being beneficial for THCS, especially the inclusion of end users and the ecosystem approach to fostering innovation. This ecosystem approach is represented in a dedicated pillar of THCS's structure. The thematic direction of THCS also includes content produced during AAL, e.g., when it comes to digital technologies and innovation (although interviewees noted that the inclusion of this aspect needed some active advocacy). In addition, another lesson included was to involve a wide set of partners with different types of backgrounds, including from academia and industry. However, in interviews, AAL stakeholders were more critical towards the new set-up of THCS than stakeholders who were involved in other initiatives or were not involved in a previous initiative. Some stakeholders felt that there was a preconceived agreement on the design of THCS based on the TO-REACH CSA and that experiences from initiatives other than TO-REACH were not taken into account fully.

One major difference between AAL and THCS is the management and basic structure of the partnership. AAL was an Article 185 partnership, whereas THCS is an EC cofunded partnership, with a co-financing rate of 30% only. This leads to a **different set-up** when it comes to project application, evaluation or grant agreements. Consequently, accountability and reporting requirements are also different and are perceived by interviewees as higher than AAL. Many interviewees mentioned the comparison that THCS is run more like a project, which is emphasised in its work package structure and the division of tasks among different partners. It was noted that this adds complexity to the structure of the partnership. The interviewees involved in both THCS and AAL often referred to the independent secretariat of AAL as a main benefit of the AAL programme compared to THCS. Another difference is that AAL was focused on developing (technology-oriented) innovations, whereas the new THCS partnership aims to develop innovative healthcare practices, settings and workflows and help policymakers implement them. In this respect, THCS takes the experience and groundwork of AAL to the next step.

Early experiences of establishing THCS

As the partnership was officially established only at the beginning of this year (2023), outcomes cannot be assessed yet. The assessment will, therefore, focus on the perspectives of the partners in the first months of establishing THCS. Although the stakeholders were generally satisfied with how the partnership was set up, some critical voices were also present, although always noting that it is too early to make an assessment ('work in progress').

Operational set-up and thematic focus

The stakeholders interviewed for this case study were generally satisfied with the setup and focus of THCS. Depending on the background and type of organisation stakeholders were associated with; some aspects were mentioned that would have been desirable but were not included in the design of THCS. For example, some participating organisations wanted to include developing technologies in THCS's thematic focus, but this proposal was not supported by a majority of partners (given that technological aspects are already widely addressed by other call topics of different initiatives). However, in general, the SRIA is seen as comprehensive, covering all relevant aspects and was developed in an integrative and iterative process. The direction of the SRIA is generally rated as good: it covers both theoretical aspects (like methodologies and strategies) and practical aspects (like building capacities for healthcare providers or workers). It was highlighted in the interviews that the consortium is constantly working on finding an equilibrium between thematic breadth and depth, as not every aspect can be a priority (those discussions happen in WP 4).

The interviews also investigated whether, according to the stakeholders' views, the SRIA is well suited to bring about results for the transformation of health and care systems in Europe. It was stated that the SRIA is dedicated to the implementation of research results and has the potential to have a substantial impact, although some judged that it might be too ambitious. Furthermore, the planned research does not focus on one specific aspect of health and care systems transformation, as this is not desirable (because it could exclude other research aspects that are also relevant). The structure of the SRIA should make sure that enough space is given to the different approaches to health and care systems' transformation. Although implementation is certainly addressed in the SRIA, stakeholders highlighted that the partnership can only provide inputs such as guidelines or tools to aid system transformation, but the member states are responsible for their implementation. Stakeholders also noted that the SRIA aims to anticipate future needs, which constitutes an **added value**. This should ensure that the research that is being done stays relevant to future challenges.

Although the content and direction of the SRIA are generally positively rated, the necessity for a meaningful execution was repeatedly stressed by interviewees. The impact of the SRIA will depend on its implementation and, eventually, on the projects that will be selected. Interviewees agreed that the SRIA will contribute to intensifying the European exchange and research on this subject. However, some stakeholders were concerned about how the impact of the SRIA could be measured. In addition, the timeline of the partnership (2023-2030) is ambitious, and it will be difficult to produce results within this relatively short timeframe, as highlighted by some interviewees. Reforming health and care systems, bearing in mind the wide differences between systems across Europe, is unlikely to be achieved in seven years. Still, stakeholders noted that THCS could make a meaningful impact as research development and skills are lacking in many countries, and the partnership could contribute to building capacity in those countries. Additionally, the possibility to transfer knowledge within THCS and across borders was repeatedly highlighted. THCS has the capacity to establish links and increase exchanges between health and care systems.

The difference in the countries' approaches to health and care systems' transformation is another aspect that needs to be considered. In addition to the different approaches, the extent to which health systems research exists also differs between countries. Public health research is not so advanced in Europe, and the public health community is seen as fragmented by consulted stakeholders. They noted that research on health and care systems is not only about developing new tools but also about organisations, stakeholders, or different contexts that need to be taken into account. Research for health and care systems depends on the political context and cannot be applied easily to different settings (in contrast to biomedical research, which is more universal). Given those differences, work during the set-up of THCS was needed to harmonise different understandings and to find a common 'language'. The need to **adapt to different settings and create a common terminology** is a distinguishing factor of THCS compared to other initiatives under Horizon Europe in the field of health.⁴³⁹

However, stakeholders noted that it is not yet clear what THCS will focus on. Some interviewees remarked that THCS will only be able to contribute to the transformation of systems, and for that, it needs to identify the aspects that the partnership can address. For example, some topics may be more difficult to address at a European, cross-border level than other areas.

Concerning the structure of THCS, many stakeholders noted that an independent secretariat would be desirable from their point of view. However, as noted above, the attitude towards the secretariat can often be attributed to the background of the organisation surveyed, which brings about different expectations. The structure that was chosen was meant to ensure a focus on having countries working together instead of creating a central office that would do that.

Financing

Some stakeholders mentioned the financing situation as a potential constraint for the partnership. The fact that THCS is a co-funded partnership, and the budget is already set (total costs approx. EUR 305 million, EU contribution EUR 91.5 million)⁴⁴⁰ can lead to some uncertainties regarding the costs that arise for the member organisations. The budget is granted for the partnership as such, and the partners have to internally allocate the funding to the different activities. The partners then have to report eligible costs to the EC for which they will receive co-financing. Some interviewees saw this as a potential budgetary challenge as, for example, the actual amount of co-financing for the first call was not clear to some funding agencies. As the partnership is still at the beginning, it remains to be seen how well this works.

Some interview partners also reflected on the co-financing rate and voiced their concern that it might not be high enough (30%) for such a complex partnership. This might be especially relevant for research organisations. In other types of initiatives, the co-funding rate is higher (like in Art. 185).

First call

The first call was launched in April 2023. In general, the partnership foresees to launch one call per year.⁴⁴¹ The first call focusses on 'healthcare of the future' and was deliberately left quite broad. This is seen by some stakeholders as a potential problem because the proposals under this call are expected to be diverse in terms of content, scope and quality. Some stakeholders even expressed their concern that, although

⁴³⁹ For example, when it comes to medical research the vocabulary across European countries is more unform than descriptions of medical standards / procedures that differ in individual countries.

⁴⁴⁰ See CORDIS entry on THCS: https://cordis.europa.eu/project/id/101095654

⁴⁴¹ See FAQ on the first call: https://www.thcspartnership.eu/kdocs/2083788/faq_list_new_may2023.pdf.

projects might be of good quality, they will not be able to make a difference for health and care systems as no specific focus area was chosen in the call.

Box 1. Joint Transnational Call 'Healthcare of the Future'⁴⁴²

The first call of THCS was published in April 2023 and ran until 13 June 2023. The budget of the first call is around EUR 38 million. The **aim of the call** is twofold:

- a) to provide knowledge for building the future of health and care systems by addressing multiple dimensions and
- b) to support the implementation of existing successful practices on a larger scale.

The focus is on optimising the complementarity of inpatient and outpatient care, promoting prevention, personalised care, integration, continuity, and remote care. The call aims to address challenges and opportunities that arise with a shift towards distributed, community-based facilities while empowering primary care and enhancing interprofessional collaboration and workforce competencies.

Expected outcomes of the call include improved citizen/patient engagement and access to distributed, community-based facilities, enhanced primary care with integrated intervention tools, engaged health providers with customised solutions, and access to evidence-based strategies for transformative, people-centred health and care services.

Source: Compiled by the study team.

Membership and type of organisations

Stakeholders judge the membership of the partnership to be comprehensive and promising in terms of achieving the set goals. The fact that also partners from outside of the EU are involved was highlighted by some stakeholders. The combination of different types of organisations is considered advantageous as this allows to bring together different communities. THCS focuses on research funding (illustrated by the larger part of the budget dedicated to research funding (through the calls) and the smaller part for research conducted by the partnership). Despite this focus, some research organisations are involved, which are of regional and thematic importance. Through the projects 'research from other teams will be utilised, but with THCS' structure, it is also possible to conduct structured and systematic research on their own (in the different WPs). In order to support the translation of research into implementation, it is seen as beneficial that policy institutions are also part of THCS. The involvement of policymaking institutions is essential for increasing the relevance of THCS' work, highlighted some stakeholders. The approach was always (already in the drafting of the partnership's proposal)⁴⁴³ to give space to the cooperation among different countries and their funding institutions in this field of research. With the existing composition, it is likely that meaningful cooperation and sharing of knowledge can be achieved.

However, some potential challenges were identified by stakeholders. The combination of different types of partners, although highlighted in most interviews as beneficial, can prove challenging. The involvement of different types of organisations leads to the

⁴⁴² See call text: https://www.thcspartnership.eu/kdocs/2076654/call_text_version_1.1_5th_of_april_2023.pdf.

⁴⁴³ See https://research-and-innovation.ec.europa.eu/system/files/2020-06/ec_rtd_he-partnerships-health-system-transform.pdf.
inclusion of sometimes different foci that are hard to align. The partners might have different capacities available for such partnerships. All those aspects lead to the situation that it takes time to shape such a partnership. In addition, the **limited experience** of some organisations may lead to difficulties in managing work, as working within such a partnership is new for some participants. However, it was highlighted at the same time that enough experienced organisations are part of THCS, so this issue is not prevailing.

During the interview programme, it became apparent that many stakeholders missed the stronger inclusion of end users in THCS (i.e. **healthcare providers and citizens/civil society)**. However, it was also acknowledged that involving end users could be difficult to organise. In some countries, this aspect is addressed by including healthcare providers in their national mirror groups to ensure that they are aware of ongoing work and that their needs/expectations can be addressed. The existence of national mirror groups further enhances the outreach capabilities of THCS.

Concerning the **geographical representation**, the number of members per country and the distribution of countries involved is diverse. Although many countries are involved, some areas in Europe remain underrepresented, e.g. countries in Eastern Europe. Several interviewees indicated that there are some countries not involved. Germany, for example, is not involved, although it is one of the largest countries in Europe. For some participating countries, this is regrettable as Germany is a main partner in funding activities. It would be good if more countries were involved, but THCS is already seen as complex and new. However, THCS reaches out to countries outside of the EU, which is an advantage for gaining new interesting inputs. In general, stakeholders were satisfied with the geographical coverage of THCS. The short existence of THCS leaves space for further defining and creating additional relations and links with other countries.

Network

During the interviews, stakeholders widely agreed that THCS is bringing a new perspective into transforming health and care systems that would not be possible to achieve at the national level only. The programme also builds on existing networks that address different aspects of health and care systems, but many interviewees stated that the focus on the transformation aspect is novel for this size of the consortium. The different perspectives and experiences coming from the partners due to their different backgrounds and geographical origins were seen as highly valuable. For smaller countries, the sharing of knowledge and learning from other contexts was seen as particularly relevant. To illustrate this aspect, in smaller countries, the research community tends to be smaller than in larger countries. Therefore, the opportunity to strengthen the network and cooperate with other European researchers is seen as adding value to these communities. The cooperation between researchers across countries is not only beneficial for smaller countries but can strengthen the health and care systems research community in general. This aspect was highlighted by stakeholders as a positive aspect: THCS is not only providing funding but also access to networks and stakeholders. Those networks show the potential of THCS to reach a wide range of stakeholders and help them achieve their objectives. It was hoped that THCS would not only form a new R&I network but also connect networks that already exist. Concerning the stakeholders that are (potentially) reached by a network, interviewees stated that it is also needed to represent healthcare professionals, citizens and businesses. The first call can serve as an indication of how diverse the research community/stakeholders are.

Transparency

During the interview programme, stakeholders were asked how they assess the transparency of the partnership. Transparency concerns the openness of the partnership towards new members (external transparency) but also its internal transparency, i.e., how visible and accessible the work processes are among members.

Stakeholders judged the programme to be open towards new members. It was highlighted by interviewees that the leadership of the partnership has always been outgoing, transparent and open to inform about THCS. During the preparatory phase, it was easy to join the partnership, and the many organisations that have joined the programme as members support this assessment. With the official launch of THCS, the simplicity of joining THCS has changed. No new partners joined since its inauguration, but the partnership has only just started. Interviewees highlighted one central aspect as a reason why it could be difficult to include new members, which is the budgetary implications of the partnership. THCS' annual work plan is accompanied by a defined budget. Although THCS would be ready to accept members, several interviewees noted that the fixed amount of EU co-funding could mean that new partners would not get EU funding from the partnership or that the budget would need to be re-negotiated among partners, i.e., additional partners could dilute the available co-funding. The budgetary uncertainty might limit the possibility of including new members. In addition, interviewees noted that an impeding factor might be the inexperience of some organisations in working with comparable initiatives. The awareness of such European endeavours often remains in a certain community. This means that organisations that would have had the potential to contribute to THCS were perhaps not included just because they were not aware of the new partnership. The fact that a lot of the involved organisations have already been involved before in one of the preceding initiatives supports this impression.

In contrast to the openness, where some potential obstacles were highlighted, **internal transparency is rated across stakeholders as positive**. Stakeholders noted the regular meetings and/or brainstorming sessions, which are seen as open and inviting. However, given the large number of member organisations, not everyone can have a say during formal meetings. Still, everyone is given the opportunity to actively shape the annual work plan since all consortium members are asked for contributions/feedback, and the final adoption is made in the General Assembly of the programme.

However, it should be noted that there is a division between research funding agencies and research organisations when it comes to the availability of information. THCS has been careful to separate the funding from the research part: To allow research organisations to participate in the calls, they are excluded from discussions and preparations concerning the calls. This is necessary to ensure that research organisations can participate in the calls while avoiding conflict of interest.

Expectations and possible impact

In general, interviewees were positive about the **potential impact** of THCS. It was noted that the partnership has the potential to contribute towards its intended objectives. It aims to address a research field that is unequally developed in different countries and to bring together and build a stronger community of health systems researchers and innovators. Dissemination of project results is important to

demonstrate the significance of funding research in this area, as evidence is crucial for policy improvements. The partnership's ambitious goal is to meet the rising demand for healthcare solutions across Europe while acknowledging that implementing such changes and delivering transformations mostly lies with other stakeholders. Stakeholders acknowledged that clear boundaries are necessary as the partnership has no power over national/regional policymaking. Although THCS is still at an early stage of its development, the engagement of policymakers and stakeholders in WP 5 presents promising opportunities.

Concerning the partnership's coordination, interviewees appreciated the professionalism and shared values of the THCS team. However, stakeholders also expressed a desire to receive a better overview of ongoing activities. While coordination among work packages was generally judged as good, a lack of oversight of activities could potentially hamper the planning of resources.

THCS aims to provide evidence for policymakers and become an effective knowledge broker. Several stakeholders expressed the hope that THCS will become an active policy agenda-setter. Although challenges exist, such as coordination and engagement, positive experiences have been reported. For instance, stakeholders were particularly appreciative of the work of programme coordinators.

Reflections on evaluation criteria⁴⁴⁴

Relevance

The partnership is relevant as it addresses the main challenges facing health and care systems. THCS contributes to several EU priorities and acknowledges in its SRIA different reports of the EU on health and care that further illustrate that THCS's objectives and priorities align with the needs and challenges recorded at the EU level. In addition, THCS is addressing a research gap already identified by TO-REACH's work.

Coherence

The coherence of THCS with other partnerships in this area can be assessed as high. The design of THCS builds on the experiences of other partnerships/initiatives. This principle is enshrined in the SRIA ('a number of initiatives have been developed that are now ready to be consolidated under a single synergistic approach in order to build upon them and increase their impact')⁴⁴⁵ and was generally confirmed by the interview programme. The continuity ensures that knowledge can be easily transferred from one initiative to another. In addition, the partnership's SRIA outlines that synergies are sought with other European initiatives. By actively searching for synergies, THCS aims to avoid duplications, ensuring coherence between the partnership and other initiatives of Horizon Europe or other relevant EU programmes.

EU added value

Additionality in terms of facilitating R&I networks bringing together relevant and competent actors across Europe was commonly agreed upon by interviewees as being

⁴⁴⁴ As mentioned above, effectiveness and efficiency will not be addressed.

⁴⁴⁵ THCS, Strategic Research and Innovation Agenda, 2022.

one key feature of THCS. With the transnational calls, it is expected to further create such regional or cross-border networks, which are a major factor in implementing research results. Additionally, it was repeatedly pointed out that THCS is already an R&I network in itself (and may act as an 'umbrella' network). The potential is given to additionally connect with existing networks. Especially for smaller countries or countries with a small research community in the health and care systems field, the access to networks of other researchers through engaging with THCS is rated as very beneficial.

As stated in the SRIA, the THCS partnership is of high value because it brings together diverse research and innovation outcomes and stakeholders.⁴⁴⁶ Interviewees highlighted that THCS adds value as a European initiative as it enables new insights, fosters innovative thinking, broadens horizons, and enables mutual learning that would not be possible in a national programme. Its setup, focused work packages, and dedicated support actions contribute to its strength. The partnership facilitates knowledge and expertise sharing among diverse institutions, enabling learning from different organisations. By collaborating at the EU level, THCS addresses similar health and care system challenges, saving time and resources through shared knowledge. Countries involved in THCS can actively shape the work and be cocreators of strategies / new ideas that are being developed.

Key lessons learned and other important observations

TO-REACH played a significant role in informing the THCS partnership, with strong links between the two initiatives. TO-REACH's Strategic Research Agenda influenced THCS's SRIA, particularly in relation to WP 4. Many individuals involved in THCS were also part of TO-REACH, providing continuity and existing connections with the EC. AAL differs from THCS in terms of management, structure, and financing, but still, some learnings were included specifically on the relevance of end user involvement and the approach to strengthening the ecosystem. Stakeholders involved in AAL express more critical views towards THCS's setup compared to stakeholders from other initiatives.

Stakeholders express **satisfaction with the set-up and focus** of THCS while acknowledging that some aspects that they had wished for have not been included. The **SRIA is seen as comprehensive and relevant**, covering both theoretical and practical aspects of health system transformation. Stakeholders believe the SRIA has the potential to make an impact and is able to anticipate future health and care systems' needs. However, its future impact will depend on implementation and project selection. The ambitious timeline of the partnership and differences between systems in European countries pose challenges, but THCS can contribute to capacity building and knowledge transfer. Harmonising different understandings and creating a common vocabulary was crucial during THCS's establishment. Stakeholders suggested that the partnership should identify specific foci and acknowledge the diverse nature of health and care systems. Some stakeholders express a desire for an independent secretariat, but opinions vary, reflecting different organisational backgrounds.

The **financing situation is seen as a potential constraint** for THCS, with uncertainties and budgetary challenges due to the co-funding model. Some concerns

⁴⁴⁶ THCS, Strategic Research and Innovation Agenda, 2022.

were raised about the co-financing rate and its adequacy for such a complex partnership. The first call, issued in April 2023, is considered broad, leading some stakeholders to reservations about the diversity and varying quality of proposals. Some stakeholders expressed concerns that without a specific focus, projects may not make a significant impact on health and care systems. However, not every stakeholder shares this view.

The **membership of THCS is seen as comprehensive and promising**, with involvement from partners outside the EU highlighted as advantageous. The combination of different types of organisations brings together diverse communities and enhances cooperation. Challenges include aligning different foci and the varying levels of experience of member organisations. The inclusion of end users and geographical representation were identified as areas for improvement, but THCS is already reaching out to countries outside the EU and can further develop relations.

THCS is seen as **bringing a new perspective and valuable networking opportunities** to transform health and care systems, especially for countries with small research communities. Transparency of the programme is generally rated positively, with openness towards new members, although budgetary constraints and limited awareness of European initiatives may hinder the inclusion of new partners. Internal transparency is seen positively, with regular meetings and opportunities for active engagement.

Stakeholders were optimistic about the future of **THCS and hopeful with regard to its impact**. They believe that the partnership has the potential to make a significant impact on European health and care systems. Interviewees expect the partnership to bring together strategic thinking, research, technology, and ecosystem development. They see THCS as an opportunity to address a previously little-examined research field and build a strong community for health and care system transformation. Dissemination of project results is seen as essential for showcasing the importance of funding research in this area. Overall, interviewees believe that THCS has the potential to shape healthcare agendas, inform policies, and improve health and care systems across Europe.

Sources

Interviews

Country/Region	Organisation
EU	DG RTD
EU	DG RTD
AT	The Austrian Research Promotion Agency (FFG)
NL	Flanders Innovation and Entrepreneurship, VLAIO
FI	Terveyden ja hyvinvoinnin laitos (THL)
FR	Ministry of Health (FR MOH)
NL	ZonMw
RO	National Institute of Public Health (UBB)
SK	University Hospital Martin (UHM)
SI	Ministry of Public Administration - Office for Digital Transformation (ODT) / National Institute of Public Health (NIJZ)
IT	Ministero della Salute / ISS

Source: Compiled by the study team.

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Appendix 1. Intervention logic THCS



Figure 130. Intervention logic THCS

Source: THCS (2022) Strategic Research and Innovation Agenda.

Case Study No 14: ERA4Health: additionality and international positioning of the co-funded partnership

Executive Summary

Launched in 2022, **ERA4Health** aims to increase European transnational collaborative research funding in priority areas **addressing European public health needs**. The partnership will run between 2022 – 2028, while its activities are divided into two phases based on the flexible Working Plan instrument. The **focus of this case study** is dedicated to capturing additional insights and findings regarding the partnership from the perspectives of **additionality**, namely bringing additional funds, creating new networks, and a higher total budget than expected; and **international positioning and visibility**, namely the goals to reach and include Third Countries as well as the opportunities and reach that the partnership entails provides.

As the ERA4Health co-funded partnership started only in late 2022, it **does not present immediate results or realised outputs** in terms of additionality, international **positioning and visibility**. However, ERA4Health has already **achieved significant progress in setting up different processes** leading towards increased outcomes and results. The initial perceived **key successes** of ERA4Health include the experienced ERA4Health partners who have been involved in other ERA-NETs and running multi-country IICS; personal networks that could create more synergies and extend the participation in ERA4Health in the future; as well as ERA4Health building on the predecessor ERA-NETs. The **initially perceived barriers** in terms of ERA4Health additionality and international positioning and visibility include the challenging timeline in setting up the multi-national IICS and especially attracting a

sufficient number of countries (expected to involve several countries that represent approximately two-thirds of the EU's population size), funders and funding; the involvement and status of some of the Third Countries in ERA4Health; and involving all ERA4Health partners in the communication efforts. Concerning the aspects of additionality, ERA4Health is mobilising public contributions by launching two Joint Transnational thematic calls (JTCs) in 2022 as well as two additional JTCs at the end of 2023. and also actively working on setting up the multinational Investigator-Initiated Clinical Studies (IICS) pilot call which will be launched at the end of 2024. The co-funded contributions by member states are mobilised through JTCs, while, in Phase 2, ERA4Health aims to attract additional funding from funders contributing to IICS. Further funding is aimed to be mobilised through external national funders (with the United Kingdom, Switzerland, and Canada already expressing their interest) and charities. Although ERA4Health currently does not mobilise private funding, some more private contributions are envisioned for Phase 2 of the partnership. In addition to mobilising additional funding, through its activities. ERA4Health facilitates the creation and expansion of research and innovation networks. The partnership contributes to the realisation of ERA mainly by widening its efforts, particularly by focusing on the involvement of underrepresented countries in ERA via JTCs as well as the planned IICS for Phase 2. In addition, new funders from underrepresented countries have already expressed their interest in joining ERA4Health in the future, e.g. a funding organisation from Estonia. Regarding the aspects of international positioning and visibility, ERA4Health is also successfully setting up processes towards increasing outcomes and results in these areas. ERA4Health presents a high level of international cooperation. The participants in the partnership include most of the EU member states (20 out of 27). three Associated Countries (Israel, Norway, and Türkiye) and two Third countries (Egypt and Taiwan). The partnership continues to expand its international network with the potential involvement of the United Kingdom and Canada as external funders and presents intentions to involve more European and Third countries in IICS which will further increase ERA4Health's international positioning and global relevance. The partnership incorporates already as a partner of the consortia the European Clinical Research Infrastructure Network (ECRIN), a relevant actor in the IICS field and it will also collaborate with other non-state stakeholders, such as the European Medicines Agency. In addition, ERA4Health is currently actively seeking synergies with other European and global stakeholders, starting with the launch of the 1st International Annual Workshop for the search of Synergies of the Partnership ERA4Health in June. Another workshops for stakeholders interested in IICS took place in September 2023 and February 2024. Increasing the visibility of ERA4Health is currently aimed to be achieved via the use of different media channels for project communication, and the preparation of the Dissemination. Exploitation, and Communication (DEC) Plan and Strategy in 2023. Further activities are also planned to increase ERA4Health's visibility in the future, such as streamlining the communication activities to different publics. such as policymakers, researchers. clinicians, patient organisations, the general public, and others.

Introduction

ERA4Health – established in 2022 - brings the opportunity to increase European transnational collaborative research funding by creating a funding body for joint programming in priority areas addressing European public health needs. ERA4Health

is a co-funded partnership ⁴⁴⁷bringing together 32 entities (mostly funding organisations) from 22 countries to foster high-impact translational research for addressing public health needs across Europe and beyond. The partnership is running **from 2022 to 2029** with a **preliminary budget of EUR 110 million**. Currently, the partnership is in Phase 1, and its preliminary budget includes EUR 33 million of the EU co-fund budget (30% co-funding rate). The activities of ERA4Health are based on the flexible Working Plan instrument that is organised around two phases:

- Phase 1 is expected to feature the continuation of the consolidated networks that are about to finish: ERA-NET co-funds under the framework of Joint Programming Initiatives a Healthy Diet for a Healthy Life (JPI HDHL), such as ERA-HDHL and HDHL-INTIMIC, European Research Area Network on Cardiovascular Diseases (ERA-CVD) and EuroNanoMed3. It will primarily focus on cross-national joint calls, but it is also expected to establish a framework to support multinational Investigator-Initiated Clinical Studies (IICS). While Phase 1 is expected to last two years, its duration is conditional on achieving crucial objectives such as supporting a network of IICS and preparing to launch the first pilot call on multinational IICS.
- **Phase 2** is foreseen to focus on launching additional multinational calls for IICS and joint calls for other priority areas. The transition to Phase 2 is expected to be launched by the decision of the Health Programme Committee and the EC taken at the end of Phase 1 on the focus of the partnership and the distribution of the budget between IICS and other areas.

Four calls are expected to be launched during the first two years. These will focus on nutrition, lifestyle-related diseases, cardiovascular diseases, **and nanomedicine**.

Having the inputs, such as national and regional cash funding, in-kind contributions, consolidated databases, experts and advisory boards' support and their multidisciplinary expertise, the ERA4Health partnership has three goals:

- Tackling diseases and reducing disease burden
- Staying healthy in a rapidly changing society,
- And SDG 3 'Good Health and Well-being for people.'

This case study is dedicated to capturing additional insights and findings regarding the partnership from two perspectives:

- Additionality bringing additional money and funds, creating new networks, and mobilising and reaching a higher total budget than expected from the initial calculations.
- International positioning and visibility in terms of the goals to reach and include Third Countries as well as the opportunities the partnership entails and the reach it provides.

⁴⁴⁷ Co-funded European Partnerships are based on a grant agreement between the Commission and a consortium of partners. The grant agreement is signed following a call for proposals for a programme co-fund action in the work programme of Horizon Europe.

A particular focus in this case study is placed on the added value of the novelty in ERA4Health, namely the expansion of its funding to **transnational Investigator-Initiated Clinical Studies (IICS).** This case study, therefore, also explores what this novelty means for researchers, the science, and the opportunities this may introduce.

This case study is based on the **desk research and analysis** of ERA4Health documents, and **12 interviews with 14 ERA4Health stakeholders**, such as Pillar leaders, Work Package leaders, national focal points, and the European Commission's policy officers. A more extensive description of the methodological approach for this case study is presented in the Appendix.

Outcomes and results

As the ERA4Health co-funded partnership started only in late 2022, it **does not present extensive results or realised outputs** in terms of additionality, **international positioning and visibility**. The latest developments include a Canadian (CIHR), an Estonian (ETAG) and a Swiss (SNSF) funding organisation that will participate in an ERA4Health call in 2024.

In terms of **additionality**, ERA4Health, as planned, has already launched two **Joint Transnational thematic calls (JTCs)** and is actively working on setting up the **Investigator-Initiated Clinical Studies (IICS)**, whose pilot call will be launched at the end of 2024. The partnership has already launched the following JTCs:

- **CARDINNOV** under the topic "Research targeting the development of innovative therapeutic strategies in cardiovascular disease".
- **HealthEquity** under the topic "Increasing health equity through promoting healthy diets and physical activity".
- **NutriBrain** under the topic "Modulation of brain ageing through nutrition and healthy lifestyle."
- **NANOTECMEC** under the topic "Nano and advanced technologies for disease prevention, diagnostic and therapy."

ERA4Health aims to launch **two JTCs per year in the first two years** and **at least one per year for the next five years**. For the first two JTCs, the funding allocation decisions are still being made: a peer review panel will take place in September 2023, while final funding decisions will be announced by October 2023.

The partnership also intends to mobilise additional resources and achieve results through the launch of calls on multinational Investigator-Initiated Clinical Studies (IICS). To prepare for this stage, ERA4Health is identifying bottlenecks, which hinder transnational clinical studies and proposing ways to overcome them by establishing a supporting framework and new funding procedures. This analysis of the bottlenecks is already well-advanced and was presented in a Workshop on 14 and 15 September.⁴⁴⁸ The launch of a pilot call on multinational IICS is foreseen in the end of

⁴⁴⁸ ERA4Health (2023). Workshop: Analysis of the bottlenecks and challenges in designing and conducting multicounty Investigator Initiated Clinical Studies. Available at: https://era4health.eu/event/workshop-analysis-of-the-bottlenecks-and-challenges-in-designingand-conducting-multicounty-investigator-initiated-clinical-studies/

2024 and other calls in this thematic will be further implemented in **Phase 2 of the partnership**, where the outcomes and results can be assessed more thoroughly.

In terms of international positioning and visibility, ERA4Health also presents progress in setting up the processes leading to increased international positioning, visibility, and global relevance. Regarding international positioning, such progress is particularly visible in setting up workshops and involving and communicating with potential new partners from Europe and beyond. ERA4Health has launched its 1st International Annual Workshop for the search of Synergies of the Partnership ERA4Health on the 9th of June 2023. More than 50 initiatives at the European and international level were presented by the members of a Synergies Working Group (SWG) of ERA4Health. Another workshop for stakeholders interested in IICS to be launched by ERA4Health will be organised in September 2023. In addition, although ERA4Health consists mainly of the EU member states, it also involves three Associated Countries (Israel, Norway, and Türkiye) and two Third countries (Egypt and Taiwan). The partnership continues to expand its international network with the potential involvement of the United Kingdom, Switzerland and Canada as external funders as well as intentions to involve more European and Third countries in IICS in Phase 2.

Regarding **ERA4Health**'s visibility, the partnership achieved progress in setting up and using different media channels for project communication and preparing an extensive Dissemination, Exploitation, and Communication (DEC) Plan and Strategy⁴⁴⁹. ERA4Health has already established its website⁴⁵⁰ and has set up different social media networks, such as LinkedIn⁴⁵¹ and Twitter⁴⁵², while further communication platforms are discussed to **streamline the communication to different publics**, such as researchers, policymakers, citizens, clinicians, patient organisations, and others, to increase ERA4Health's visibility. In addition, in 2023, ERA4Health completed its DEC Plan and Strategy, which outlines the key five goals of how ERA4Health's visibility will be further promoted and increased.

Critical success factors and perceived barriers

Some **perceived success factors and barriers** can be observed within the first year of ERA4Health's implementation in terms of additionality, international positioning, and visibility. As ERA4Health is still at the very beginning of its activities, such success factors and barriers were mainly perceived by the interviewed stakeholders, while their extent should be evaluated later when more of the ERA4Health activities are **implemented**.

In terms of **additionality, international positioning and visibility**, the interviewed stakeholders highlighted the **key success factors** of experienced ERA4Health partners who, before ERA4Health, have been involved in other ERA-NETs and running multi-country IICS, personal networks that could create more synergies and extend the participation in ERA4Health in the future; as well as ERA4Health building on the predecessor ERA-NETs. The interviewed stakeholders emphasised that the previous partners' involvement in other ERA-NETs and multi-country IICS as well as

⁴⁴⁹ ERA4Health Partnership (2023). D4.1 Dissemination, Exploitation and Communication (DEC) Plan and Strategy. WP4 450 ERA4Health Partnership (n.d.) https://era4health.eu/

⁴⁵¹ LinkedIn (n.d.). ERA4Health Partnership https://www.linkedin.com/company/era4health/

⁴⁵² Twitter (n.d.) ERA4Health_Partnership. https://twitter.com/ERA4Health_EU

the use of personal networks can help ERA4Health to create eand visibility. The interviewed stakeholders also observed some challenges regarding the additionality, international positioning, and visibility of ERA4Health. The main challenges, as observed by the interviewed stakeholders, include the tight timeline in setting up the multi-national IICS and especially attracting a sufficient number of countries, funders and funding; the involvement and status of some of the Third countries in ERA4Health; and involving all ERA4Health partners in the communication efforts. Regarding **IICS**, some interviewed stakeholders mentioned the **challenging** timeline to set up the processes for the first pilot IICS call in 2024. These processes include the identification of research funders while ensuring that a sufficient number of countries, funders, and funding will be dedicated to IICS to make them successful on a European scale. In addition, different funders will need to agree on the common best practices on how to fund and evaluate IICS which might be challenging given different national practices and regulations. Other challenges include the difficult legal aspects to involve some of the Third countries, such as the United Kingdom. however, such countries are expected to be involved as external funders and not directly as partnership members. Lastly, given the size of ERA4Health's partnership, it could be difficult to engage all stakeholders in ERA4Health's activities towards increasing its visibility. Some of the interviewed stakeholders highlighted that it may be difficult for them to be involved in all of ERA4Health's activities and events due to their own increased workload and participation in more than one EU partnership, initiative, or project. However, internal communication systems within ERA4Health are being set up to facilitate this communication between ERA4Health partners.

(PSC1): How much private and/or public R&I contributions have been mobilised on EU priorities thanks to ERA4Health?

The ERA4Health co-funded partnership and establishment is **based on the European Council's adopted conclusions on the new European Research Area** (ERA).⁴⁵³ Horizon Europe framework programme is the main funding source for supporting the implementation of the new ERA. Between 2021-2027, Horizon Europe presents a budget of approximately EUR 95.5 billion, where 3.3% is planned to be used for **widening participation and strengthening the ERA**, particularly with the support of the EU countries that are involved less in the research and innovation efforts. In addition, the new ERA will address the previously observed gap in European investments in biomedical and health research of Member States, where only 10% of the overall European budget for biomedical and health research and development is considered to contribute to collaborative research. Within the new ERA, some of the interviewed stakeholders emphasised that ERA4Health's goal is to **coordinate the investment in public health research** while involving the funds from the European Commission and the funding organizations from the EU Member States and Associated Countries.

The overall preliminary **budget for ERA4Health is approximately EUR 110 million**. The share of the European Commission's funding is 30% or approximately EUR 33 million.⁴⁵⁴ The first year and its budget will be mainly dedicated to establishing managerial duties, such as the working procedures and bodies, and to preparing,

⁴⁵³ European Council (2021). European Research Area. https://www.consilium.europa.eu/en/policies/european-research-area/ 454 ERA4Health Partnership (n.d.) General information. https://era4health.eu/general-information/

launching and evaluating the first two calls⁴⁵⁵ that **mobilise the public contributions** from ERA4Health partners.

ERA4Health primarily **mobilises public R&I contributions**. These contributions are mainly **mobilised through the launch of Joint Transnational thematic calls** (JTCs). ERA4Health aims to create an instrumental platform for the joint programming of national research programmes that will be implemented within seven years. The partnership aims to launch two JTCs per year in the first two years and at least one per year for the next five years. The partnership has already launched the following JTCs:

- **CARDINNOV** under the topic "Research targeting the development of innovative therapeutic strategies in cardiovascular disease".
- **HealthEquity** under the topic "Increasing health equity through promoting healthy diets and physical activity".
- **NutriBrain** under the topic "Modulation of brain ageing through nutrition and healthy lifestyle."
- **NANOTECMEC** under the topic "Nano and advanced technologies for disease prevention, diagnostic and therapy".

Overall, **HealthEquity** funded 10 projects, and 15 countries and 53 research groups were involved.⁴⁵⁶ Meanwhile, **CARDINNOV** funded 17 projects, including 13 countries and 72 research groups.⁴⁵⁷

The funding commitments of EU Member States and Associated Countries reach **approximately EUR 19 million for the CARDINNOV call** and **approximately EUR 16 million for the HealthEquity** call. The Figure below shows the contributions to both calls by country (alphabetically). The interviewed stakeholders representing national focal points within ERA4Health emphasised that countries decide on their participation in the calls and the commitment to the funding amount based on the **national needs**, **research priorities**, **strategies**, **and the funding available**.

⁴⁵⁵ European Commission (2022).Fostering a European Research Area for Health Research. 1st Annual Work Plan

⁴⁵⁶ ERA4Health Partnership (December 1, 2023). Results of the ERA4Health HEALTHEQUITY Call 2023. Available at: https://era4health.eu/results-of-the-era4health-healthequity-call-2023/

⁴⁵⁷ ERA4Health Partnership (December 1, 2023). Results of the ERA4Health CARDINNOV Call 2023. Available at: https://era4health.eu/results-of-the-era4health-cardinnov-call-2023/



Figure 131. EU Member States and Associated Countries' contributions to CARDINNOV and HealthEquity calls

Source: Compiled by the study team.

The initial financial commitment for the first five JTCs funding of ERA4Health is approximately EUR 87 million. Interviewed stakeholders highlighted that an increased financial commitment is expected and aimed to be achieved in the second phase of ERA4Health, especially through funding IICS calls. Interviewed stakeholders highlighted other potential instruments that could be implemented through JTCs, such as calls for networks, knowledge hubs, or mobility grants. Overall, ERA4Health remains flexible and open to public research and innovation funders

at both national and regional levels in the EU and from Associated Countries to Horizon Europe and Third Countries, as well as other funders sharing the ERA4Health objectives (e.g., philanthropic organisations and industry).⁴⁵⁸

As emphasised by the interviewed stakeholders, private contributions are expected only to a limited extent. ERA4Health mainly consists of public institutions' funding, including national and regional funders, as well as contributions by the EU, while private funding is currently not available and is envisioned only to a limited extent. The interviewed stakeholders highlighted that private funding might contribute to ERA4Health during Phase 2, mainly by the different charities that could provide further financial contributions. The challenges for private contributions particularly relate to the complexities in the ERA4Health second phase, the main goal of which is to develop IICS that are not funded by the private industry, such as pharmaceutical companies. However, some of the interviewed stakeholders representing national focal points expressed the possibility for private industry to participate in the projects funded through JTCs if they contribute their funding. However, it is not a common practice, while other national funders cannot fund private organisations based on the national regulations.

(PSC1.1): What is the partnerships' budget leverage factor in mobilising additional resources on top of contributions from partners?

On top of the contributions from other partners, **ERA4Health intends to mobilise additional resources through the launch of Investigator-Initiated Clinical Studies (IICS)**. While the joint translational calls are more directed towards preclinical research or diagnosis, IICS entails clinical research. ERA4Health will launch a pilot call for IICS at the end of 2024. **New funders are expected to be enrolled in the Partnership** to develop the capacity of ERA4Health to fund IICS.⁴⁵⁹ To prepare for this stage, ERA4Health will identify bottlenecks that hinder transnational clinical studies and propose ways to overcome them by establishing a supporting framework and new funding procedures. The **direct and direct leverage factors cannot be calculated yet as ERA4Health has not funded projects yet, and the projects' expenses are un**known.

ERA4Health dedicates **several work packages to the preparation for IICS and its calls**. Work Package 15 of ERA4Health aims to **coordinate the funding of IICSs** through the ERA4Health mechanisms with all the other funding sources able to fund multinational clinical studies. In addition, the work package dedicates efforts to identifying the initiatives and organisations that could provide support to the planning, design, and conduct of multinational IICS. Meanwhile, work package 16 identifies **alternative schemes that might facilitate a setup for multi-national IICS**. Lastly, work package 17 aims to identify how **ERA4Health can improve the quality of the projects** that will apply for IICS funding in future calls.

The interviewed stakeholders also emphasised some **challenges relevant to the IICS activities**, including the involvement of additional funds. They include the challenging timeline to prepare the pilot call for IICS to be launched in December 2024; some

⁴⁵⁸ ERA4Health Partnership (2022). Strategic Research and Innovation Agenda. ERA4Health. Fostering a European Research Area for Health. Available at: https://era4health.eu/wp-content/uploads/2022/11/ec_rtd_he-partnerships-era-for-health-1.pdf Page 6 459 ERA4Health Partnership (2022). Strategic Research and Innovation Agenda. ERA4Health. Fostering a European Research Area for Health. Available at: https://era4health.eu/wp-content/uploads/2022/11/ec_rtd_he-partnerships-era-for-health-1.pdf Page 6

difficulties in working with other stakeholders, such as EMA, due to the high administrative demands considering the tight timeline for the pilot call launch; and receiving a response from research funders considering their heavy workload. Some of the interviewed stakeholders mentioned a potential challenge of reaching a consensus among funders within several countries on how IICS should be selected, funded, and performed and how these procedures can be improved based on ERA4Health's current identification efforts.

Based on these challenges, one of the main needs for IICS activities is to reach an agreement across all the funding bodies that will support IICS, particularly considering that many funders will need to be involved. Some of the interviewed stakeholders emphasised that to conduct a multi-country IICS, it is not sufficient to involve only a few middle-sized countries in Europe and that they would need to involve at least one major country in Europe, such as Italy, Spain, France, Germany, or Poland. The main reason for a broader country and funder involvement is the efficiency of IICS because they need to cover a sufficient percentage of the European population to have access to the patients. For instance, Germany, Spain, Italy, Poland, and other countries represent 80% of the population size, and ERA4Health intends to reach at least two-thirds of the European population. As further emphasised by interviewed stakeholders, the funding amount for IICS is also important. ERA4Health intends for bigger EU countries to provide approximately EUR 1 million each of their funding capacity per year to the IICS, which might also be challenging compared to other funding commitments.

As highlighted by some interviewed stakeholders, **other additional budget leverage factors** include the potential compatibility with **Cohesion Policy Funds**. For the 2021-2027 period, the Cohesion Fund concerns Bulgaria, Czechia, Estonia, Greece, Croatia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Portugal, Romania, Slovakia and Slovenia.⁴⁶⁰ Therefore, these countries can dedicate their co-fund to the ERA4Health calls from the Cohesion Fund. As already mentioned above, **other potential financial commitments can come from external funders** that can participate in future ERA4Health calls without being part of the consortia, with the approval of the ERA4Health Management Board.

(PSC1.2): How does ERA4Health facilitate the creation and expansion of R&I networks that bring together relevant and competent actors from across Europe, thus contributing to the realisation of the ERA?

ERA4Health facilitates the creation and expansion of R&I networks and contributes to the realisation of ERA mainly by widening efforts towards ERA. The interviewed stakeholders confirmed that ERA4Health fosters the ERA by widening it, particularly by focusing on the involvement of underrepresented countries in ERA. Such a widening process occurs through joint transnational calls, allowing partners with lower participation in ERA to be involved. For instance, in JTCs, a minimum of three eligible and a maximum of five eligible partners from at least three different countries can participate in the call. However, the maximum number of eligible partners can be increased to six or seven if they include one or two partners from underrepresented countries, such as Latvia, Lithuania, Slovakia, or Türkiye.⁴⁶¹ This

⁴⁶⁰ European Commission (n.d.) Cohesion Fund. https://ec.europa.eu/regional_policy/funding/cohesion-fund_en 461 ERA4Health Partnership (2022). ERA4Health Call for transnational research proposals. Increasing health equity through promoting healthy diets and physical activity (HealthEquity). Page 7

also concerns **IICS**, as their implementation will involve several countries. Therefore, both the creation and funding of transnational research consortia through the JTCs and future IICS calls will contribute to the realisation of the ERA by strengthening cooperation in research and innovation across Europe.

International positioning and visibility

(PSC3): To what extent is ERA4Health acting as a global ambassador for the European R&I system/establishing global relevance/achieving scientific and technological reputation in the international context/ serve as hubs for international cooperation, where appropriate?

(PSC3.1): What is the level of international cooperation at the partnership and project level, and how does this result in visibility for the European partnership?

(PSC3): To what extent is ERA4Health acting as a global ambassador for the European R&I system/establishing global relevance/achieving scientific and technological reputation in the international context/ serve as hubs for international cooperation, where appropriate?

As ERA4Health started its activities only later in 2022, it is too early to evaluate to what extent the partnership is acting as a global ambassador for the European R&I system, establishing global relevance, achieving scientific and technological reputation in the international context, and serving as hubs for international cooperation. However, ERA4Health is setting up processes regarding its international positioning, including the potential global relevance in the future.

One of the ways ERA4Health is working towards its international positioning and global relevance concerns the active search and work with creating synergies with other EU partnerships, funded projects, funders, and global stakeholders, among others. For instance, the potential synergies are intended with the Global Alliance for Chronic Diseases (GACD), which brings together major international research funding agencies specifically to address the growing burden of non-communicable diseases (NCDs) in lower-to-middle income (LMICs) and high-income (HICs) countries. The GACD Research Network of investigators is active in more than 73 countries around the world.⁴⁶² Other interviewed stakeholders highlighted the involvement of the European Society of Cardiology in ERA4Health, which is a global learned society that combines many different national cardiovascular associations under one umbrella. It is also a partner in the Strategic Advisory Board of ERA4Health; therefore, certain governing or advisory bodies of ERA4Health are global organizations. Such global and international synergies and cooperations are expected to increase ERA4Health's international visibility as well as potential global relevance. The future implementation of IICS is another mechanism of how ERA4Health can be a global ambassador for the European R&I system, establish global relevance, achieve a scientific and technological reputation in the international context, and serve as a hub for international cooperation. Some of the interviewed stakeholders highlighted that if IICS conducted by ERA4Health in the European context are successful and generate trust, they can also be conducted on an international level. This would also be facilitated with ERA4Health partners' networks, for instance, with Canada or Japan, as the researchers there are already interested in IICS in Europe. Therefore, through

⁴⁶² ERA4Health Partnership. D8.1-D1.3.2 Synergies Working Group Establishment WP8. Page 16

the IICS mechanism, countries in Europe and beyond would have the same projects and protocols that would be evaluated according to the same criteria and evaluation procedures, while external countries would pay for the cost of the investigation in their settings. To this end, ERA4Health has a high potential to be a global ambassador for the European R&I system and establish global relevance for the European-led multi-country IICS. A workshop was organised in September 2023 for stakeholders interested in collaborating in IICS with ERA4Health.

(PSC3.1): What is the level of international cooperation at the partnership and project level, and how does this result in visibility for the European partnership?

The ERA4Health presents a high level of international cooperation in the partnership. Currently, ERA4Health involves 33 institutions from 17 out of the 27 EU Member States; three Associated Countries with Horizon Europe, namely Israel, Norway, and Türkiye; and two Third countries: Egypt and Taiwan. ERA4Health is also open towards expanding participation in the partnership. Some of the interviewed stakeholders confirmed that new partners will be integrated into ERA4Health as well as other external funders (e.g., from Canada, Switzerland or the UK) because they have expressed their interest in participating in ERA4Health in the future. The European Medicines Agency has also expressed its interest in collaborating with ERA4Health in some specific activities through its procedures for collaboration without being formally integrated into the consortia.

The current ERA4Health cooperation mainly includes European partners but there is increasing anticipation and plans to involve more Third Countries. Currently, Taiwan and Egypt are the two Third countries that are officially involved in the ERA4Health partnership. However, some of the interviewed stakeholders emphasised that within their networks in other world regions, such as Brazil, Australia, Japan, or Canada, they discussed possibilities to contribute to ERA4Health activities in the future, particularly in IICS. However, Third Countries are not eligible for the 30 per cent of co-fund from the European Commission towards their project funding and the integration in the consortia of new funders from underrepresented countries (e.g. Estonia has expressed their interest in joining the ERA4Health Partnership).

Overall, through the **establishment of transnational consortia**, ERA4Health is expected to serve as a hub for international research cooperation, while also providing **higher visibility to the partnership**. Although it is still too early to assess ERA4Health's international visibility, **extensive efforts and plans are already in place** or being set up on how to achieve this. The processes of communication and dissemination were already highlighted in ERA4Health's Strategic Research and Innovation Agenda (SRIA) in 2021.⁴⁶³ To reach ERA4Health visibility goals, in 2023, ERA4Health completed its Dissemination, Exploitation, and Communication (DEC) Plan and Strategy.⁴⁶⁴ The **main five goals to increase ERA4Health's international visibility** are raising awareness and interest and informing the various stakeholders and the general public on the ERA4Health; engaging in a dialogue with policymakers and other R&I funders to foster ERA4Health; financially supporting a joint transnational research project portfolio; fostering the engagement of citizens in the research and ensuring the utility of project results; and achieving the political commitment at

⁴⁶³ ERA4Health Partnership (2022). Strategic Research and Innovation Agenda. ERA4Health. Fostering a European Research Area for Health. Available at: https://era4health.eu/wp-content/uploads/2022/11/ec_rtd_he-partnerships-era-for-health-1.pdf Page 10 464 ERA4Health Partnership (2023). D4.1 Dissemination, Exploitation and Communication (DEC) Plan and Strategy. WP4

national/regional level for participation in the long term, assuring partnership sustainability. These goals are intended to enable exposure to ERA4Health's activities and outcomes, enhance visibility, encourage engagement, and increase the impact and sustainability of the partnership and its network in the long run.⁴⁶⁵ The interviewed stakeholders also emphasised the importance of these goals as well **as the need for the involvement of all ERA4Health partners in the efforts towards increasing visibility**.

Conclusion

The ERA4Health co-funded partnership started in late 2022 and it brings the opportunity to increase European transnational collaborative research funding addressing European public health needs. Although currently, ERA4Health **does not present immediate results or realised outputs** in terms of **additionality and international positioning and visibility**, it has already **achieved significant progress in setting up different processes** leading towards increased outcomes and results.

Regarding additionality, ERA4Health has launched four Joint Transnational thematic calls (JTCs) in 2022-2023 and it is also actively setting up calls for the Investigator-Initiated Clinical Studies (IICS) whose pilot call will be launched at the end of 2024. Through these activities, ERA4Health mainly mobilises public funding, mainly through the co-funding mechanisms of participating states, while further funding is aimed to be mobilised through additional external national funders, charities, and additional funds dedicated to IICS. Although ERA4Health currently does not mobilise private funding, some more private contributions are envisioned for Phase 2 of the partnership. In addition, through its activities, ERA4Health facilitates the creation and expansion of research and innovation networks. The partnership contributes to the realisation of ERA mainly by widening efforts towards ERA, particularly by focusing on the involvement of underrepresented countries in ERA via JTCs as well as IICS in the future.

ERA4Health is also successfully setting up processes regarding its international positioning and visibility. ERA4Health presents a high level of international cooperation as its participants include most of the EU member states, three Associated Countries and two Third countries. The partnership continues to expand its international network with the potential involvement of the United Kingdom and Canada as external funders and presents intentions to involve more European and Third countries in IICS which will further increase ERA4Health's international positioning and global relevance. The partnership is also currently actively seeking synergies with other European and global stakeholders. The partnership has launched its 1st International Annual Workshop for the search of Synergies of the Partnership ERA4Health in June, while another workshop for stakeholders interested in IICS will take place in September 2023. Regarding visibility, ERA4Health uses the processes of streamlining its communication via different media channels to reach different publics and prepares an extensive DEC Plan and Strategy.

⁴⁶⁵ ERA4Health Partnership (2023). D4.1 Dissemination, Exploitation and Communication (DEC) Plan and Strategy. WP4 Page 5

Key lessons learned and other important observations

As ERA4Health only started its activities in late 2022, the key lessons learned in additionality, international positioning and visibility should be assessed later once the partnership has already implemented some of its activities.

Despite the partnership still being early in its efforts, ERA4Health partners **present a high level of engagement in the partnership** and bring extensive experience from previous ERA-NETs, including the predecessor ERA-NETs of ERA4Health. The **lessons learned, experiences, and networks** from other ERA-NETs, as well as other EU-funded initiatives and projects, can help ERA4Health partners to **implement its activities more effectively and successfully**, such as JTCs and IICS, create synergies on European and global levels, and expand ERA4Health funding as well as the number of partners.

Appendix 1. The outline of the case study

This Appendix presents the outline of the case study's evaluation questions, methods, evaluation criteria, and purpose, among others.

The outline of the case study

 Table 121. Operationalised evaluation questions for ERA4Health case study:

 additionality and international positioning and visibility

Title	Evaluation questions	Methods	Evaluation criteria	Programm e part	Purpose
ERA4Healt h: additionalit y and internation al positioning of the co- funded partnership	PSC1: How much private and/or public R&I contributions have been mobilised on EU priorities thanks to ERA4Health? PSC1.1: What is the partnerships' budget leverage factor (separate direct from indirect leverage) in mobilising additional resources on top of contributions from partners? PSC1.2: How does ERA4Health facilitate the creation and expansion of R&I networks that bring together	Desk research ; Interview s	Additionalit y; Internation al positioning & visibility	Co-funded partnershi p	The case study will assess ERA4Health from two perspectives: 1) Additionality, in terms of bringing additional money and funds, as well as creating new networks/attracti ng new countries. Also, in terms of the ability to mobilise and reach a higher total budget than expected from the initial calculations as well as which funds are leveraged into the programme

relevant and competent actors from across Europe, thus contributing to the realisation of the ERA? PSC3: To what extent is ERA4Health acting as a global ambassador for the European R&I system/establishi ng global relevance/achievi ng scientific and technological reputation in the international context/ serve as hubs for international cooperation, where appropriate? PSC3.1: What is the level of international cooperation at the partnership and project level, and how does this result in visibility for the European Partnership?

from Third Countries through international cooperation. 2) International positioning and visibility - the partnership tries to go far beyond Europe, including Third Countries. The opportunities the partnership entails and the reach it provides.

Source: Compiled by the study team.

Case Study No 15: European Partnership for the Assessment of Risks from Chemicals – PARC

Introduction

This evaluation study report addresses the European Partnership for the Assessment of Risks from Chemicals (PARC) 2022-2029.⁴⁶⁶ PARC is targeted at supporting EU and national chemical risk assessment (RA) and risk management (RM) bodies to drive innovation in the management of chemical safety challenges with the help of new data, knowledge, methods, networks and skills. It is a co-funded partnership involving Member States, Associated Countries and Third Countries. **PARC is aimed at public organisations only: government agencies in charge of chemical risk assessment and universities and research organisations with established links**

⁴⁶⁶ PARC's CORDIS homepage: https://cordis.europa.eu/project/id/101057014; PARC's homepage: https://www.eu-parc.eu/

to these risk-assessing institutions.⁴⁶⁷ The coordinator of PARC is ANSES, the French Agency for Food, Environmental and Occupational Health & Safety. The evaluation is conducted as part of the "Resilient Europe" study (RTD/2021/SC/021), feeding into the European Commission's interim evaluation of the Horizon Europe Framework Programme.

The analysis follows the Better Regulation Guidelines (BRG) criteria of relevance, coherence, efficiency, effectiveness, the EU added value and the partnership-specific criteria. The early phase of the partnership implementation - PARC finished its first operating year in spring 2023 - is taken into account when conclusions and suggestions are made based on the evaluation findings. The report is structured as follows:

- Purpose, scope and methodological approach of the study.
- Background of PARC, covering the intervention logic and baseline.
- Implementation state of play, including the overview of the implementation process.
- Findings on the evaluation criteria of relevance, coherence, efficiency, effectiveness, the EU added value and the partnership-specific criteria.
- A summarising conclusion.
- Discussion on the lessons learned and suggestions for improvement.

Purpose of the evaluation

The study at hand provides input into the interim evaluation of Horizon Europe by reviewing the PARC's activities from the point of view of the BRG criteria of relevance, coherence, efficiency, effectiveness, and the EU added value. Also, the partnership-specific criteria of additionality, directionality, international positioning & visibility, and transparency & openness are addressed. The study is aimed at illuminating **the added value of PARC in the European context of chemical RA**. It is also aimed at supporting policy learning on co-funded partnerships by reporting **beneficiaries' experiences on what has worked well and less well during the launching phase of PARC**.

Scope of the evaluation

The scope of the study is the first operating year of the PARC partnership programme, from the beginning of May 2022 to the end of April 2023.

Methodological approach

The data used in the evaluation is based on 1) desk research on the policy and administrative documents relevant to PARC (see Table below), 2) interviews with the PARC coordination team and task leaders (7 interviewees) in June 2023, 3) analysis of EC monitoring data, and 4) analysis of responses given on PARC in the Common Indicator Survey for the Biennial Monitoring Report on Partnerships in Horizon Europe 2023. Before the evaluation work, an exploratory interview was organised with the

⁴⁶⁷ EC (2021). Horizon Europe Work Programme 2021-2022 4. Health, p. 56. Available: https://ec.europa.eu/info/fundingtenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-4-health_horizon-2021-2022_en.pdf.

Policy Officers responsible for PARC in March 2023. The emphasis of data analysis is on the interview data considering the early phase of PARC with limited reporting material and monitoring data available.

For desk research, the reporting documents of PARC, Annual Work Plan (AWP) Year 1, and Annual Summary Report (ASR) Year 1 were reviewed. It should be noted that the ASR of PARC covered the period from May 2022 to December 2022. In addition, the Biennial Monitoring Report 2022 on partnerships in Horizon Europe (BMR 2022) was reviewed regarding the PARC-specific sections. The EU's chemicals strategy for sustainability and PARC's website material were used in desk research, as well.

Table 122. Documents reviewed

Source: Compiled by the study team.

Document	Link
ANSES (2020). Draft proposal for a European Partnership under Horizon Europe. Partnership for the Assessment of Risk from Chemicals (PARC).	https://research-and- innovation.ec.europa.eu/system/files/2020- 06/ec_rtd_he-partnerships-chemical-risk- assessment.pdf
EC (2020). Chemicals strategy for sustainability.	https://eur-lex.europa.eu/legal- content/EN/TXT/?uri=COM%3A2020%3A667%3A FIN
EC (2022a). European Partnership for the assessment of risks from chemicals (PARC).	https://cordis.europa.eu/programme/id/HORIZON_ HORIZON-HLTH-2021-ENVHLTH-03-01
EC (2022b). Performance of European Partnerships: Biennial Monitoring Report 2022 on partnerships in Horizon Europe.	https://op.europa.eu/en/publication-detail/- /publication/a6cbe152-d19e-11ec-a95f- 01aa75ed71a1
Marx-Stoelting, P., Rivière, G., Luijten, M., Aiello-Holden, K., Bandow, N., Baken, K., & Sanders, P. (2023). A walk in the PARC: Developing and implementing 21st century chemical risk assessment in Europe. <i>Archives</i> <i>of toxicology</i> , 97(3), 893-908.	https://link.springer.com/article/10.1007/s00204- 022-03435-7
PARC (2022). Deliverable D1.1. Annual Work Plan (AWP) Y1 including rolling SRIA.	https://www.eu-parc.eu/sites/default/files/2023- 05/PARC_D1.1.pdf
PARC (2023). Deliverable D1.4. Annual Summary Report (ASR) Y1.	https://www.eu-parc.eu/sites/default/files/2023- 05/PARC_D1.4.pdf
PARC (2023). Governance structure.	https://www.eu-parc.eu/about- us/governance#governance-executive-bodies

The interviewees involved in the evaluation study consisted of the coordination team, national hub co-coordinators, and task leaders of impact evaluation and performance monitoring of PARC. The interviews were semi-structured following the BRG and partnership-specific evaluation criteria (see Appendix below). All the interviews were recorded, and interview minutes were sent to the interviewees for checking after the interview had taken place.

EC monitoring data was analysed regarding PARC's participant data and assigned EC contribution. Also, the geographical location of the PARC's participants was analysed at the aggregate level. A similar analysis was done for all co-funded partnerships (see Appendix below).

Background to the initiative

According to PARC's mission and vision statement⁴⁶⁸, the Partnership will support EU and national chemical RA and RM with new data, knowledge, methods, networks and skills to drive innovation in chemical risk assessment. PARC will facilitate the transition to the next-generation risk assessment (NGRA) to protect human health and the environment better. PARC will also address user needs to anticipate and respond to the challenges and priorities of the new European policies in the field of chemical RA. By promoting the high-level network of expertise on chemical RA at the national and EU levels, PARC will contribute to the EC's overall targets for **strengthening the chemical science-policy interface** as stated in the EU's chemical strategy for sustainability.⁴⁶⁹

In line with the mission and vision statement, PARC organises its activities to respond to three specific objectives:

- 1. An EU-wide sustainable cross-disciplinary network to identify and agree on research and innovation needs and to support research uptake into regulatory chemical RA.
- 2. Joint EU R&I activities responding to identified priorities in support of current regulatory RA processes for chemical substances and to emerging challenges.
- 3. Strengthening existing capacities and building new transdisciplinary platforms to support chemical RA.⁴⁷⁰

PARC builds on the experience of the **European Human Biomonitoring Initiative** (**HBM4EU**)⁴⁷¹ that ran from January 2017 to June 2022 with a budget of EUR 74.9 million and 121 participants. The main difference between PARC and HBM4EU is that PARC encompasses a wider set of chemical risk assessment activities, including environmental monitoring and human biomonitoring. Moreover, the budget of PARC is EUR 400 million, and the number of participants, 199, is significantly larger than that of HBM4EU. The funding rate of PARC is 50%, while the funding rate of HBM4EU was 70%, which means that the relative partner contribution has also increased in PARC.

Intervention logic

According to the intervention logic presented in the draft proposal for PARC⁴⁷², the general challenges to which PARC responds include the increasing number and diversity of chemicals in everyday life and gaps in knowledge of which chemicals, single or in combination, and what concentrations, humans and the environment are being exposed to. Furthermore, only a small fraction of the chemicals have been sufficiently characterised regarding their hazardous toxicological properties or are

Europe., p. 235. Available: https://op.europa.eu/en/publication-detail/-/publication/a6cbe152-d19e-11ec-a95f-01aa75ed71a1.

content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN.

⁴⁶⁸ EC (2022b). Performance of European Partnerships: Biennial Monitoring Report 2022 on partnerships in Horizon

⁴⁶⁹ EC (2020). Chemicals strategy for sustainability, p. 21: https://eur-lex.europa.eu/legal-

⁴⁷⁰ PARC's CORDIS homepage: https://cordis.europa.eu/project/id/101057014.

⁴⁷¹ HBM4EU's CORDIS homepage: https://cordis.europa.eu/project/id/733032.

⁴⁷² ANSES (2020). Draft proposal for a European Partnership under Horizon Europe. Partnership for the Assessment of Risk from Chemicals (PARC): https://research-and-innovation.ec.europa.eu/system/files/2020-06/ec_rtd_he-partnerships-chemical-risk-assessment.pdf.

regularly monitored. These challenges create R&I needs regarding human biomonitoring, high-quality toxicological data, data platforms for chemicals, health impacts of chemicals, and cooperation of sectors, among others. By strengthening research and innovation capacity for chemical RA to protect human health and the environment, **PARC will ultimately enable Europe to lead innovation in chemical RA while optimising the protection of human health and the environment**. The full description of the intervention logic of PARC is presented in the Appendix below.

Baseline

No dedicated evaluation report is available on the predecessor of PARC, HBM4EU. It should be noted, however, that HBM4EU collected a large set of indicator data regarding its results and outcomes, including the scope of national hub activities, the number of aligned human biomonitoring studies within HBM4EU, and the volume of scientific communication.⁴⁷³

Implementation state of play

There are about 200 participants in PARC (see Figure below). Regarding participant numbers, higher education institutions (universities, etc.) form the largest participant group of PARC (c. 43%). In terms of assigned EC contribution, however, the public research organisations receive the largest share, almost 60% of the total EC contribution of PARC. The data on the geographical location of PARC's participants shows that the EU-14 countries form the largest group with a share of c. 67% of the participants of PARC, while the share of the EU-13 countries is c. 18%.⁴⁷⁴ The shares of participants coming from the EU-13 countries are close to the overall figures of co-funded partnerships of Horizon Europe both in terms of numbers and the EC contribution (see Appendix below). The participating Associated Countries include Island, Israel and Norway. The participating Third Countries of PARC are Switzerland and the UK. All the EU Member States participate in PARC except for Bulgaria, Malta and Romania.⁴⁷⁵

⁴⁷³ HBM4EU's indicators of success: https://www.hbm4eu.eu/result/indicators_of_success/.

⁴⁷⁴ The EU-13 countries refer to the thirteen countries added to the EU since 2004: Bulgaria, Croatia, Cyprus, Czechia, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia.

⁴⁷⁵ The beneficiaries informed that Ireland, which did not previously participate in PARC, is now represented among the PARC participants.



Figure 132. Participants of PARC and their geographical location (n=199)⁴⁷⁶

Source: Compiled by the study team using own calculations and CORDA data.

PARC does not publish open calls, but instead, it funds in-house research and innovation activities performed by its participants. These activities are executed through activities and projects grouped and organised under the work packages and tasks within PARC.

The project review process of PARC contains the following phases and reporting actions:

- 1) Initiation phase, during which a project initiation request is submitted and reviewed in order to ensure that it contributes to the PARC objectives.
- 2) The planning phase when a project planning document is created as a reference document for the project.
- 3) The implementation phase includes the creation of an implementation document and intermediate reports.
- 4) Closing phase, including final reporting.⁴⁷⁷

⁴⁷⁶ Total number of participants analysed: 199. Total amount of EC contribution analysed: EUR 200 million. Note: REC = research organizations, PUB = public bodies, PRC = private sector, HES = higher education institutions, OTH = other participants.

⁴⁷⁷ PARC (2023). Deliverable D1.4. Annual Summary Report (ASR) Y1, p 17: https://www.eu-parc.eu/sites/default/files/2023-05/PARC_D1.4.pdf

According to the ASR document for Year 1, 60 projects were in the implementation phase, and five new projects were about to start in Year 2.⁴⁷⁸ The projects are carried out under the following thematic areas that form **the rolling Strategic Research and Innovation Agenda (SRIA) of PARC**:

- Monitoring and exposure (WP4)
- Hazard Assessment (WP5)
- Innovation in regulatory RA (WP6)
- FAIR data (WP7)
- Concepts and toolboxes (WP8)
- Building infrastructural and human capacities (WP9)⁴⁷⁹

Work Packages 1-3, which are not listed above, are dedicated to partnership management and coordination, creating a common science-policy agenda (priority setting), and finding synergies and collaborations with external initiatives.⁴⁸⁰

Findings

In the following sections, the main findings regarding the BRG and partnership-specific criteria are presented.

Relevance

Based on the policy documents reviewed and beneficiary interviews, the three specific objectives of PARC are still relevant. Especially most of the EC's overall targets for strengthening the chemical science-policy interface, as stated in the EC's chemicals strategy for sustainability, are in line with the research and innovation activities carried out within PARC:

- Establish and update a research and innovation agenda for chemicals;
- Foster multidisciplinary research and digital innovations for advanced tools, methods and models, and data analysis capacities;
- Provide financial support for EU-wide human and environmental (bio)monitoring capacities; and
- Develop an EU early warning and action system for chemicals.⁴⁸¹

Regarding the last item on the list, **the EU early warning and action system for chemicals**, the PARC's beneficiaries reported that there is an ongoing process to establish a response mechanism that can collect needs from the EC and Member

parc.eu/sites/default/files/2023-05/PARC_D1.4.pdf.

⁴⁷⁸ PARC (2023). Deliverable D1.4. Annual Summary Report (ASR) Y1, p 18: https://www.eu-

⁴⁷⁹ PARC (2022). Deliverable D1.1. Annual Work Plan (AWP) Y1 including rolling SRIA: https://www.euparc.eu/sites/default/files/2023-05/PARC_D1.1.pdf.

⁴⁸⁰ PARC (2022). Deliverable D1.1. Annual Work Plan (AWP) Y1 including rolling SRIA: https://www.euparc.eu/sites/default/files/2023-05/PARC_D1.1.pdf.

⁴⁸¹ EC (2020). Chemicals strategy for sustainability, p. 21: https://eur-lex.europa.eu/legal-

content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN.

States to provide timely responses and solutions relating to chemical risks. The experiences gained with the Rapid Response Mechanism of HBM4EU inform the establishment of the response mechanism of PARC.⁴⁸²

The beneficiaries of PARC see that the partnership has succeeded in enabling collaboration between different research teams in chemical RA, which is necessary for advancing RA and RM and meeting the needs of the industry and regulatory bodies, especially when considering that **national agencies are perceived to be lagging behind in adopting new technologies of RA**. Regarding the engagement of citizens, PARC's activities are in the planning stage and not yet operational.

Coherence

According to the Biennial Monitoring Report 2022 on partnerships in Horizon Europe (BMR 2022), PARC continues the development of monitoring capacity acquired in HBM4EU by extending the human biomonitoring (HBM) platform and enhancing the collaboration between the teams working in the fields of HBM and environmental monitoring. PARC also collaborates closely with the European Human Exposome Network (EHEN) and, for the environment, with the NORMAN network with emerging contaminants experience.⁴⁸³

The beneficiaries see that PARC avoids overlapping activities and **ensures synergy with existing programmes, mainly through coordination with regulatory bodies**, such as the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA). Furthermore, PARC has a governing board with representatives from national ministries, Directorates-General (DGs) of the EC and funding agencies to prevent overlapping activities with other funding programmes.

For collaboration with other initiatives, PARC has established SYNnet. SYNnet is an open network designed to facilitate collaboration and knowledge sharing on the project level with other environmental, food, and human health initiatives and organisations working in chemical RA, including actions and initiatives of Cluster 1 of Horizon Europe and other Clusters, such as Cluster 4.⁴⁸⁴

These parties are especially invited to collaborate with PARC:

- National organizations responsible for chemical RA and safety regulation;
- European and international organizations focusing on chemical safety and environmental protection;
- Scientific associations and professional societies involved in toxicology, environmental science, human health, and related fields;
- Academic and research institutions working in relevant areas such as chemistry, biology, environmental science, and toxicology;

⁴⁸² HBM4EU's Rapid Response Mechanism: https://www.hbm4eu.eu/rapid-response-mechanism/.

⁴⁸³ EC (2022b). Performance of European Partnerships: Biennial Monitoring Report 2022 on partnerships in Horizon Europe, p. 236: https://op.europa.eu/en/publication-detail/-/publication/a6cbe152-d19e-11ec-a95f-01aa75ed71a1.

⁴⁸⁴ Collaboration is sought, e.g., with a CSA action IRISS of Cluster 4: https://cordis.europa.eu/project/id/101058245. PARC's synergies: https://www.eu-parc.eu/synnet.

- Non-governmental organizations (NGOs) and civil society groups focusing on environmental health and chemical safety issues;
- Industry associations and companies involved in the production, use, and disposal of chemicals; and
- Health organizations and medical professionals are concerned with the health effects of chemical exposure.⁴⁸⁵

Regarding the EU programmes referenced in Annex IV of the Horizon Europe regulation⁴⁸⁶ (e.g., the EU4Health programme), the beneficiaries do not mention specific actions taking place at this point.⁴⁸⁷

In terms of global development, **the International Board of PARC**, consisting mostly of scientists residing outside Europe, provides insights into global developments in the field of RA. Also, PARC has contact points and ongoing collaborations with international organizations, such as the UN Environment Programme.

Efficiency

The SRIA of PARC defines expected costs in terms of person months and other direct costs per each project funded under the work packages. The PARC beneficiaries do not have observations on the cost-effectiveness of PARC. From the coordination point of view, **an initial challenge has been the large size of PARC**, which requires effective management to demonstrate its feasibility. To answer this, the coordination team of PARC consists of 8 persons supported by the administrative, legal and financial departments of the coordinating organisation, ANSES.

The beneficiaries report that the existing financial reporting system of the partnership and the bureaucratic nature of budget management create complexities and difficulties for project management. Especially, the separation of budget per participant (instead of activities) creates additional challenges in managing the overall budget effectively.

Effectiveness

According to the PARC beneficiaries, PARC has already succeeded in integrating various domains relevant to chemical RA, thus bridging regulatory silos and **facilitating cooperation at the national and European levels**. PARC has created a platform for sharing information and expertise, the **Stakeholder Forum**, involving a large number of organisations and enabling the transfer of knowledge and impact creation in the wider society. Stakeholder Forum gathers stakeholders together to share their vision on how to improve chemical RA in Europe, collect recommendations and develop synergies at the EU and international levels. Currently, Stakeholder Forum includes NGOs, industry associations, employer and worker bodies, health

⁴⁸⁵ PARC's synergies: https://www.eu-parc.eu/synnet.

⁴⁸⁶ Horizon Europe Regulation. Annex IV: Synergies with other union programmes. Available: https://eur-lex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:32021R0695.

⁴⁸⁷ The responses given on PARC in the Common Indicator Survey for the Biennial Monitoring Report on Partnerships in Horizon Europe 2023 call attention to the lack of concrete synergies with other EU programmes at the level of activities and/or at the level of expenditure. Practical, simple and shared solutions, particularly in terms of co-financing rules, are called for.

professionals and consumer organisations, such as CHEM Trust, European Chemical Industry Council, and The European Trade Union Institute.

Regarding the gender dimension in R&I content, the differences between males and females in the assessment of many chemicals make consideration of the gender dimension necessary in R&I work. Indicators are regularly used to monitor the gender equilibrium in HBM projects of PARC along with other demographic aspects, such as socio-economic status and regional considerations.

The work on Key Performance Indicators (KPIs) of PARC is ongoing and they are not yet publicly available.⁴⁸⁸

EU value added

During the planning phase of PARC, the co-funded partnership funding model was seen as an optimal instrument to support collaboration between national public organisations, which conduct chemical RA and RM, the EC, and the contributing research community. According to the draft proposal for PARC, the EU added value of aligning these activities lies in more efficient use of resources and knowledge transfer taking place between countries and with the EU organisations.⁴⁸⁹

The key mechanism for creating EU value added at the national level is **National Hubs**. The countries involved in PARC establish National Hubs that aim at developing collaboration and ensuring that PARC's activities are aligned with national activities. While the construction of National Hubs is based on the country's needs, it is expected that relevant ministries, research entities and other stakeholders are involved. National Hubs are coordinated by the National Hub co-coordinators of PARC.

According to the beneficiaries, the collaboration between National Hubs and the coordination team of PARC has been close and effective. The coordination team has supported National Hubs in various ways, such as preparing a SharePoint platform for knowledge sharing and addressing their requests. The beneficiaries report that PARC has accelerated national human biomonitoring studies and influenced funding decisions in the UK, and, in Slovakia, PARC has improved intersectoral communication and collaboration on chemical regulations, for example.

Regarding challenges, the funding rate of PARC (50%) is lower than in HBM4EU, which has hindered participation and required countries to allocate more funding from national sources. Smaller countries, especially those lacking national system-level resources and infrastructures for chemical risk assessment, have faced **challenges** in participating in PARC due to the co-funding requirement. Also, some larger countries have faced challenges in this respect due to funding allocation issues (national funding of R&I is tied to open calls). In addition to the funding issues, there is also a lack of other resources important for human biomonitoring in some participating countries, such as logistics solutions and experienced personnel.

⁴⁸⁸ An initial list of KPIs has been presented in the Grant Agreement of PARC to monitor partnership's progress towards societal, scientific and economic impacts.

⁴⁸⁹ ANSES (2020). Draft proposal for a European Partnership under Horizon Europe. Partnership for the Assessment of Risk from Chemicals (PARC), p. 38: https://research-and-innovation.ec.europa.eu/system/files/2020-06/ec_rtd_he-partnerships-chemical-risk-assessment.pdf.

Additionality

PARC has neither company participants nor connections to companies because it addresses only public bodies and public research actors of chemical risk assessment. This means that the mobilisation of private R&I investments is out of the scope of PARC's activities. Information on the additional resources mobilised from the public sector - in addition to EUR 200 million of partner contribution - is not available.

Additionality in terms of facilitating R&I networks bringing together relevant and competent actors across Europe in chemical RA is at the core of the specific objectives of PARC. As stated above, countries are not in equal positions to benefit from cross-border collaboration as some have more existing national resources and expertise in chemical RA than others. **PARC facilitates the integration of less advanced countries by providing them with training and experience exchange**, e.g., in developing laboratory capacities and implementing standardisation approaches (WP9).

According to the beneficiaries, **national collaboration and involvement are greatly enhanced by the perceived opportunity for national input to and participation in European decision-making processes through PARC and its networks.** National Hubs of PARC play a crucial role in ensuring that the national voice is heard and facilitating feedback and communication between stakeholders.

Directionality

PARC's vision is to contribute to the EU goal of a pollutant-free environment and sustainable development in Europe.⁴⁹⁰ To achieve this, the partnership brings together circa 200 cross-sectorial public partners working on chemicals risk assessment from 24 EU Member States and five other countries, which would not have been possible to achieve by traditional calls. PARC applies the Partnership Specific Impact Pathways (PSIPs) approach and Key Performance Indicators (KPIs) for monitoring directionally in terms of fulfilling the mission and vision statement of PARC. The subset of impact KPIs presented in BMR 2022 focuses on the following impacts:

- Endorsement of chemical RA innovation in policy measured by the number of citations of PARC outputs/results in policy documents.
- Citizen trust in science and regulations measured by the number of activities that target citizens.
- Support toward the 'one substance one assessment' approach⁴⁹¹ is measured by the number of activities that contribute to the 'one substance, one assessment' approach.⁴⁹²

The beneficiaries of PARC see that the development of impact assessment and KPIs for PARC is a continuation of the experience acquired within HBM4EU. The

content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN.

⁴⁹⁰ PARC's vision statement: https://www.eu-parc.eu/what-we-do/mission-vision-and-objectives.

⁴⁹¹ The 'one substance, one assessment' approach refers to ensuring that the initiation and priority setting of the safety assessments are done in a coordinated, transparent and synchronised manner taking into account the specificities of each sector. EC (2020). Chemicals strategy for sustainability, p. 15: https://eur-lex.europa.eu/legal-

⁴⁹² EC (2022b). Performance of European Partnerships: Biennial Monitoring Report 2022 on partnerships in Horizon Europe.

beneficiaries report that since PARC covers a broader range of activities than HBM4EU, gathering information for the KPIs is a challenging and time-consuming process requiring close collaboration with the WP and Task leaders. With this respect, the coordinator has played a crucial role in providing an overview of the projects of PARC and facilitating the collection of information. At the moment, work on the optimised list of indicators is ongoing (Deliverable 1.6).

International positioning and visibility

Associated Countries and Third Countries participating in PARC (Island, Israel, Norway, Switzerland and the UK) are the same as in HBM4EU. The number of organisations coming from these countries has increased from 14 to 31. Information on the cost budgets of Third Country participants is not available.

According to the beneficiaries, there is cooperation with Japan in the field of HBM, but further collaboration is called for. Similarly, there is interaction with South Africa, but a more structured agenda and international programme are required for broader engagement.

The International Board of PARC, consisting of 15 international experts, provides a venue for the international positioning of PARC through board discussions and interactions.⁴⁹³ In addition, the PARC participants are enrolled in several international working groups, such as OECD and WHO working groups, thus bridging PARC activities to global relevance. Monitoring of international policy interactions is included in the indicator framework of PARC.

In terms of scientific visibility, PARC aims to produce scientific publications in top-level journals, and participation in international conferences is expected from the participants of PARC. One of the WPs of PARC focuses on **open and fair data sharing** (WP7), thus contributing to Europe's position at the forefront of science and the best practices of data sharing globally.

PARC has 11 participants from the UK. According to the beneficiaries, the British participants have shown great involvement in PARC, including voluntary contributions, even though Brexit has caused significant changes in funding terms (only national funding is available for the British participants) and regulatory systems (UK REACH).

Transparency and openness

As PARC is aimed at public organisations only, it is not accessible to industry or SMEs. However, the beneficiaries report that the participating academic research groups collaborate with researchers of startup companies in specific projects and share tools and resources with them through open platforms.

PARC's website is regularly updated, and it introduces partnership activities in a comprehensive manner, including PARC's internal and external governance

⁴⁹³ PARC's International Board: https://www.eu-parc.eu/about-us/governance#governance-advising-bodies.

structures.⁴⁹⁴ In addition, newsletters and social media channels are utilized for communication and information-sharing purposes.⁴⁹⁵

According to the beneficiaries, the National Hubs of PARC play a crucial role in communicating and exchanging information about PARC at the national level. Communication efforts are ongoing to ensure that everyone working in the domain can identify national contacts and participate in discussions related to PARC. Also, the interactions within the Stakeholder Forum are seen as important in this respect.

89 participating organisations of HBM4EU (74%) have joined PARC. After one year of implementation, Ireland has become a new participant of PARC. The beneficiaries see potential new participants among Associated Countries and Member States not yet represented in PARC (Bulgaria, Malta and Romania). Formal procedures for new beneficiaries and affiliated entities to join PARC are in place, starting by contacting PARC's coordinator.

PARC has a dedicated work package (WP7) to ensure openness in the use of research results. PARC also has a dedicated work package (WP2) to involve stakeholders (regulators and researchers) in the identification of priorities. The gender balance in the governance structures of PARC: Coordination team: 4 females and 4 males, WP leaders: 10 females and 6 males; Task leaders: 35 females and 32 males.

Phasing out preparedness

As PARC is based on a grant agreement of limited duration, the evaluation question of phasing out preparedness is not relevant.

Conclusions

After one year of it its implementation, the objectives of PARC are still relevant and in line with the EC's overall targets for strengthening the chemical science-policy interface. Coherence with other initiatives and policy measures is ensured via coordination with regulatory bodies and networking activities. Concerning citizen engagement, PARC's activities are in the planning stage and not yet operational.

From the point of view of efficiency, an initial challenge has been the large size of PARC in terms of the number of participants and thematic areas addressed. While it is too early to assess the overall effectiveness of PARC, it has already succeeded in integrating various domains relevant to chemical RA and, thus, bridging regulatory silos at the national and European levels.

For creating EU added value, the establishment of National Hubs, which include relevant ministries, research entities and other stakeholders of participating countries, has played an important role. National Hubs aim to develop collaboration and ensure that PARC's activities are aligned with national activities. The funding rate of PARC (50%) has hindered wider participation in some participating countries. Especially those countries that are lacking behind in terms of existing national resources and infrastructures have faced challenges in participating in PARC due to the co-funding requirements but, nevertheless, are benefitting from being part of the network even

⁴⁹⁴ PARC's home page: https://www.eu-parc.eu/.

⁴⁹⁵ PARC's Twitter channel: https://twitter.com/PARC_chemicals.

with a lower participation rate. PARC facilitates the integration of less advanced countries by providing them with training and experience exchange.

For monitoring the directionality of PARC, PSIPs and KPIs are in use. With this regard, work on the optimised list of indicators is ongoing. The international positioning and visibility of PARC are supported by multiple measures, including the International Board of PARC, consisting of 15 international experts. PARC's transparency is supported by a comprehensive website, newsletters and use of social media. PARC has paid attention to management measures related to potential newcomers, such as integration activities. Recently, Ireland became a new participant of PARC.

Lessons learned and suggestions for improvement

The beneficiaries of PARC see that the main drivers for the partnership are high expectations and active involvement of ministries and relevant public bodies. They see that PARC already contributes to the harmonization, development of compliant methods and solving challenges of chemical RA. With this regard, utilization of the experience and resources derived from the preceding HBM4EU has been important.

According to the beneficiaries, the main barriers to PARC are related to financial and budgetary issues. First, smaller countries lacking national system-level resources and infrastructures for chemical risk assessment have faced challenges in participating in PARC due to the co-funding requirement. Second, the existing financial reporting system and the bureaucratic nature of budget management create complexities and difficulties in PARC's overall coordination and reporting. The separation of budget per participant creates additional challenges in managing the overall budget effectively. The beneficiaries of PARC call for more flexibility regarding the EC's funding tools and funding rates to better support the partnership activities and budget management. For instance, allowing more budget reserves at the beginning of the partnership and allocating budgets to activities rather than participants are seen as beneficial.496

Recommendations:

- Particular attention should be paid to the participants from countries lacking national resources and infrastructures to integrate them into the full-scale partnership activities.
- The EC and co-funded partnerships should engage in a joint discussion on more flexible budget management supporting effective partnership management.

⁴⁹⁶ In addition, the responses given on PARC in the Common Indicator Survey for the Biennial Monitoring Report on Partnerships in Horizon Europe 2023 point out that the current monitoring and reporting tools and templates used by the partnerships are not apt for large-scale partnerships, such as PARC. As a concrete example, collecting required information on researchers involved is a formidable challenge when the partnership has more than 1,400 individuals involved like PARC. Furthermore, The Funding and Tenders Portal is not designed to accommodate this scale of data input.

Appendix 1: Detailed methodological approach

Table 123.	Evaluation	criteria and	description

Description				
Criteria based on Batter Regulation Guidelines				
To what extent have the objectives of the partnership been, and are s relevant regarding the challenges and needs addressed in this area b the Framework Programme? How flexible the partnership proved to b in updating the Strategic Research Innovation Agenda, or equivalent strategic documents, adjusting objectives, activities and resources to changing market and/or policy needs?				
How is the level of coherence between this partnership and the other partnerships and the Framework Programme activities in this area? Is this partnership more effective in achieving synergies, compared to other modalities of the programme?				
How cost-effective has this partnership been?				
To what extent has this partnership achieved its objectives and contributed to achieving the objectives of the Framework Programme in this area? Has the gender dimension been integrated into R&I content and how (Horizon Europe regulation requirement)?				
What is the value resulting from this partnership that is additional to the value that could result from interventions carried out at the regional or national level?				
Partnership-specific criteria				
How much private and/or public R&I contributions have been mobilised on EU priorities thanks to this partnership? What is the partnership's budget leverage factor, in mobilising additional resources, on top of contributions from partners? How does the partnership facilitate the creation and expansion of R&I networks that bring together relevant and competent actors from across Europe, thus contributing to the realisation of the ERA?				
What is the progress towards the strategic vision of the European Partnership? Does the partnership clearly demonstrate progress in the delivery of results for the EU and its citizens, notably global challenges and competitiveness, which cannot be achieved by traditional calls alone?				
How open is the partnership to new participants? Are there procedures/mechanisms in place to expand the partnership to involve new members at partnership and project level, as well as gradually engage a broader set of stakeholders across Europe? What is the extent of gender balance in the governance structures of the partnership? Are there open and transparent processes for consulting all relevant stakeholders and constituent entities in the identification of priorities? What is the level of openness in the use of research results? To what extent is the partnership (notably with industry participation) accessible for SMEs?				
What are the foreseen measures and conditions set for the orderly phasing-out of the Partnership from the Framework Programme funding? Are these measures appropriate with regard to a possible phasing-out (or renewal) of the partnership?				

Source: Compiled by the study team based on the guidelines provided by the EC.

Appendix 2: Intervention Logic of PARC

Challenges	Number and diversity of chemicals	Incomplete occurrence and exposure data		Gaps in toxicology		Information and data access
V	Public concern and health costs	Separate policy frameworks		New risk paradigm		The right skills
R&I needs	Human biomonitoring; expos effect biomarkers; methods a models to track exposure sou route, non-targeted and susg screening methods; determin exposure; linking external an exposure; limit values	Human biomonitoring; exposure and effect biomarkers; methods and models to track exposure source and route, non-targeted and suspect screening methods; determinants of exposure; linking external and internal exposure; limit values		ind validated toxicological thods and guidelines, Iternative assessment plicability and validation of t-based methods; mixture s, new technologies to effects		Data Platform for Chemicals; data harmonisation, data exchange, FAIR data, GDPR compliance
Ţ	Health impacts; uptake of scientific knowledge in legislation awareness and understanding of scientific evidence and regulatory procedures	Cooperation between sectors for coherence, knowledge sharing, consensus building, Early Warning System		New risk assessment approaches and holistic frameworks, new decision support tools, Safe and Sustainable-by- Design concept		Enhance the skills of scientists, risk assessors and managers; make the risk assessment profession attractive to young students
	Consolidate and strengthen the EU's research and innovation capacity for chemical risk assessment to protect huma health and the environment and contribute to a non-toxic environment and a circular economy.				sessment to protect human ircular economy.	
	Set up an EU-wide cross- disciplinary network to identify and agree on research and innovation needs and support research uptake into regulatory chemical risk assessment		Carry out joint EU research and innovation activities supporting the current regulatory risk assessment processes and responding to emerging challenges		Strengthen existing capacities and build new EU-wide, transdisciplinary research and innovation platforms to support chemical risk assessment	
Actions	High-level group of EU and national risk assessors and managers Sustainable network of National Hubs Common R&I strategic agenda to address knowledge needs Utake of knowledge produced risk assessment and regulatory processes. Cooperation in Europe and international leadership for R&I in chemical risk assessment - Communicate and disseminate knowledge ensure acressibility		 Annual R&I work programmes Extend the human biomonitoring platform and network of laboratories from HBM4EU Facilitate the acceptance and use of the results in risk assessment processes 		 A FAIR data culture enabling oper science and exchange of data Fit-for-purpose capacities and networks of laboratories and research centers New models and innovative concepts for risk assessment Training programmes 	
Outcome	A sustainable EU-wide R&I platform for chemical risk assessment supporting EU and national chemical risk assessment/management authorities and processes.					
Impact	Europe leading innovation in chemical risk assessment and has optimised protection of human health and the environment.					

Figure 133. Intervention logic PARC presented in the draft proposal

Source: ANSES (2020). Draft proposal for a European Partnership under Horizon Europe. Partnership for the Assessment of Risk from Chemicals (PARC).⁴⁹⁷

⁴⁹⁷ https://research-and-innovation.ec.europa.eu/system/files/2020-06/ec_rtd_he-partnerships-chemical-risk-assessment.pdf
Appendix 3: Participation of co-funded partnerships



Figure 134. Participants of co-funded partnerships of Horizon Europe.⁴⁹⁸

Source: Compiled by the study team using its own calculations and CORDA data.

The co-funded partnerships analysed in the Figure above:

- 1. A climate neutral, sustainable and productive blue economy Partnership SBEP;
- 2. Clean Energy Transition Partnership CETP;
- 3. European Partnership Driving Urban Transitions DUT;
- 4. European Partnership on Innovative SMEs InnovativeSMEs;
- 5. European Partnership on Transforming Health and Care Systems THCS;
- 6. Fostering a European Research Area for Health Research ERA4Health;
- Improve Interconnected innovation ecosystems supporting Actions for Citizen awareness and Twin Transition in the entire cosmetic value chain -ACTT4Cosmetics;
- 8. Partnership for the Assessment of Risks from Chemicals PARC;
- 9. The European Biodiversity Partnership Biodiversa-plus;
- 10. Water4All Water Security for the Planet.

⁴⁹⁸ Total number of participants analysed: 699. Total amount of EC contribution analysed: EUR 592 million. Note: REC = research organizations, PUB = public bodies, PRC = private sector, HES = higher education institutions, OTH = other participants.

Annex 5: Benchmark reports

The study covered **4 benchmark** studies as a part of the Resilient Europe study, feeding into the Final Report for the evaluation of the European Framework Programmes for Research and Innovation for a Resilient Europe. Completed benchmark reports are presented in this Annex 5 which is a separate document.

Table 124.	Resilient Eu	ope under	Horizon	Europe:	Benchmark	studies

No	Title of the benchmark study
B1	National Institutes of Health (NIH) response to COVID-19
B2	Gender equality and inclusion practices
B3	Measuring the societal impact of social sciences and humanities research in the context of the Horizon Europe programme and the UK Research Excellence Framework
B4	Meeting stakeholder needs in Research for Civil Security Programme of Federal Ministry of Education and Research (BMBF), Germany

Source: Compiled by the study team.

Annex 6: Co-funded partnership reports (6-pagers)

The study covered **3 Co-funded partnership reports (6-pagers)** as a part of the Resilient Europe study, feeding into the Final Report for the evaluation of the European Framework Programmes for Research and Innovation for a Resilient Europe. The 6-pagers were particularly relevant to Cluster 1 Health and complemented the analysis. Completed partnership reports are presented in Annex 6, separate from this document.

Table 125. Resilient Europe under Horizon Europe: Co-funded partnership reports (6-pagers)

Title of the co-funded partnership report (6-pager)				
THCS	European Partnership for Transforming Health and Care Systems			
PRAC	European Partnership for the Assessment of Risks from Chemicals			
ERA4Health	Fostering a European Research Area for Health Research Partnership			

Source: Compiled by the study team.

Annex 7: Analysis of the Online Public Consultation results

The EC organised an Online Public Consultation (OPC) as part of the European Union Framework Programmes (FP) for Research and Innovation (R&). It aimed to collect the views and opinions of research institutions, citizens, businesses, business organisations, non-governmental organisations, public authorities and stakeholders on the "past, present and future of the European Research & Innovation Framework Programmes 2014-2027". The public consultation took place between 01 December 2022 and 23 February 2023 and was accessible through the EUSurvey.

Following the consultation, on 18 April 2023, the EC published a Factual Summary Report which features further information, such as an overview of respondents, information on organised campaigns and an overview of position papers. In addition, a Synopsis Report of the consultation was published, which features results of **Section**

D of the questionnaire "Looking into the R&I future priorities 2025-2027" of the OPC questionnaire. The study team understands that another synopsis report of the consultation results is expected to be published by the EC in late June 2023, which may cover the remaining questions in detail.

According to the Factual Summary Report⁴⁹⁹, the consultation addressed the European Union Framework Programmes (FP) for Research and Innovation, namely Horizon 2020 (8th FP) and Horizon Europe (9th FP), as well as Horizon Europe's Strategic Plan for 2025-202. Respondents were asked to complete **Section C**, dedicated to **"Performance of Horizon Europe"**, **Section D**, dedicated to **"Looking into the R&I future priorities 2025-2027"**, and **Section E**, dedicated to **"Key lessons learned and messages for the future"**. The sections mentioned above feed into the mid-term evaluation of Horizon Europe. The results of particular interest to the Resilient Europe Study are further presented in this Annex.

This Annex provides a detailed overview of the OPC contributions that fed into the supporting study of the interim evaluation of Horizon Europe, largely providing insights into the evaluation questions on relevance, coherence and EU added value, as well as some input to other evaluation criteria-related questions.

Overview of respondents

A total of **2 782 respondents** provided feedback to the OPC, representing various stakeholders and beneficiaries such as the **academic/research institutions (49.1%)**, **companies/businesses (17.1%)**, **EU citizens (13.2%)**, **public authority (5.1%)**, **other (4.9%)**, **non-governmental organisations (NGOs) (4.7%)**, **non-EU citizens (3.1%)**, **business associations (2.6%)**, **environmental organisations (0.3%)**, **and trade unions (0.1%)**⁵⁰⁰. The geographical scope of the respondents included all EU countries, with the most participants from the following five countries: Italy (13%), Germany (11%), France (11%), Spain (10%) and Belgium (6%) and non-EU countries, e.g., United Kingdom (3%), Turkey (2%), Switzerland (2%), Ukraine (0%), Israel (0%).

The number of responses for each question varies as the respondents had the option to choose which questions to complete.

1.9. Results of interest to the Resilient Europe Study

The study team analysed the raw data of the selected questionnaire responses. Specifically, the team looked at questions feeding into the mid-term evaluation of Horizon Europe. The raw data of the OPC consultation shared by the EC has been cleaned and analysed accordingly. We filtered and did not consider incomplete responses (e.g., empty questionnaire), as well as responses with less than three answers. Out of the remaining **2 732 responses**, the study team produced figures presenting the results of the relevant questions. The study team is aware that the above-mentioned Factual Summary Report and a Synopsis Report present an overview of respondents specifically for Sections C and D, respectively. However, we performed this brief selective overview of the OPC raw data as a whole (including all

⁴⁹⁹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13444-Horizon-2020-programme-finalevaluation/public-consultation en

⁵⁰⁰ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13444-Horizon-2020-programme-finalevaluation/public-consultation en

the relevant sections for our study). Thus, the final number of responses might differ from what a Factual Summary Report and a Synopsis Report present.

The section below presents the results of the OPC relevant to the Resilient Europe Study from Section C ("Performance of Horizon Europe), Section D ("Strategic Plan of Horizon Europe") and Section E ("key lessons learned and messages for the future"). Section C – Performance of Horizon Europe

Section C features opinions regarding the **Performance of Horizon Europe**, focusing on assessing what stakeholders are experiencing to adapt current actions possibly. **Section C ("Performance of Horzion Europe")** feeds into the midterm evaluation of Horizon Europe, covering 2021 – 2023.

1.9.1. According to you, what are the main benefits of participating in Horizon Europe compared to national and/or regional R&I programmes in EU Member States or Associated Countries?

Respondents were asked to identify the main benefits of participating in Horizon Europe compared to the national and/or regional R&I programmes in EU Member States or Associated Countries. The Figure below presents a list of potential benefits Horizon Europe offers compared to national and/or regional R&I programmes. Out of 14 different given benefits, respondents were asked to select a maximum of 3 answer options. A total of **1 593 respondents** answered this question, and the Figure below is accompanied by the number of respondents who have chosen the option as a perceived advantage.

As a result, the data reveals that participating in Horizon Europe offers numerous advantages over national and/or regional R&I programmes. Approximately **half of the respondents** found **improved cooperation with partners from other countries and** *improved excellence in research and innovation* as the main benefits of participating in Horizon Europe. Only **9 respondents** claimed that *Horizon Europe brings no additional benefits compared to national/regional support*. Thus, the data and figures reinforce the notion that Horizon Europe presents valuable opportunities for researchers and innovators to thrive on a larger and more impactful scale.

Figure 135. Main benefits of participating in Horizon Europe compared to national and/or regional R&I programmes in EU Member States or Associated Countries

Main benefits of participating in Horizon Europe compared to national and/or regional R&I programmes in EU Member States or Associated countries



Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 593.

1.9.2. In your view, what are the main reasons that may have prevented of potential beneficiaries from participating in Horizon Europe?

The Figure below presents a list of potential reasons that may have prevented beneficiaries' participation in Horizon Europe. Out of 12 presented reasons, respondents were asked to select a maximum of 3 answers. A total of **1 582 respondents** answered this question, and the Figure below is accompanied by the number of respondents who have chosen the option as a perceived obstacle to participating in Horizon Europe.

As a result, data reveals that participating in Horizon Europe is subject to some challenges. These include success rates need to be higher in Horizon Europe to be worth applying to, as indicated by 914 participants (58%), followed by the Horizon Europe application process being cumbersome, as indicated by 663 participants, which is almost half (42%) of the participants. Almost half of the participants indicated that inadequate knowledge of the EU research and innovation framework programme (643 respondents) and limited financial/human resources to prepare a proposal (629 respondents) are some of the main reasons hindering participation.

In addition, respondents were asked to share any other reasons that may have prevented potential beneficiaries from participating in Horizon Europe. A total of **294 respondents provided** a reply to this open-ended question listing various main reasons. Some of the examples include:

- Heavy administrative burden throughout the duration of the project;
- Challenging proposal process;
- Lack of funding;
- Lack of experience;
- The complexity of the requirements in terms of size and scope;
- Geographical barriers;
- Unfair competition between large and small institutions.

Thus, while the data and figures reinforce the notion that although Horizon Europe provides valuable opportunities for beneficiaries, it also presents certain obstacles and challenges that, according to the respondents of the OPC, hinder participation in the programme.

Figure 136. Main reasons that may have prevented of potential beneficiaries from participating in Horizon Europe

Main reasons that may have prevented of potential beneficiaries from participating in Horizon Europe



Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 582.

1.9.3. In your view, to what extent do the following changes introduced in Horizon Europe contribute to strengthening the impact of European research and innovation?

Participants were asked to identify to what extent the different challenges introduced in Horizon Europe contribute to strengthening the impact of European research and innovation. The Figure below presents a list of challenges introduced in Horizon Europe that may have strengthened the impact of European research and innovation. For 8 presented changes, respondents were asked to provide their opinion to what extent they consider the contribution of the changes impactful by choosing the following answer options: "not at all", "a little", "does not make a difference, "somewhat", "to a great extent", "I do not know/no opinion". A total of **1 577 respondents** answered this question, and the Figure below is accompanied by the number of respondents who have chosen the option as a perceived contribution to the impact.

As illustrated in the Figure below, in all cases, **almost half** of the respondents perceive the changes introduced in Horizon Europe to be **somewhat impactful**, except for **the** *implementation of an open science policy*, which is considered **highly impactful** by almost half of the participants. When examining individual opinions within the categories, there is no significant difference in their tendencies. Only a **few participants (i.e., 44, 39, 51)** consider the contribution **not to be significant enough**.

In conclusion, the changes introduced in Horizon Europe happen to have a noticeable impact on the public consultation participants.



Figure 137. Contribution of the changes introduced in Horizon Europe to the impact of European research and innovation

Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 577.

1.9.4. To what extent do you agree with the following statements concerning proposal evaluation under Horizon Europe?

Respondents were asked to evaluate the 3 given statements (i.e., on evaluation of proposals, clarity of the feedback, and time taken to sign the grant agreements) concerning proposal evaluation under Horizon Europe. The Figure below presents the statements to which respondents

could indicate their position by noting the extent to which they agree or disagree with the statements. Out of **1 579 respondents, the majority** indicated that they agree with the 3 statements. What concerns the time taken to evaluate proposals is adequate, and the time taken to sign the grant agreement is adequate, **830 (53%) and 800 (51%) participants** agreed with those statements, respectively. Some **567 (36%)** participants agreed that the feedback received regarding the evaluation was clear and informative.

Out of 1 579 respondents, some indicated that they disagree or neither agree nor disagree with the 3 statements. 177 (11%) participants disagreed and 240 (15%) neither agreed nor disagreed that the time taken to evaluate the proposal was adequate. 305 (19%) disagreed, and 343 (22%) neither agreed nor disagreed that the feedback received regarding the evaluation was clear and informative. 102 (6%) disagreed, and 208 (13%) neither agreed nor disagreed that the time taken to sign the agreement was adequate.

Thus, the data and figures reinforce the notion that most proposal evaluation under Horizon Europe is flexible and adequate for the programme participants.





Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 579.

1.9.5. To what extent do you agree with the following statements concerning the project implementation under Horizon Europe?

Respondents were asked to evaluate the 7 statements concerning project implementation under Horizon Europe (i.e., on support, costs, accounting, mechanisms for project monitoring and reporting, templates, single audit principle, lump sum funding). The Figure below presents the statements to which respondents could indicate their position by agreeing or disagreeing with them. A total of **1 567 respondents** answered this question, and the Figure below is accompanied by the number of respondents who have chosen the option as perceived position.

Overall, the key tendency observed from the data is that respondents generally had mixed opinions and varied levels of agreement or disagreement on the statements concerning project implementation under Horizon Europe. There is no clear consensus or dominant trend in the responses. Different respondents had different perspectives and experiences, resulting in diverse opinions across the statements.

However, looking closer at the key highlights, as illustrated in the Figure below, almost half of the participants agree with the notions that they are satisfied with the support they receive from EC services, the cost calculation rules are clear, their organisations' usual practices were accepted, and more than half of the participants agree that the mechanisms for project monitoring and reporting are adequate, followed by the extension of the single audit principle reducing the burden of beneficiaries. Although responses across the categories are guite similar, it is important to note that a large number of participants (i.e. 499, 486, 338) do not hold any particular knowledge or opinion, and across all the categories, a number of respondents (i.e. 94, 141, 179, 41) express their disagreement. The latter can be explained by the fact that projects are still ongoing, and respondents might not have been exposed to particular features.



Figure 139. Project implementation under Horizon Europe

Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 567.

1.9.6. What is your level of satisfaction with the way the European Commission implements the following types of support under Horizon Europe?

Respondents were asked to evaluate their level of satisfaction with the way the European Commission implements various support under Horizon Europe. The Figure below presents 10 different supports. A total of **1 625 respondents** answered this question, and the Figure below is accompanied by the number of respondents who have chosen the option as perceived position.

Overall, the data reveals that respondents' satisfaction levels varied across different types of support under Horizon Europe, with some areas receiving higher levels of satisfaction. In comparison, others showed mixed opinions or lower levels of satisfaction.

Looking individually at the categories, as illustrated in the Figure, it is clear that a **significant portion** (in some cases **more than half** or **almost half**) of the participants either **do not hold any particular opinion or have not used the particular support**. It is also clear that a **large number of participants (793, which is almost half)** expressed their **satisfaction** with the grants for collaborative projects. All the other answers are quite similar across the categories, however, it is important to note that across all the given support, a few participants expressed their **dissatisfaction** (i.e. 64, 97, 147 participants).

To conclude, although a significant amount of respondents did express their satisfaction, a large number of participants remain unaware or unexposed to particular support.



Figure 140. Level of satisfaction with the European Commission's implementations under Horizon Europe

Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1625.

1.9.7. Do you think the different types of support made available by Horizon Europe are suitable for your needs?

Respondents were asked to identify whether the different types of support made available by Horizon Europe are suitable for their needs. The Figure below illustrates the distribution of responses in percentages. A total of **1 576 respondents** answered this question, and the Figure below presents their perceived opinions.

Overall, out of 1 576 respondents, **nearly half (45%)** view the support provided by Horizon Europe as largely suitable for their needs, while less than half, yet a significant amount of participants, hold a *neutral position* (31%) and a few (10%) view the **support provided** *scarcely suitable*. In addition, respondents were asked to elaborate on their answers or share any other needs they might have from Horizon Europe. 567 respondents provided a reply to this open-ended question. Some examples of the responses include the following:

- Clarity and simplification
- Smaller scale scopes to reach faster uptake
- A closer interaction between projects and policy DGs needed
- A contact person in case of a technical issue or a professional question
- Support for language learning
- More bottom-up calls
- More transparency
- More training sessions
- Easier access for SMEs

In conclusion, although a large number of participants consider different types of support made available by Horizon Europe largely important for their needs, it is important to consider the diverse perspectives and individual requirements when assessing the effectiveness of Horizon Europe's support programmes.

Figure 141. Different types of support made available by Horizon Europe



Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 576.

1.9.8. The effort needed to participate in Horizon Europe compared to Horizon 2020 is:

Respondents were asked to identify the level of effort needed to participate in Horizon Europe compared to Horizon 2020. The Figure below illustrates the distribution of responses in percentages. A total of **1 578 respondents** answered this question, and the Figure presents their perceived opinions.

Overall, while more than half of the participants (55%) do not hold any particular opinion, a significant amount of participants (36%) view the level of effort to participate in Horizon Europe compared to Horizon 2020 as similar and 8% view the effort as *greater*.

The presented results are important to understand the perceived participation efforts when evaluating the transition from Horizon 2020 to Horizon Europe.

Figure 142. The effort needed to participate in Horizon Europe compared to Horizon 2020



Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 578.

1.9.9. The effort needed to participate in Horizon Europe compared to that of other similar international research and innovation programmes was:

Respondents were asked to identify the level of effort needed to participate in Horizon Europe compared to other similar international research and innovation programmes. The Figure below illustrates the distribution of responses in percentages. A total of **1 572 respondents** answered this question, and the Figure presents their perceived opinions.

Overall, while **41% of the respondents indicated that they** do not hold any particular opinion, around **a third of respondents (32%)** consider that it takes them a *greater level of effort* to participate in Horizon Europe activities compared to other similar R&I programmes. About a **quarter (24%)** said that it takes them a *similar effort*, while

only **3%** indicated that it takes them a *lower effort* to participate in Horizon Europe compared to other international R&I programmes.

The presented results are important to understand the perceived participation efforts when evaluating Horizon Europe compared to similar R&I programmes.

Figure 143. The effort needed to participate in Horizon Europe compared to other similar international research and innovation programmes



Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 572.

1.9.10. Approximately how much time did the proposal preparation for Horizon Europe take overall? Please indicate the total number of person-days.

Participants were asked how much time the proposal preparation for Horizon Europe took. The Figure below presents 8 different numbers of persondays that participants had to choose from. A total of **1 437 respondents** answered this question, and the Figure below is accompanied by the number of responses and percentages participants consider relevant.

The data reveals that **281 participants (20%)** needed *more than 60 but below 100 person-days*, **231 participants (16%)** needed *more than 30 but below 40 person-days* and **213 participants (15%)** needed *more than 100 person-days*, which concludes that approximately **half of the respondents spent on proposal preparation less than 30 and more than 100 person-days**. Overall, the presented data provide valuable insights for effective project planning, risk assessment and consideration for future improvement.

Figure 144. The time needed for the proposal preparation for Horizon Europe



The time needed for the proposal preparation for Horizon Europe

Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 437.

1.9.11. Approximately how much time does your project spend on managing participation in Horizon Europe? Please indicate the total number of person-days spent overall on managing participation.

Participants were asked how much time managing participation in Horizon Europe took. A total of **1 033 respondents** answered this open-ended question and specified the total number of person-days spent overall on managing participation. As a result, person-days spent on managing participation vary depending on the programme and its duration. Some examples of the responses included the following:

- 2 person-day for a project of 24 months
- 15 person-days per year
- 15 days per 36 months
- Approximately 30 person-days in total for a project duration of 48 months
- Approximately 20 person-days in a 24-month project (as a partner)
- 50 person-days for a project of 36 months
- 72 days on 36 months
- Approximately 90 person-days in total for a project duration of 36 months
- 180 person-days for a project of 48 months
- 200 person-days for 12 months
- Approximately 240 person-days in total for a project duration of 60 months
- Approximately 500 person-days in total for a project duration of 48 months
- Approx 600 person-days in total for a project duration of 48 months
- 800 persons-days in total for a project duration of 24 months

Awareness of the time commitment involved in managing participation in Horizon Europe is important for stakeholders to optimise their efforts and resources and contribute to more efficient programme implementation.

Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 033.

1.9.12. How can the administrative burden for applicants and participants be further reduced (regarding the application process, reporting requirements, cost calculation etc.)?

Respondents were asked how the administrative burden for applicants and participants could be further reduced. A total of **826 respondents** answered this openended question. The responses highlight various ways in which the administrative burden can be reduced. Some of the key examples are the following:

- Standardising requirements: Respondents suggest that certain requirements, such as data management issues, could be standardised to reduce the burden on applicants. They believe that these requirements are often redundant and distract from the scientific concept of the proposals.
- Faster process: Respondents emphasise the need for a faster process to avoid mobilising staff between the proposal and contract stages. A quicker process would save time and resources for the applicants.
- Al support systems: Developing Al support systems that assist with completing documents, such as application processes, reporting requirements, and cost calculations, could alleviate administrative tasks and allow administrations to focus on other necessary tasks.
- Streamlined templates: Respondents recommend better and simpler templates for applications to reduce complexity and repetition.
- Improved guidance and information: Providing more information on specific issues, simplifying processes, and offering more help to applicants and participants can reduce the administrative burden.
- Two-stage calls: Increasing the number of two-stage calls, where the initial step involves shorter applications and only selected applicants proceed to submit full proposals, can save time and effort for applicants.
- The clarity in communication: Respondents highlight the need for clearer communication and messages from the EU portal to avoid misunderstandings and confusion among applicants and participants.
- Standardisation and harmonisation: Respondents suggest standardising and harmonising practices across different aspects, such as requirements for governing bodies and evaluation processes, to reduce redundancy and contradictions.
- Reduction in reporting: Respondents recommend reducing the frequency and volume of reporting requirements during the project to minimise administrative burden.
- Lump sum funding: Some respondents propose the use of lump sum funding and outcome-based reporting instead of detailed financial auditing, which could simplify the administrative processes for beneficiaries.

In conclusion, the suggestions address the challenges applicants and participants face while participating in the programme to reduce the administrative burden that can ensure the programme's efficiency.

Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=826.

1.9.13. To what extent do you agree that Horizon Europe is on track to deliver on the following objectives?

Participants were asked to assess to what extent Horizon Europe is on track to deliver the objectives. The Figure below presents a list of objectives introduced in Horizon Europe. For 10 presented changes, respondents were asked to provide their opinion by agreeing or disagreeing with the objectives being on track under Horizon Europe. A total of **1 564 respondents** answered this question, and the Figure below is accompanied by the number of respondents who have chosen their perceived opinion.

As a result, it is clear from the Figure below that in all cases, **approximately half** of the respondents agreed that Horizon Europe is on track to deliver the given objectives. Having said this, for all of the listed objectives, approximately **9% of respondents** *disagreed or strongly disagreed* with the Horizon Europe being on track to deliver the objectives. This could be due to a variety of reasons, such as delays with the projects starting or due to the majority still ongoing.



Figure 145. Horizon Europe delivering the objectives

Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 564.

1.9.14. To what extent do you agree that the implementation so far of EU Missions is on track to deliver on their objectives?

Respondents were asked to evaluate to what extent they agree that EU Mission's implementation is on track to deliver on their objectives, including prevention, cure and solutions for cancer. A total of **1 539 respondents** addressed their opinion, and the Figure below is accompanied by the number of respondents who have chosen the option as perceived position.

As illustrated in the Figure, a large number of participants (55%) do not hold any particular opinion, 17% neither agree nor disagree, 15% agree, and 6% strongly agree that EU Missions are on track to deliver cancer mission-related objectives.

Additionally, respondents were asked to elaborate on the EU Missions overall. **338 respondents** answered this open-ended question. Some of the examples are the following: EU Missions introduced too much complexity in the global understanding of EU funding schemes, the missions have been an unclear programme which makes it difficult to assess and participate, Ineffective, projects slow, not linked to real change.

The findings suggest that the respondents might lack knowledge or feel uncertain regarding the progress of cancer mission-related objectives. This could be due to the fact that the activities, for example, of the Mission on Cancer, are still in the early implementation stages, and there is no clear conclusion regarding the effectiveness of the partnerships and Missions under Horizon Europe.

Figure 146. EU missions delivering the objectives



Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 539.

1.9.15. Compared to Horizon 2020, the use of public-public and public-private partnerships has been streamlined with fewer but more impact-oriented partnerships, which can take three forms: co-funded, co-programmed and institutionalised European Partnerships. To what extent do you agree with the following statements?

Participants were asked to assess whether public-public and public-private partnerships have been streamlined with fewer but more impactoriented partnerships in the forms of co-funded, co-programmed and institutionalised European partnerships. The Figure below presents the 2 statements in which respondents could indicate their position by agreeing or disagreeing. A total of **1 550 respondents** answered this question, and the Figure below is accompanied by the number of respondents who have chosen the option as perceived opinion.

As illustrated in the Figure below, for both presented statements, it is clearly demonstrated that **almost half** of the participants (42% and 43%) do not hold any particular opinion and, only less than half of the participants (23% and 22%) agree that the rationalisation of European Partnerships has allowed additional public and private investments in research and innovation to be leveraged and that the rationalisation of the Europen Partnerships has led to delivering more solutions for the benefits of society, the environment and the economy. Notably, the number of participants (18% and 20%) who neither agreed nor disagreed with the statements is comparable to the number of participants who agreed with them.

Overall, while some agreed with the statements, a significant portion either held no opinion or remained neutral on the matter. This suggests a need for more knowledge among the participants regarding the impact of the rationalisation of European Partnerships.



Figure 147. The use of public-public and public-private partnerships

Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 550.

1.9.16. In your opinion, to what extent are European Partnerships and EU Missions supported by Horizon Europe effective compared to regular collaborative research projects in achieving Horizon Europe's objectives?

Respondents were asked to assess to what extent the European Partnerships and EU Missions supported by Horizon Europe are effective compared to regular collaborative research projects in achieving Horizon Europe's objectives. A total of **1 541 respondents** answered this question, and the Figure below is accompanied by the number of respondents who have chosen the option as perceived opinion.

As illustrated in the Figure below, almost half of the participants (37% and 44%) do not hold any particular opinion or knowledge regarding the effectiveness of European Partnerships and EU Missions supported by Horizon Europe. 23% and 22% of participants consider *European Partnerships to a great extent and somewhat effective*, respectively, which is less than half of the participants. Regarding the effectiveness of the *EU missions*, 12% and 20% consider *EU missions to a great extent and somewhat* effective, respectively. A larger proportion of participants have a favourable perception of the effectiveness of European. However, it is important to note that neither represents a majority of the total participants. Thus, there is no clear conclusion regarding their overall impact. Among those who expressed an opinion, less than half believe in the effectiveness of these initiatives. This indicates that further efforts may be needed to increase awareness and understanding of these programmes.



Figure 148. Effectiveness of European Partnerships and EU Missions supported by Horizon Europe

Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 541.

1.9.17. According to o you, to what extent is your research or innovation project impacted by the exceptional limitations on participation in Horizon Europe by non-EU legal entities (justified to safeguard the Union's strategic assets, interests, autonomy or security)?

Participants were asked to assess the extent to which their research or innovation project was impacted by the exceptional limitations on participation in Horizon Europe by non-EU legal entities. A total of **1 531 respondents** answered this question, and the Figure below is accompanied by the number and percentage of respondents who have chosen the option as a perceived opinion.

Close to a quarter of respondents (ranging from 19% to 24%) perceived research or innovation projects to be impacted, a little, somewhat, or not at all impacted by the exceptional limitations. Some 10% of respondents perceived the impact "to a great extent". While 24% claimed no particular opinion.

Figure 149. Research or innovation projects impacted by the exceptional limitations on participation in Horizon Europe by non-EU legal entities



Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 513.

1.10. Section D – Looking into the R&I future priorities 2025-2027

Section D features opinions for the upcoming Strategic Plan of Horizon Europe (2025 – 2027), focusing on the societal challenges that should shape future EU R&I activities, EU Missions, European Partnerships, synergies, etc.

The results of **Section D** ("Looking into the R&I future priorities 2025-2027") are featured in a Synopsis Report published by EC in April 2023. In this section, respondents identify priorities and societal challenges for the future, expected impacts across the Clusters, synergies and complementarities, EU Missions, and European Partnerships. The results featured in **Section D** that concerns the interim evaluation of Horizon Europe are the following:

Identifying priorities and societal challenges for the future

- The most important R&I solution over the next 10 years
- The most important societal challenges in the next 10 years
- The most important challenges in the next 3 years
- The Horizon Europe clusters address the societal challenges
- Scientific areas of strengths or weaknesses which should be prioritised in Horizon Europe to keep Europe at the forefront of international scientific competition

Expected impacts across the Clusters

- Cluster 1 Health
- Cluster 2 Culture, creativity and inclusive society
- Cluster 3 Civil security for society.

Synergies and complementarities

- Between Horizon Europe clusters
- With other parts of Horizon Europe
- With other EU programmes.
- EU Missions, European Partnerships and specific issues
 - The EU Missions added value
 - Areas in which the partnership approach could deliver more impacts
 - Specific issues in the Strategic Plan.

1.11. Section E – Key lessons learned and messages for the future

Section E features opinions about the key lessons learned and messages for the future on the intervention models and types of action, on identifying funding priorities and on implementing the programme/projects and procedures.

1.11.1. What are your key lessons from the past and present European Framework Programmes for Research and Innovation and the messages you would like to pass on for the future of the programme?

Respondents were asked to identify key lessons learned from the past and present European Framework Programmes for Research and Innovation and the messages they would like to pass on for the future of the programme. A total of **1 263 respondents** answered this open-ended question addressing a variety of the lessons learned and messages. Respondents were asked to indicate their opinion *on the intervention modes and types of action, on the identification of funding priorities* and *on the implementation of the programme/projects and procedures.* The key examples of the responses are the following:

On the intervention modes and types of action:

- Simplified funding and reporting: Implement simplified forms of funding and reporting to enhance the program's attractiveness.
- Increased support for SME participation: Provide further support to ensure the active participation of small and medium enterprises (SMEs) in the program.
- Restore specific calls for Science in Society (SWAFS): Reinstate dedicated calls for Science in Society to address the unique needs and priorities within this theme.
- Simplify schemes to reduce bureaucracy: Simplify program schemes to enable researchers to focus on research rather than navigating complex administrative processes.
- Encourage international participation: Foster international participation, particularly from low and middle-income countries, to strengthen Europe's position as a leading research actor on a global scale.
- Enhance flexibility and agility: Introduce more flexibility in intervention modes to adapt to changes in the social, technological, and other landscapes. Differentiate between types of actions to better align with their specific requirements and provide support and guidance to smaller companies to join these actions.
- Promote networks and support young talent: Promote the creation of networks across Europe, support the development of young talent, attract talent, and uphold European values within the program.
- Strive for a balance between RIA and IA actions: Address the current struggle between Research and Innovation Actions (RIA) and Innovation Actions (IA) by finding a better balance. Shift focus back to groundbreaking research while ensuring effective productisation and commercialisation.
- Essential collaboration between industry and research organisations: Emphasise the importance of collaboration between industry and research organisations to drive innovation and create impactful outcomes.

- Achieve better balance in TRL calls: Seek a better balance between lower and higher Technology Readiness Level (TRL) calls in the cluster work programs of Pillar II. Create more opportunities for collaboration between industry and universities and establish a research and innovation chain. Reduce prescriptive topics at lower TRLs, allowing researchers greater autonomy in defining their approach while incentivising interdisciplinarity.
- Foster cooperation with European cities: Increase cooperation with European cities to leverage their resources, expertise, and potential for research and innovation.
- Improve synergies: Enhance coordination and synergies between different initiatives, programs, and stakeholders to maximise the impact and effectiveness of the program.
- On the identification of funding priorities:
- Gender equality and inclusiveness: Prioritise initiatives that promote gender equality and foster inclusivity within the program.
- Climate change, energy, and cybersecurity: Allocate significant funding to address these major challenges facing the European region.
- Transparency and societal involvement: Enhance transparency in decision-making processes and actively involve stakeholders from various sectors of society.
- Innovation-driven and resource-neutral growth: Emphasise innovation and sustainable economic growth, as other aspects are likely to follow suit with successful implementation.
- Active involvement of experts: Seek greater engagement of industry and research stakeholders, including participants from previously funded actions in relevant areas.
- Open source software: Give priority to projects and initiatives that utilise open-source software to promote collaboration and knowledge sharing.
- Streamlined funding programs: Reduce the number of funding programs to provide clarity and simplicity, making it easier for stakeholders to navigate.
- Focus on game-changing innovation and cross-disciplinary knowledge: Support research and initiatives that have the potential for transformative impact and generate cross-disciplinary knowledge.
- Support for disruptive SMEs: Improve access to financing for small and medium-sized enterprises (SMEs) to foster their role as disruptive innovators. Develop a stronger market for patents and licensing to enhance returns on innovation.
- Addressing key concerns: Address prominent concerns such as biodiversity, climate change, ageing-related health issues, and energy in the program's strategic priorities.
- Reduced bureaucracy: Streamline administrative processes to minimise bureaucratic hurdles and enhance efficiency in program implementation.

On the implementation of the programme/projects and procedures:

- Further simplification: Continue efforts to simplify the program's processes and procedures.
- Facilitate implementation of cascade funding: Make it easier for participants to access and utilise cascade funding opportunities.
- Effective monitoring with less reporting: Streamline reporting requirements and prioritise more effective monitoring mechanisms.
- Quality over bureaucratic considerations: Ensure that the quality of proposals takes precedence over bureaucratic considerations.
- Simplified application procedure: Simplify the application process to reduce complexity and improve accessibility.
- Enhanced transparency: Increase transparency by providing comprehensive information on cascading funds, partnerships, missions, and prizes through platforms like eCORDA.
- Avoidance of lump sums: Minimise the use of lump sums and utilise time-sheet-based reporting for greater accuracy.
- Increased flexibility and adaptation: Enhance the capacity for projects to adapt and align with specific requirements, providing more flexibility within EC rules.
- Balancing applied research and low/medium TRL activities: While addressing applied research and societal needs, allocate attention and resources to low and medium Technology Readiness Level (TRL) research activities to foster disruptive R&D for future innovation. Consider Member States' priorities in program implementation.
- Streamlined bureaucracy with appropriate control and supervision: Reduce unnecessary bureaucracy while maintaining appropriate control and supervision measures.
- Assessing lump sum pilot for collaborative projects: Conduct a thorough assessment of the lump sum pilot for collaborative projects, addressing concerns and clarifying guidelines before expanding its usage.

Other:

- Simplify funding structures and tools: Streamline and simplify the diverse funding structures to make them more accessible and less complicated. Develop tools that aid applicants in selecting the appropriate funding scheme for their specific concepts. Additionally, simplify the proposal submission process by reducing the number of pages and implementing common templates across different funding schemes.
- Early communication of work programs: Provide applicants with early and timely information about the work programs. Three months between the publication of a work program and the first submission deadline is considered insufficient, so efforts should be made to ensure applicants have adequate time to prepare and submit their proposals.

 Although participants' experiences differ, the key messages revolve around simplification, support for SMEs, flexibility, collaboration, balanced funding priorities, reduced bureaucracy, and transparency. The survey responses provide valuable insights to guide the future development and improvement of the European Framework Programmes for Research and Innovation.

Source: Compiled by the study team based on the results of the EC OPC on the past, present and future of the European Research & Innovation Framework programmes 2014-2027, N=1 263.

Annex 8: Surveys

For the evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe, a survey programme has been carried out. Two surveys – 1) successful applicant organisations and 2) unsuccessful applicant organisations – have been launched on May 22 and May 19 2023, respectively.

The Annex 8 provides overall scope and results of the survey programme, overview of respondents and results of interest to the present study and methodological aspects and steps taken in cleaning partial survey responses.

1.12. Overall scope and results of the survey programme

The design of the survey programme enables the comparison of organisations that benefitted from participation in Horizon Europe (the "treated group") and similar organisations that did not benefit from participation in Horizon Europe ("comparison/control group").

The successful applicant organisations' survey included several questions that can be answered by participants of the outlined programme parts (i.e., MSCA, Research Infrastructures; Global Challenges & European Industrial Competitiveness (Cluster 1-4); WIDERA). Some questions particularly applicable to the Resilient Europe study have been included, such as the question on the Cancer Mission, ethics appraisal processes, barriers caused by the COVID-19 pandemic, and the role of civil society representatives and/or governmental institutions.

The unsuccessful applicant organisations survey featured questions that applied to MSCA (Doctoral Networks; Staff exchanges; and COFUND), Research Infrastructures; Global Challenges & European Industrial Competitiveness (Clusters 1-4); EIE and EIC (Transition and Pathways) WIDERA.

The Table below demonstrates a list of question areas/topics that were asked in each survey. The full questionnaires can be found in the parallel study titled *Excellent Science*.

Survey 1: Successful applicant organisations	Survey 2: Unsuccessful applicant organisations		
Background information (e.g., organisation type, country);	Background information (e.g., organisation type, country);		
The efficiency of application and administration processes;	The efficiency of application and proposal preparation resources and support needed;		
Inclusion of international partners;	Inclusion of external consultancy firms/experts;		
Involvement of the external consultants;	Relevance/ motivation to apply (e.g. (e.g., on Horizon Europe providing sufficient funding, Horizon Europe responding to the needs of the organisation);		

Table 126. Question areas for surveys
Programme's coherence and synergies (e.g., applying for additional funding, collaboration between programme parts and other EU initiatives);

Relevance/ motivation to apply (e.g., on Horizon Europe providing sufficient funding, Horizon Europe responding to the needs of the organisation, activities that could be integrated or further developed through funding under Horizon Europe);

Effectiveness (e.g., on potential/produced outputs by the Horizon Europe projects);

Outcomes and expected results;

Barriers and success factors;

Dissemination, exploitation and communication of results (e.g., publishing project results in open access, engaging civil society, presence of exploitation activities, update of results);

EU added value.

Source: Compiled by the study team.

Surveys' schedule

As of 5 July 2023, **2 863 participants responded to survey 1 (successful applicant organisations)** and **7 174 to survey 2 (unsuccessful applicant organisations).** As mentioned above, the survey population received their first invitation to participate in the surveys between May 19 and 22 May 2023. Following this, the response rates for each programme part were monitored closely, and **two rounds of reminders were sent** to the population to boost the response rate or the number of responses further.

- The first rounds of reminders went out between 1 and 5 June 2023. This reminder was sent to the programme parts with the smallest populations (e.g. Cluster 3). The rationale behind this reminder was not that those programme parts had a poor response rate but rather that their general population was the smallest, and the goal was to boost the number of responses instead of the actual rate.
- The second round of reminders went out to the entire population except for the Horizon Europe MSCA Postdoctoral Fellowships (not applicable to the Resilient Europe study's scope) between 19 and 22 June 2023. This second reminder significantly boosted the response rate of unsuccessful applicants and brought in thousands of responses.

Survey programme	Launch date	Reminder 1	Reminder 2	Closure date
Successful applicants, organisations	May 22	June 1	June 19-21	July 5
Unsuccessful applicants, organisations	May 19	June 5	June 19-21	July 5

Table 127. Survey schedule

Source: Composed by the study team.

Information about the developments following unsuccessful project application.

1.13. Overview of respondents

As of 5 July2023, **10 037 participants** who work in the programme areas related to Clusters 1, 2 and 3 responded to the two surveys. The Table below depicts the completed responses and response rates per programme part for each survey.

Programme part	Complete responses	Partial responses	Total responses (complete+partial)	Population/sent (valid)	Response rate (completes)	Response rate (total)	Launch date	Reminder round 1	Reminder round 2
Cluster 1	385	65	450	2 864	13.4%	15.7%	May 22	June 1	June 19-21
Cluster 2	336	51	387	1413	23.8%	27.4%	May 22	June 1	June 19-21
Cluster 3	150	25	175	796	18.9%	22.0%	May 22	June 1	June 19-21
Total (successful applicants)	871	141	1 012	5 073	56.1%	65.1%			

Table 128. Completed responses and response rates per programme part for survey one

Source: Compiled by the study team.

Table 129. Completed responses and response rates per programme part for survey two

Programme part	Complete responses	Partial responses	Total responses (complete+partial)	Population/sent (valid)	Response rate (completes)	Response rate (total)	Launch date	Reminder round 1	Reminder round 2
Cluster 1	847	64	911	10 537	8.0%	8.7%	May 19	-	June 19-21
Cluster 2	739	66	805	6 335	11.7%	12.7%	May 19	-	June 19-21
Cluster 3	286	20	306	2 251	12.7%	13.6%	May 19	June 5	June 19-21
Total (Unsuccessful applicants)	1 872	150	2022	19 123	32.4%	25.0%			

Source: Compiled by the study team.

1.14. Results of interest to the present study

Particularly for this Annex, the study team analysed the raw data of the selected questions within the scope of the present study. Specifically, the team looked at questions feeding into the evaluation of Horizon Europe, Clusters 1 (incl. The Mission on Cancer), 2 and 3. The steps taken to clean the partial survey responses are explained in Section 1.15. Out of the remaining 10 037 responses, the study team produced figures presenting the results of the relevant questions.

1.15. Methodological aspects and steps taken in cleaning partial survey responses

The surveys implemented for this study were programmed and sent out through the Alchemer⁵⁰¹ tool, which has been used extensively by the study team in other evaluation projects. One important feature of this tool is that it collects partial responses to the survey questionnaires, which allows for accessing survey response data even when a respondent does not fully complete the questionnaire (or when a questionnaire is complete but the 'submit' button is not clicked). This feature is particularly important in the case of long questionnaires, which may result in some respondents dropping out.

However, partial survey responses needed to be dealt with caution. A significant portion of those partials came from respondents who opened the survey and responded to very few background questions without reaching the main section of the questionnaire. Other respondents may have skimmed through the survey questions while selecting random responses just to be able to see what the survey was about without providing accurate or valid information. In order to exclude these cases and provide an analysis based on sound, accurate and valuable data, our study team conducted a thorough cleaning of partial survey responses.

The study team applied the following criteria for cleaning out all the partial responses:

- Partial responses that provided answers to background questions were removed. This eliminated responses that did not provide relevant information to answer evaluation questions (i.e. in addition to background information).
- Partial responses with suspicious answer patterns were excluded (e.g., a person has always picked the first answer option in all the multiple choice answers or always selected the same response option in matrices (e.g. always either "very important" or "important").
- Finally, respondents who took less than 2 minutes to answer the survey questionnaire were also excluded.

⁵⁰¹ https://www.alchemer.com/

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The portal <u>data.europa.eu</u> provides access to open datasets from the EU institutions, bodies, and agencies. These can be downloaded and reused for free, for both commercial and non-commercial purposes. The portal also provides access to a wealth of datasets from European countries. This final report provides the results of the 'Resilient Europe study' implemented in the period between January 2023 and January 2024. The study was completed by a consortium consisting of PPMI Group, Prognos, VTT and Maastricht University. Using a wide range of qualitative and quantitative methods, the study covers Horizon Europe activities that contribute to building a more resilient Europe in terms of addressing the following global challenges: Cluster 1; Cluster 2; Cluster 3. In parallel, the study also assesses the following partnerships: IMI2/IHI, EDCTP2/EDCTP3, EIT Health, THCS, ERA4Health and PARC.

Studies and reports

