innovative health initiative

IHI

9th Call for proposals

Single-stage call

COCIR Advancing Healthcare · efpia · EuropaBio The European Association for Bioindustries · MedTech Europe from diagnosis to cure · Vaccines Europe

Co-funded by the European Union

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Introduction

The Innovative Health Initiative Joint Undertaking (IHI JU) is a partnership between the European Union and industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry).

IHI JU aims to pioneer a new, more integrated approach to health research and builds on the experience gained from the Innovative Medicine Initiative 2 Joint Undertaking (IMI2 JU).

IHI JU aims to translate health research and innovation into real benefits for patients and society, and ensure that Europe remains at the cutting edge of interdisciplinary, sustainable, patient-centric health research. Health research and care increasingly involve diverse sectors. By supporting projects that bring these sectors together, IHI JU will pave the way for a more integrated approach to health care, covering prevention, diagnosis, treatment, and disease management.

As current health challenges and threats are global, IHI JU should be open to participation by international academic, industrial and regulatory actors, in order to benefit from wider access to data and expertise, to respond to emerging health threats and to achieve the necessary societal impact, in particular improved health outcomes for Union citizens.

Topics overview

HORIZON-JU-IHI-2025-09-01 **Boosting innovation for a better understanding of the determinants of health**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 25 000 000. Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.
HORIZON-JU-IHI-2025-09-02 **Boosting innovation through better integration of fragmented health R&I efforts**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 100 000 000. Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.
HORIZON-JU-IHI-2025-09-03 **Boosting innovation for peopled centred integrated healthcare solutions**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 30 000 000. Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.
HORIZON-JU-IHI-2025-09-04 **Boosting innovation through exploitation of digitalisation and data exchange in healthcare**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000. Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.

HORIZON-JU-IHI-2025-09-05 **Boosting innovation for better assessment of the added value of innovative integrated healthcare solutions**	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 12 000 000. Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.	Research and Innovation Action (RIA) Single-stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.

Call conditions for single stage and two-stage calls

For Call 9 please refer to the conditions relevant to the single-stage call

The submission deadline for full proposals (FPs) will be 29/04/2025.

Scientific evaluation of the single-stage call will take place in Q2 2025. Grant Agreement Preparation (GAP) will be completed within 3 (three) months from the notification to applicants of the evaluation results of the full proposal, and maximum eight months from the final date of submission of the FPs, in line with the applicable time to grant (TTG).

Conditions of the calls and call management rules

For call management, IHI JU will utilise the EC IT infrastructure available under Funding & Tender opportunities – Single Electronic Data Interchange Area (SEDIA).

The General Annexes of the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* to the calls for proposals covered by this Work Programme, including the "Restrictions for the protection of European communication networks" under General Annex B. In accordance with Article 5(2)(a) of the Council Regulation (EU) 2021/2085, in duly justified cases, derogations related to the specificities for IHI JU may be introduced in the relevant Work Programme. Where necessary, this will be done when the topic texts are identified in this Work Programme.

To maximise the efficiency of the calls management, IHI JU will continuously explore and implement simplifications and improve its processes while maintaining the highest standards of the evaluation process, in line with the applicable Horizon Europe rules.

All proposals must conform to the conditions set out in Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination.

GENERAL CONDITIONS RELATING TO THE IHI JU CALLS	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Financial and operational capacity and exclusion	The conditions are described in General Annex C.
Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.

Legal and financial set-up of the grant agreements	The conditions are described in General Annex G.

Any specificity for IHI JU is highlighted in the below sections:

STANDARD ADMISSIBILITY CONDITIONS, PAGE LIMITS AND SUPPORTING DOCUMENTS

General Annex A ('Admissibility') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

In addition, page limits will apply to proposals as follows:

- for a single-stage call, the limit for RIA full proposals is 50 pages;
- at the first stage of a two-stage call, the limit for RIA short proposals is 20 pages;
- at the second stage of a two-stage call, the limit for RIA full proposals is 50 pages.

STANDARD ELIGIBILITY CONDITIONS

General Annex B to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme unless otherwise provided in this Work Programme.

Per the above and by way of derogation from General Annex B of the Horizon Europe Work Programme 2023-2025:

According to Article 119 of the Council Regulation (EU) 2021/2085, for indirect actions selected under calls for proposals covered by this Work Programme:

- applicant consortia must ensure that at least 45% of the action's eligible costs and costs for additional activities related to the action are provided by contributions (IKOP, FC, IKAA) from private members which are members of IHI JU, their constituent or affiliated entities, and contributing partners;
- While the constituent or affiliated entities of the members other than the union of IHI JU can contribute any of those contribution types, contributing partners can only contribute IKOP and FC, not IKAA;
- further to the above, the applicant consortium must submit a self-declaration that the required percentage of 45% contributions will be provided;
- the eligibility condition above and the self-declaration requirement do not apply to the first stage of a two-stage application;
- at project level, the maximum amount of non-EU IKOP is set to:
  - Twenty percent (20%) for IHI JU Call 9[1]
  - One hundred percent (100%) for IHI JU Call 10

This is justified as a means to ensure the achievement of project objectives based on Article 119(5) of Council Regulation (EU) 2021/2085, and to ensure full openness to non-EU IKOP in these calls[2].

[1] Even if this threshold of 20% is not intended as an eligibility condition *per se*, proposals recommended for funding that will feature a non-EU IKOP amount higher than the 20% of IKOP, will be requested to remove the exceeding part. If this is the case, this non-EU IKOP reduction exercise will need to comply with eligibility criteria whereby at least 45% of the action's eligible costs and costs for additional activities related to the action are provided by contributions (IKOP, FC, IKAA) from private members which are members of IHI JU, their constituent or affiliated entities, and contributing partners.

[2] It has to be noted that, pursuant to Article 119(4) of Council Regulation (EU) 2021/2085, at the level of the IHI JU programme, non-EU IKOP must not exceed 20% of in-kind contributions to operational costs provided by private members which are IHI JU members, their constituent or affiliated entities, and contributing partners. Furthermore, at the level of the IHI JU programme, IKAA shall not constitute more than 40% of in-kind contributions provided by private members which are IHI JU members.

ENTITIES ELIGIBLE FOR FUNDING

In relation to the single-stage calls for proposals covered by this Work Programme, the relevant provisions of the General Annex B to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis*.

By way of derogation, in relation to the two-stage calls for proposals covered by this Work Programme, the following provisions shall apply:

- Legal entities identified in the topic text of the call for proposals shall not be eligible for funding from IHI JU. Nevertheless:

- These entities will be entitled to provide contributions as IHI JU members other than Union or contributing partners or as constituent or affiliated entities of either.

- Legal entities participating in indirect actions selected under this type of calls for proposals shall not be eligible for funding where:

    a) they are for-profit legal entities with an annual turnover of EUR 500 million or more;

    b) they are under the direct or indirect control of a legal entity described in point (a), or under the same direct or indirect control as a legal entity described in point (a);

    c) they are directly or indirectly controlling a legal entity referred to in point (a).

In line with Article 5(2)(a) (additional conditions in duly justified cases) and Article 119(3) (private contributions to amount of at least 45% of an indirect action's eligible costs and costs of its related additional activities) of the Council Regulation (EU) 2021/2085, under two-stage submission procedures, the following additional condition applies:

- The applicants which are IHI JU members other than the Union, or their constituent entities and affiliated entities, and contributing partners and that are pre-identified in the topics – under the section 'Industry consortium' – of a call for proposals shall not apply at the first stage of the call. The applicant consortium selected at the first stage shall, in preparation for the proposal submission at the second stage, merge with the pre-identified industry consortium.

- In addition, in line with Articles 11 and 119(1) and (3) of the Council Regulation (EU) 2021/2085, legal entities providing in-kind contributions as constituent entities or affiliated entities of IHI JU private members or as contributing partners that are:

    - Not eligible for funding in two-stage calls for proposals; or

    - Not established in a country generally eligible for funding in accordance with Part B of the General Annexes to the Horizon Europe Work Programme 2023 – 2025,

may exceptionally sign the grant agreement.

This is subject to the following conditions:

- Their participation is considered essential for implementing the action by the granting authority; and
- They participate without requesting any funding.

The essentiality of non-EU legal entities for implementing the action shall be ascertained by the granting authority.

LIST OF COUNTRIES AND APPLICABLE RULES FOR FUNDING

With reference to Article 23 of the Council Regulation (EU) 2021/2085, the eligibility of participants in a proposal submitted to a call for proposals for any of the topics in this Work Programme will take into

account any application of Art 22(5) of the Horizon Europe Regulation as well as Union legislation and guidance relevant for its application triggered for topics from other Horizon Europe Work Programmes for proposals with similar scope.

TYPES OF ACTION: SPECIFIC PROVISIONS AND FUNDING RATES

General Annex B ('Eligibility') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

EVALUATION RULES

General Annex D ('Award Criteria') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme with the following additions: The relevant calls for proposals launched under this Work Programme shall specify whether the call for proposals is a single-stage or two-stage call, and the predefined submission deadline.

Award criteria and scores:

Experts will evaluate the proposals on the basis of criteria of 'Excellence', 'Impact' and 'Quality and efficiency of the implementation' according to the type of action, as follows:

	Excellence Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:	**Impact** Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:	**Quality and efficiency of the implementation** Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:
First stage evaluation of two-stage procedure	• Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art. • Soundness of the overall methodology.	• Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.	• Quality and effectiveness of the outline of the work plan. • Capacity of each participant, and extent to which the consortium as a whole brings together the necessary expertise.
Single-stage and second stage of two-stage procedure	• Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art. • Soundness of the proposed methodology, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open	• Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project. • Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.	• Quality and effectiveness of the work plan, assessment of risks (including risk of falling below 45% contribution threshold), appropriateness of the effort assigned to work packages, and the resources overall. • Capacity and role of each participant, and extent to which the consortium as a whole establishes a public-private collaboration and brings together the necessary expertise. If relevant capacity and role of the contributing partner(s) to the consortium. • Clearly defined and effective integration of in-kind and financial contributions of IHI JU private members, their

	science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.		constituent or affiliated entities to enable a successful public-private partnership. If relevant clearly defined and effective integration of in-kind and financial contribution of contributing partner(s).

For all evaluated proposals, each criterion will be scored out of 5. Half marks may be given.

For the evaluation of proposals under both single-stage and two-stage submission procedures:

- the threshold for individual criteria will be 3;
- the overall threshold, applying to the sum of the three individual scores, will be 10;
- proposals that pass individual thresholds and the overall threshold will be considered for funding, within the limits of the available budget. Proposals that do not pass these thresholds will be rejected.

Under the single-stage evaluation procedure, evaluated proposals will be ranked in one single list. With the exception of those provisions herein for establishing priority order for proposals with the same score within the same budget envelope, General Annex F ('Procedure') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis.*

For proposals with the same score within a single budget envelope (with the exception of the first stage of two-stage submissions) the method to establish the **priority order** is as follows:

Starting with the group achieving the highest score and continuing in descending order:

1) Proposals that address aspects of the call that have not otherwise been covered by more highly ranked proposals will be considered to have the highest priority.
2) The proposals identified under 1), if any, will themselves be prioritised according to the scores they have been awarded for 'Excellence'. When those scores are equal, priority will be based on scores for 'Impact'.
3) Proposals that include the highest number of IHI JU private members and constituent and affiliated entities of the IHI JU private members.
4) Proposals that provide the highest percentage of contributions (IKOP, IKAA and financial contributions) from the IHI JU private members and contributing partners and the constituent and affiliated entities of both, of the proposal's eligible costs and costs for the related additional activities.
5) If necessary, the gender balance among the researchers named in the researchers table in the proposal, will be used as a factor for prioritisation.
6) If necessary, any further prioritisation will be based on geographical diversity, defined as the number of Member States or Associated Countries represented in the proposal, not otherwise receiving funds from projects higher up the ranking list (and if equal in number, then by budget).
7) If a distinction still cannot be made, the panel may decide to further prioritise by considering other factors related to the objectives of the call, or to IHI JU in general. These may include, for example, enhancing the quality of the project portfolio through synergies between projects or, where relevant and feasible, involving SMEs. These factors will be documented in the panel report.
8) The method described in 1) to 6) will then be applied to the remaining equally ranked proposals in the group.

The highest ranked proposals, within the framework of the available budget, will be invited to prepare a Grant Agreement.

Under the two-stage evaluation procedure, and on the basis of the outcome of the first stage evaluation, the applicant consortium of the highest ranked short proposal (first stage) for each topic will be invited to discuss with the relevant industry consortium the feasibility of jointly developing a full proposal (second stage).

If the first-ranked consortium and industry consortium decide that the preparation of a joint full proposal is not feasible, they must formally notify IHI JU within 30 days from the invitation to submit the second stage proposal. This notification must be accompanied by a joint report clearly stating the reasons why a second stage proposal is considered not feasible. In the absence of a joint notification within the deadline, it is deemed that the first ranked applicant consortium and the industry consortium are going to submit the joint second stage proposal. Accordingly, the second and third-ranked short proposals will be formally rejected.

If the preliminary discussions with the higher ranked proposal and the industry consortium fail, the applicant consortia of the second and third-ranked short proposals (first stage) for each topic may be invited by IHI JU, in priority order, for preliminary discussions with the industry consortium. The decision to invite lower-ranked consortia to enter into discussions with the industry consortium will take into account the content of the report from the joint report from the first-ranked consortium and industry consortium.

Under the two-stage evaluation procedure, contacts or discussions about a given topic between potential applicant consortia (or any of their members) and any member of the relevant industry consortium are prohibited throughout the procedure until the results of the first stage evaluation are communicated to the applicants[3].

As part of the panel deliberations, IHI JU may organise hearings with the applicants to:

1) clarify the proposals and help the panel establish their final assessment and scores, and/or;

2) improve the experts' understanding of the information presented.

In cases clearly identified in the relevant call for proposals where a given topic is composed of two or more sub-topics, one short proposal per sub-topic will be invited.

The IHI JU evaluation procedure is confidential.

The members of the applicant consortia shall avoid taking any actions that could jeopardise confidentiality.

Following each evaluation stage, applicants will receive an ESR (evaluation summary report) regarding their proposal.

INDICATIVE TIMETABLE FOR EVALUATION AND GRANT AGREEMENT PREPARATION

Information on the outcome of the evaluation (single-stage, or first stage of a two-stage):

- Single-stage: Maximum 5 months from the submission deadline at the single-stage.
- Two-stage: Maximum 5 months from the submission deadline at the first stage.

[3] Failure to observe this restriction may result in IHI JU rejecting either the breaching participant or the full proposal per Article 141 point 1, letter (c) of the REGULATION (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision.

Information on the outcome of the evaluation (second stage of a two-stage):

- Maximum 5 months from the submission deadline at the second stage.

Indicative date for the signing of grant agreement:

- Single-stage: Maximum 8 months from the submission deadline.
- Two-stage: Maximum 8 months from the submission deadline at the second stage.

General Annex G ('Legal and Financial setup of the Grant Agreements') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

BUDGET FLEXIBILITY

General Annex F to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* to the calls for proposals covered by this Work Programme.

SUBMISSION TOOL

Proposals in response to a topic of an IHI JU call for proposals must be submitted online, before the call deadline, by the coordinator via the Submission Service section of the relevant topic page available under Funding & Tender opportunities – Single Electronic Data Interchange Area (SEDIA). No other means of submission will be accepted.

PROPOSALS INCLUDING CLINICAL STUDIES[4]

Under the single-stage submission procedures and for the second stage of the two-stage submission procedures: Applicants envisaging including clinical studies must provide details of their clinical studies in the dedicated annex using the template provided in the submission system[5].

SPECIFIC CONDITIONS ON AVAILABILITY, ACCESSIBILITY AND AFFORDABILITY (3A)[6]

When the specific topic condition so requires, the following conditions shall apply:

- The participants must, during the lifetime of the project and for a period of four years after project end, use their best efforts to ensure that those products or services that are developed by any of the participants and are totally or partly based on the results of clinical studies performed as part of the activities of the selected project, will be broadly[7] available and accessible, at fair and reasonable conditions.

- In particular, and always to the extent permitted by applicable competition law:

  a) At the proposal stage[8], and as part of the Plan for the Dissemination, Exploitation, and Communication Activities ('PDECA') which forms part of the proposal, the applicant consortium

[4] Clinical study covers clinical studies/trials/investigations/cohorts and means, for the purpose of this document, any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on *in vitro* diagnostic medical devices).

[5] Template for providing essential information in proposals involving clinical studies - https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx

[6] Article 125(3) of the Council Regulation (EU) 2021/2085.

[7] This covers EU Member States and countries that are associated to Horizon Europe at the time of call opening.

[8] For those 3A specific projects, the 3A content in the PDECA will be checked during the evaluation stage. Omission/inadequate treatment of 3A would be identified as a shortcoming. The content however, once considered adequate, will not be utilised for positive scoring and will not contribute towards any evaluation criteria.

must identify potential and expected project results that may be subject to the 3A conditions and broadly outline their strategy to achieve the above objectives.[9]

b) At the project interim review stage, if relevant[10], the PDECA should be updated with a revised 3A strategy. This update should be based on the progress of the clinical studies conducted or to be conducted as part of the project and include any pertinent action to be implemented both during the project and over the four years after project end.

c) At the end of the project, the PDECA should be updated, to provide the expected planning for further product development and (if already scheduled) product launch, within the timeframe of four years after the project end and in order to meet those objectives laid out under point 1 above.[11]

d) Within 12 months from the project end date, and on a yearly basis thereafter for a period of 3 years (totalling four years from project end), a confidential report[12] must be submitted to IHI JU by the owner of the project result describing the status of the development of the product and of any other exploitation actions, planned or undertaken, concerning the products/services.

JU RIGHT TO OBJECT TO TRANSFER/EXCLUSIVE LICENSING

According to the Horizon Europe rules, and in order to protect Union interests, the right for IHI JU to object to transfers of ownership of results or to grants of an exclusive licence regarding results should apply to participants. Therefore, the provisions set out in General Annex G to the Horizon Europe Work Programme 2023-2025 on the right to object apply generally. It should be noted that in accordance with the Council Regulation (EU) 2021/2085 and the Horizon Europe model Grant Agreement, the right to object applies also to participants that have not received funding from IHI JU and for the periods set therein. In choosing whether to exercise the right to object, IHI JU will, on a case-by-case basis, make a reasoned decision in compliance with the legal basis.

FINANCIAL SUPPORT TO THIRD PARTIES

Financial support for third parties in IHI projects is allowed for the call(s) covered by this work programme. The additional conditions contained in General Annex B to the Horizon Europe Work Programme 2023-2025 for Financial Support to Third Parties shall apply *mutatis mutandis.*

[9] Suggested components would be 1) Identification of planned clinical studies that might generate results for which the provisions are relevant; 2) Confirmation that the consortium members are aware of the provisions and will consider them accordingly. 3)Tentatively identifying markets/areas where the product/service could be made affordable, accessible, available. These points could be checked at the evaluation stage.

[10] This interim point allows a realistic appraisal of the 3A possibilities during the project lifetime, particularly as to the viability of specific expected 3A results.

[11] Per the Model Grant Agreement ('MGA') Article 16, the beneficiaries must complete the Results Ownership List ('ROL') which identifies each result generated in the project and the owner thereof. The ROL should inform on the relevant results for which owners implement the 3A strategy in the PDECA for the four years following the project.

[12] Cognisant of IP sensitivities, confidential info, and commercial realties, the IHI JU suggests that the confidential report PDECA could, if needed, be composed of two parts:

1. **A high-level abstract**, to be made publicly available (not containing confidential information), comprising:
   a) Broad summary of the result's development to this point, including a detailed description of the result and the potential product or service that could incorporate or partly incorporate the result;
   b) Broad description of expected downstream actions (including product and service applications);
   c) broad assessment of expected impact of the above downstream actions towards ensuring affordability, availability, and accessibility.
2. **A Confidential Annex** in which:
   a) The owning beneficiary explains if the result is a product or service (or is expected to become one within 4 years) or not, and if yes, further confirms:
      i. The planned measures to be taken to effect the 3A obligations;
      ii. That the owning beneficiary will undertake all necessary actions to adhere to the 3A provisions to the best of its capacity;
      iii. That the owing beneficiary will keep the IHI JU updated on a yearly basis on the progress.

Boosting innovation for a competitive European health ecosystem

Introduction to the Call and general elements to be considered for all topics.

This call aims to fund pre-competitive[13] Research and Innovation Actions that contribute to addressing the IHI JU's Specific Objectives, as defined in IHI JU's legal basis[14] and described in more detail in the IHI JU Strategic Research and Innovation Agenda (SRIA).

The call contains five topics, each focusing on one of the five IHI JU Specific Objectives (SOs):

Topic 1 (SO1): contribute towards a better understanding of the determinants of health and priority disease areas;

Topic 2 (SO2): integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users;

Topic 3 (SO3): demonstrate the feasibility of people-centred, integrated healthcare solutions;

Topic 4 (SO4): exploit the full potential of digitalisation and data exchange in healthcare;

Topic 5 (SO5): enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions.

The scope of each of the topics is broad in order to harness new science and technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat and manage diseases and enable recovery more efficiently, and that could ultimately be integrated/implemented into the healthcare ecosystem for the benefit of patients and society.

In line with the first IHI JU general objective '*to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations*', actions to be funded under this call are expected to perform at scale activities that drive concrete and transformational outcomes.

Furthermore, actions to be funded under this call should address unmet public health needs in line with the second IHI JU general objective "*deliver safe, effective health innovations that cover the entire spectrum of care – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need"*.

Unmet public health needs are needs that are currently not addressed by the healthcare systems for various reasons; for example, if no health technologies[15] are known to tackle a disease effectively, or because of a general overload on health care systems that challenges the capacity to deliver the right care at the right time.

[13] meaning it will not deliver products or services directly into healthcare systems or the market.

[14] Article 115 of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

[15] Health technology means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in health care.

In this context applicants should consider at least one of the below points:

- the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
- the high economic impact of the disease for patients and society;
- the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).

Most activities are expected to be cross-sectoral, reflecting the integrative nature of IHI as a public-private partnership, and to consider the different innovation cycles of the pharmaceutical and medical technology industries. In particular, the call welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and implementation of novel treatments and healthcare solutions.

Proposals that aim to demonstrate the feasibility and/or scalability of integrating solutions into global, national, or regional healthcare systems and/or of innovations are welcomed. However, the research supported by this call for proposals should remain at the pre-competitive level.

Proposals submitted under the topics of this call may cover activities over the whole health innovation chain including, but not limited to:

- discovery of new molecules, mechanisms of action, processes, technologies;
- development and testing of these discoveries;
- development of methodologies for assessment of safety, health outcomes or health-economic evaluation;
- standardisation activities;
- contribution to regulatory science;
- pilots/proofs of feasibility including *in-silico* trials.

To emphasise the people-driven mission and the inclusive objectives of the call, applicants are strongly encouraged to provide open access to project-generated outputs such as standards, GDPR compliant data sets and other research results.

As proposals can only be submitted under one topic, applicants must carefully consider which Specific Objective is the most relevant to the primary focus of their proposal and submit it only under the corresponding topic. Applicants must clearly justify the alignment of the objectives of their proposed work with the Specific Objective selected. Considering the complementarity of the IHI JU Specific Objectives, proposals may also cover aspects related to other Specific Objective(s). If so, applicants should also highlight this in their proposal.

Applicants are therefore encouraged to read the IHI JU SRIA[16] carefully for full information on the Specific Objectives.

NOTE: While under each topic some examples are provided, these are only suggestions and applicants should refer to the text in the SRIA under each Specific Objective for full details on the scope covered by each topic.

[16] https://www.ihi.europa.eu/sites/default/files/flmngr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

Topic 1: Boosting innovation for a better understanding of the determinants of health

NOTE: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

Expected outcomes

Applicants must define the outcomes expected to be achieved by the project, ensuring that they contribute to at least one of IHI JU's potential outputs linked to the IHI JU's Specific Objective 1 '*contribute towards a better understanding of the determinants of health and priority disease areas*', as set out in the IHI JU Strategic Research and Innovation Agenda (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science17.

Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies etc. that will foster the development of health innovations to prevent, intercept, diagnose, treat, and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU, that is capable of addressing the challenge(s) and scope of the IHI JU Specific Objective 1 *'contribute towards a better understanding of the determinants of health and priority disease areas'*, as defined in IHI JU's legal basis[18] and described in more detail in the IHI JU SRIA[19]:

Applicants should consider the following points in their proposals:

a) address an unmet public health need based on at least one of the below:
   - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
   - the high economic impact of the disease for patients and society;

[17] In the context of IHI, 'implementation science' refers to the development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, uptake, scale-up, piloting in healthcare).

[18] Article 115 of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

[19] https://www.ihi.europa.eu/sites/default/files/flmngr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

- the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).

b) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or in industrial processes.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, including open science, and taking demographic trends into account as relevant.

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs, and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in-vitro* diagnostic devices, health technology assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services, such as the Innovation Task Force and qualification advice.

As relevant, consideration should also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation[20] in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how to synergise with these initiatives.

Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

a) contribute to one or more of IHI JU's expected impacts linked to Specific Objective 1 as set out in the IHI JU SRIA, i.e.:

- patients benefit from preventive treatment or early disease intervention before onset of symptoms;
- prevention and early diagnosis of disease combined with better understanding of the mechanisms involved, leading to the development of more cost-effective strategies;
- patients benefitting from improved healthcare through regular monitoring of critical parameters using validated tools;
- development of new vaccine strategies targeted to specific sub-populations;
- increased preparedness of EU healthcare systems for disease outbreaks.

b) contribute to strengthening the competitiveness of the EU's health industry, via increased economic activity in the development of health technologies, in particular, integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.

The actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Human Twins Initiative, the European Health Emergency Preparedness and Response Authority (HERA), the European

[20] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf

Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act[21], where relevant.

Why the expected outcomes can only be achieved by an IHI JU project

Science and technologies are changing rapidly, and their successful implementation requires increasing cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users therefore requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as charitable foundations / philanthropic organisations with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 25 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 is necessary to allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude the submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension, as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members and the contributing partners. IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and/or their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI website).

Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

[21] EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act

Examples of activities that could fall under this topic (indicative only and not prescriptive or limiting)

- Activities to deliver new insights into mechanisms of diseases and factors contributing to health status.
- Activities to identify and validate biomarkers as well as to elucidate potential new mechanisms for therapeutic actions, including innovative methods of data exploitation.
- Standardisation activities to facilitate the development of new health technologies, better identify individuals with disease predisposition, predict and monitor disease progression, and assess the efficacy of targeted treatments.
- Use of the opportunity offered by emerging industrial technologies (e.g. innovative imaging methods, robotics or artificial intelligence, smart medical devices) to provide better targets and approaches to develop new and more precise personalised health innovations for prevention, diagnosis and therapy, as well as facilitating good health while aging.

Topic 2: Boosting innovation through better integration of fragmented health R&I efforts

NOTE: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

Expected outcomes

Applicants must define the outcomes expected to be achieved by the project, ensuring that they contribute to at least one of IHI JU's potential outputs linked to the IHI JU Specific Objective 2 *'integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users'* as set out in the IHI JU Strategic Research and Innovation Agenda (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science[22].

Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies etc. that will foster the development of health innovations to prevent, intercept, diagnose, treat, and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU, that is capable of addressing the challenge(s) and scope of the IHI JU Specific Objective 2 *'integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users'* as defined in IHI JU's legal basis[23] and described in more detail in the IHI JU SRIA[24]:

Applicants should consider the following points in their proposals:

a) address an unmet public health need based on at least one of the below:

[22] In the context of IHI, 'implementation science' refers to the development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, uptake, scale-up, piloting in healthcare).

[23] Article 115 of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

[24] https://www.ihi.europa.eu/sites/default/files/flmngr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

- the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
- the high economic impact of the disease for patients and society;
- the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).

b) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or industrial processes.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, including open science and taking demographic trends into account as relevant.

Proposals may address specific target populations, underserved communities or areas with limited resources, and/or support challenging unmet needs and diagnostic or treatment gaps.

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technologies assessment (HTA) agencies and the European Medicines Agency (EMA) through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation[25] in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how they propose to synergise with these initiatives.

Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

a) contribute to one or more of IHI JU's expected impacts linked to IHI JU's Specific Objective 2, as set out in the IHI JU SRIA, i.e.

- breaking down fragmentation between various disciplines of medicine and technological areas in order to conceive and develop technologically and socially innovative, people-centred, integrated healthcare solutions that can seamlessly be introduced in healthcare systems;
- fostering development of safe and effective innovative health technologies and their combinations thanks to new and harmonised approaches to data generation;
- better and faster integration of future products, services and tools along the healthcare pathway (including health promotion and disease prevention), responding to patients' specific needs and leading to improved health outcomes and patient well-being;
- patients and industry benefit from innovative manufacturing processes such as 3D printing, on-demand small-scale good manufacturing practice (GMP) synthesis, on-site portable production systems etc.;

[25] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf

- green transition enabled across all aspects of healthcare, both in the delivery of healthcare to patients, and in the technologies and products that emerge from a competitive European industry.

b) contribute to strengthening the competitiveness of the EU's health industry, via increased economic activity in the development of health technologies, in particular, integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.

The actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act[26], where relevant.

Why the expected outcomes can only be achieved by an IHI JU project

Science and technologies are changing rapidly, and their successful implementation requires increasing cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users therefore requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as charitable foundations / philanthropic organisations with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 100 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 15 000 000 is necessary to allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude the submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members and/or the contributing partners (if any). IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and/or their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI website).

[26] EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act

Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

Examples of activities that could fall under this topic (indicative only and not prescriptive or limiting)

- Break down fragmentation between various disciplines of medicine – including computational and technological areas – to accelerate innovations from early discovery to patient treatment.
- Integrate diverse components (e.g. from focused mission-based research projects, collaborative platforms, databases, AI/ML to diagnostics, medicinal products, medical devices, wearables, digital solutions) in order to foster the development of people-centred, ambitious, large-scale and transformative solutions along the healthcare pathway from beginning to end, including treatment discovery.
- Novel and harmonised approaches to data generation and federation, algorithm optimisation and applicable ML outputs.
- Activities to deliver open-source computational outputs such as machine learning methods for prediction at scale derived from a collaborative, community-driven ecosystem.
- Activities that catalyse data-driven AI/ML-influenced discoveries and therapies e.g. integration of *in vitro*, *in vivo* approaches, small molecules, screening platforms, manufacturing processes (such as mass protein expression), diagnostics and prognostics (for early and adapted treatment, for multimodal disease and/or cross-therapy area applications or for management approaches).
- Activities addressing innovations and outcomes within the context of the European Green Deal, so that advances are part of Europe's sustainability goals, supporting the commercial sustainability transition and reducing the overall environmental impact of healthcare.

Topic 3: Boosting innovation for people-centred integrated healthcare solutions

NOTE: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

Expected outcomes

Applicants must define the outcomes expected to be achieved by the project ensuring that they contribute to at least one of IHI JU's potential outputs linked to the IHI JU's Specific Objective 3 '*demonstrate the feasibility of people-centred, integrated healthcare solutions'*, as reflected in the IHI JU Strategic Research and Innovation Agenda (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science[27].

Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies etc. that will foster the development of health innovations to prevent, intercept, diagnose, treat and manage diseases, and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU that is capable of addressing the challenge(s) and scope of the IHI JU's Specific Objective 3 *'demonstrate the feasibility of people-centred, integrated healthcare solutions',* as defined in IHI JU's legal basis[28] and described in more detail in the IHI JU SRIA[29].

Applicants should consider the following points in their proposals:

a) address an unmet public health need based on at least one of the below:

- the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
- the high economic impact of the disease for patients and society;

[27] In the context of IHI, 'implementation science' refers to the development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, uptake, scale-up, piloting in healthcare).

[28] Article 115 of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

[29] https://www.ihi.europa.eu/sites/default/files/flmngr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

- the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).

b) have people-centric, rather than product- and pathology-centric, approaches – the focus being on the patient and citizen journey through health care, with the help of most suitable health technologies and social innovations and taking account of demographic trends;

c) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or into industrial processes.

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technologies assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation[30] in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how they propose to synergise with these initiatives.

Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

a) contribute to one or more of IHI JU's expected impacts linked to IHI JU's Specific Objective 3, as set out in the IHI JU SRIA, i.e.

- raised awareness among citizens and patients on their own role in managing their health;
- improved patient adherence to prevention programmes and medical interventions;
- people, including vulnerable populations (e.g. elderly and children as well as their carers and/or representatives), are better able to make informed decisions with their healthcare professionals about prevention, treatment interventions and disease management;
- increased frequency and quality of cooperation between patients, citizens and industrial stakeholders in the development of healthcare solutions, in particular integrated care solutions;
- patients benefit from prevention and treatment better adapted to their needs through improved diagnostic and monitoring;
- integrated healthcare solutions, including those based on the use of digital solutions, better responding to the needs and preferences of patients and citizens, supporting an inclusive approach;
- successful implementation of digital solutions supporting people-centred care;
- facilitated introduction of innovative solutions for improved home care of patients;

[30] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf

- healthcare solutions assessed according to criteria that matter to patients and citizens (in particular, patient reported outcome measures (PROMs) and patient reported experience measures (PREMs) contributing to achieving people-centred healthcare.

b) contribute to strengthening the competitiveness of the EU's health industry via increased economic activity in the development of health technologies, in particular, integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.

The actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Human Twins Initiative, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act[31], where relevant.

Why the expected outcomes can only be achieved by an IHI JU project

Science and technologies are changing rapidly, and their successful implementation requires increasing cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions suitable for end-users therefore, requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as charitable foundations / philanthropic organisations with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 30 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 is necessary to allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude the submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin, e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members and/or the contributing partners, if relevant. IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and/or their affiliated entities cannot contribute IKAA.

[31] EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act

See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI website).

Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

Examples of activities that could fall under this topic (indicative only and not prescriptive or limiting)

Activities to foster the development of integrated healthcare solutions, combining different technological areas and taking into account the needs of patients and citizens to, among others: a) facilitate patient contributions to R&I activities; b) support shared decision-making with healthcare professionals; and c) enable self-management of disease and health, *de facto* engaging in social innovation.
In this context, amongst others, the following elements could be relevant for the proposals:

- the development of harmonised patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs),
- the development of methods to elicit people's preferences and digital tools to enable patient involvement.
- accessibility and inclusivity, particularly for patients with limited digital skills or disabilities.
- considerations for how patient feedback will be gathered and applied in the design of the healthcare solutions.
- considerations regarding health economics aspects.

Topic 4: Boosting innovation through exploitation of digitalisation and data exchange in healthcare

NOTE: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

Expected outcomes

Applicants must define the outcomes expected to be achieved by the project ensuring that they contribute to at least one of IHI JU's potential outputs linked to the IHI JU's Specific Objective 4 '*exploit the full potential of digitalisation and data exchange in healthcare*', as reflected in the IHI JU Strategic Research and Innovation Agenda (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science[32].

Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies etc. that will foster the development of health innovations to prevent, intercept, diagnose, treat and manage diseases and enable recovery more efficiently**.**

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU that is capable of directly addressing the challenge(s) and scope of the IHI JU Specific Objective 4 '*exploit the full potential of digitalisation and data exchange in healthcare'*, as defined in IHI JU's legal basis[33] and described in more detail in the IHI JU SRIA[34]:

Applicants should consider the following points in their proposals:

a) address an unmet public health need based on at least one of the below:
   - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
   - the high economic impact of the disease for patients and society;

[32] In the context of IHI, 'implementation science' refers to the development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, uptake, scale-up, piloting in healthcare).

[33] Article 115 of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

[34] https://www.ihi.europa.eu/sites/default/files/flmngr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

- the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).

b) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or into industrial processes.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, including open science and taking demographic trends into account as relevant.

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs, and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technologies assessment (HTA) agencies, and the European Medicines Agency (EMA), through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation[35] in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how to synergise with these initiatives.

Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

a) contribute to one or more of IHI JU's expected impacts linked to IHI JU's Specific Objective 4, as reflected in the IHI JU SRIA, i.e.:

- wider availability of interoperable, quality data, respecting FAIR (findable, accessible, interoperable, reusable) principles, facilitating research and the development of integrated products and services;
- improved insight into the real-life behaviour and challenges of patients with complex, chronic diseases and co-morbidities thanks to m-health and e-health technologies;
- advanced analytics / artificial intelligence supporting health R&I, resulting in a) clinical decision support for increased accuracy of diagnosis and efficacy of treatment; b) shorter times to market; c) wider availability of personalised health interventions to end-users; d) better evidence of the added value from new digital health and artificial intelligence tools, including reduced risk of bias due to improved methodologies.

b) contribute to strengthening the competitiveness of the EU's health industry via increased economic activity in the development of health technologies, in particular, integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.

The actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Human Twins Initiative, the European Health Emergency Preparedness and Response Authority (HERA), the European

[35] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf

Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act[36], where relevant.

Why the expected outcomes can only be achieved by an IHI JU project

Science and technologies are changing rapidly, and their successful implementation requires increasing cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions suitable for end-users therefore, requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as charitable foundations / philanthropic organisations with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 24 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 is necessary to allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude the submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members and/or the contributing partners, if relevant. IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI website).

Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

[36] EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act

Examples of activities that could fall under this topic (indicative only and not prescriptive or limiting)

- Activities to support the generation, pooling, integration and sharing of high-quality, harmonised, interoperable data (either existing or generated de novo), as well as the use of advanced analytical tools (including artificial intelligence, computational modelling and simulation or digital twin approaches).
- Activities to support the development of better assistance systems for healthcare professionals to facilitate timely decision-making over the course of a disease, thereby improving patient outcomes.

Amongst others, considerations on health economics aspects could be relevant.

Topic 5: Boosting innovation for better assessment of the added value of innovative integrated healthcare solutions

NOTE: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

Expected outcomes

Applicants must define the outcomes expected to be achieved by the project ensuring that they contribute to at least one of IHI JU's potential outputs linked to the IHI JU's specific objective 5 '*enable the development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions' as* reflected in the IHI JU Strategic Research and Innovation Agenda (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science[37].

Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies etc. that will foster the development of health innovations to prevent, intercept, diagnose, treat, and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU that is capable of addressing challenge(s) and scope of the IHI JU's Specific Objective 5 '*enable the development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions'*; as defined in IHI JU's legal basis[38] and described in more detail in the IHI JU SRIA[39].

Applicants should consider the following points in their proposals:

a) address an unmet public health need based on at least one of the below:

- the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
- the high economic impact of the disease for patients and society;

[37] In the context of IHI, 'implementation science' refers to the development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, uptake, scale-up, piloting in healthcare).

[38] Article 115 of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

[39] https://www.ihi.europa.eu/sites/default/files/flmngr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf

- the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).

b) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or into industrial processes.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, including open science and taking demographic trends into account as relevant.

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs, and as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technology assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation[40] in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how they propose to synergise with these initiatives.

Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

a) contribute to one or more of IHI JU's expected impacts linked to IHI JU's Specific Objective 5, as reflected in the IHI JU SRIA, i.e.:

- seamless and successful implementation in healthcare settings of cross-sectoral innovations, integrated products and services delivering proven benefits to patients, healthcare systems and society as a whole;
- patients have improved access to innovations that meet their needs and those of the healthcare systems;
- better informed decision-making at different levels of the healthcare system (authorities, organisations), that will in turn contribute to a better allocation of resources towards cost-effective innovations;
- faster entry to the market of cost-effective innovative solutions developed by industry, which could translate to a positive effect on their R&I investments.

b) contribute to strengthening the competitiveness of the EU's health industry, via increased economic activity in the development of health technologies, in particular, integrated health solutions, and thus fostering European technological leadership and the digital transformation of our societies.

The actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Twins Initiatives, the European Health Emergency Preparedness and Response Authority (HERA), the European

[40] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf

Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act[41], where relevant.

Why the expected outcomes can only be achieved by an IHI JU project

Science and technologies are changing rapidly, and their successful implementation requires increasing cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions suitable for end-users, therefore, requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, tax payers) as well as charitable foundations / philanthropic organisations with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 12 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 5 000 000 is necessary to allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude the submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members and/or the contributing partners, if relevant. IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI website).

Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' apply.

[41] EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act

Examples of activities that could fall under this topic (indicative only and not prescriptive or limiting)

Activities to develop methods and tools to assess the added value of emerging and converging health technologies, taking into consideration different stakeholders' value dimensions, to support harmonised approaches for evidence generation.

Glossary

Acronym	Meaning
AI/ML	Artificial intelligence/Machine Learning
EHDS	European Health Data Space
EMA	European Medicines Agency
FCs	Financial contributions
GMP	good manufacturing practice
HERA	European Health Emergency Preparedness and Response Authority
HTA	Health Technology Assessment
IKAA	in-kind contributions to additional activities
IKOP	in-kind contributions to operational activities
PREMs	Patient-reported experience measures
PROMs	Patient-reported outcomes measures
R&I	Research and Innovation
SO	Specific Objective
SRIA	Strategic Research and Innovation Agenda