Boosting innovation for a competitive European health ecosystem

IHI call 9 – topics 1 to 5



Before we start...

- We are recording this session and it will be published on the IHI website.
 We will also publish the presentation slides.
- The call will be launched shortly and all links and details of how to apply will be published on the IHI website and the Funding and Tenders Portal.
- Final approved call 9 text already available <u>here</u>.
- If you want to ask a question please use the Q&A function on the right corner of your screen.



Today's webinar

• Will cover:

- Introduction to IHI programme
- IHI call 9, topics 1 to 5
- Proposal submission & evaluation
- Tips for writing a successful proposal

Will not cover

- rules and procedures
- how to prepare the financial proposal

Look at the <u>webinars</u> on call 9 financial aspects of the proposal and rules and procedures for single-stage calls





Innovative Health Initiative

EU partnership in health between:

- the European Union represented by the European Commission
- Healthcare industry associations:
 - COCIR (medical imaging, radiotherapy, health ICT and electromedical industries)
 - EFPIA, including Vaccines Europe (pharmaceutical and vaccine industries)
 - EuropaBio (biotechnology industry)
 - MedTech Europe (medical technology industry)













IHI's general objectives

- Turn health research and innovation into real benefits for patients and society
- 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
- Make Europe's health industries globally competitive.



IHI projects are...

- Created via open and competitive calls for proposals
- Cross sectorial public private partnerships leveraging:
 - Contributions from industrial partners from the IHI industry associations (COCIR, EFPIA including Vaccines Europe, EuropaBio, MedTechEurope)
 - if relevant, contributions from contributing partners (must be approved by IHI GB)

and

Public funding via European Commission (Horizon Europe)



Strategic Research & Innovation Agenda

Focus

 Cross-sectoral approaches to facilitate creation of new products and services to prevent, intercept, diagnose, treat and manage diseases and foster recovery more efficiently.

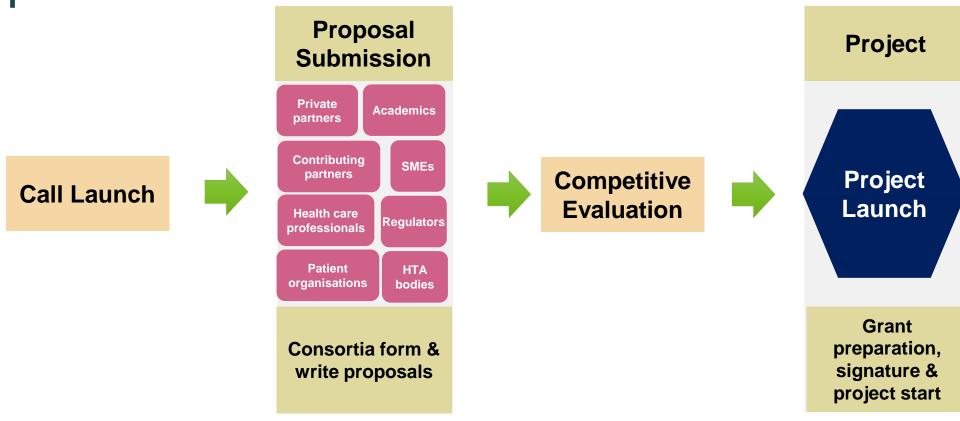
Goal

• Lay foundations for development of safer and more effective health care products or solutions that respond to unmet public health needs and that can be implemented into healthcare systems.

Research supported by IHI should remain at precompetitive level



How does IHI work? Single-stage procedure







Boosting innovation for a competitive European health ecosystem through a novel, applicant-driven approach



IHI Call 9

- IHI Call 9 comprises 5 topics, each focusing on one of the five IHI JU Specific Objectives (SOs)
- The call contains an introduction and general elements to be considered for all topics
- The overall aim is to fund <u>pre-competitive</u> research and innovation actions that are in line with the general objectives of IHI and address at least one of IHI SOs as set out in the IHI <u>Strategic</u> <u>Research and Innovation Agenda (SRIA)</u>



IHI Call 9 - Topics

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

Addressing SO1: "contribute towards a better understanding of the determinants of health and priority disease areas"

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

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

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

Addressing SO3: "demonstrate the feasibility of people-centred integrated healthcare solutions"



IHI Call 9 – Topics cont.

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

Addressing SO4: "exploit the full potential of digitalisation and data exchange in healthcare"

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

Addressing 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."



Please read carefully the introduction to the Call and general elements to be considered for all topics

- Scope broad 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.
- Actions to be funded under this call:
 - are expected to perform at scale activities that drive concrete and transformational outcomes
 - should address unmet public health needs



Please read carefully the introduction to the Call and general elements to be considered for all topics

- 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
- Proposals that aim to demonstrate the feasibility and/or scalability of integrating solutions into national or regional healthcare systems and/or of innovations are welcomed.



Research should remain at the pre-competitive level.



Please read carefully the introduction to the Call and general elements to be considered for all topics

- Activities may cover 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.



Read carefully the introduction to the Call and general elements to be considered for all topics

- 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.
- Proposals can only be submitted under one topic, so please consider which Specific Objective is the most relevant to the primary focus of your 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

For each topic (T1 to T5)

 With a view to harnessing new science and technologies, fund precompetitive 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 selected IHI JU's Specific Objective and described in more detail in the IHI JU SRIA.



Scope – example for topic 1

Accordingly, applicants assemble a collaborative publicprivate 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 'contribute towards a better understanding the determinants of health and priority disease areas', defined in IHI JU's legal basis and described in more detail in the IHI JU SRIA:



Strategic Research and Innovation Agenda



SPECIFIC OBJECTIVE 1:

Contribute towards a better understanding of the determinants of health and priority disease areas

CHALLENGE:

For many health conditions, we lack full understanding of the underlying mechanisms, including the predisposition to disease, how environmental and genetic factors affect the occurrence and course of the diseases, what affects treatment success, etc. Consequently, it is difficult to develop adequate prevention strategies, accurate and timely diagnostics, and targeted therapeutic interventions. In order to develop innovative interventions ranging from health promotion to treatment, a better knowledge and understanding of the biological mechanisms is paramount. By elucidating the mechanisms of diseases and factors contributing to health status, IHI can 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.

SCOPE:

The Innovative Health Initiative will cover the identification of new mechanisms underlying health status and disease development, biomarker identification and validation as well as elucidating potential new mechanisms for therapeutic actions, including innovative methods of data exploitation. The scope will also cover 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.

In the specific context of IHI as a cross-sectoral partnership, more efficient use of various research tools or paradigms offered by emerging industry sectors (e.g. innovative imaging methods, robotics or artificial intelligence) may bring a new insight to understanding of health and disease. Using the services from European Research Infrastructures (**) for digitalised research (with reproducible workflows, data management and analysis, complex modelling and *in silico* simulation) could be beneficial.

POTENTIAL OUTPUTS (18):

- Increased understanding of health and disease mechanisms at a molecular level.
- Newly identified and validated biomarkers for disease interception, diagnosis, progression and treatment monitoring tested in real-world settings.
- Identification of common environmental factors, including social, with understanding of their impact on molecular mechanisms.
- Novel tools or hypotheses for new treatments tested preclinically and/or in early-stage clinical or in silico trials.
- Novel methods and tools to identify pre-symptomatic individuals.
- Validated protocols, diagnostic and prognostic tools (including those based on wearable devices).

^(*) The Strategy Report on Research Infrastructures Part 3 describes – through dedicated cards – each ESFRI Project and each ESFRI Landmark. A short description of the RI is given as well as updated information on the legal status, the timeline for construction/operation, and the estimated costs. https://roadmap2021esfri.eu/media/1252/mg21-part-3.pdf

^(*) Output: immediate use or uptake of R&I results: e.g. results of productive interactions between producers and users of R&I (short and medium term)

For topics 1, 4 and 5

Applicants should consider the following points in their proposals:

- a) Address an unmet public health need based on at least one of the below:
 - high burden of disease for patients and/or society
 - high economic impact of the disease for patients and society;
 - transformational nature of the potential results on innovation processes
- b) Demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem and/or in industrial processes.

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

For topic 2

- a) Address an unmet public health need based on at least one of the below:
 - high burden of disease for patients and/or society
 - high economic impact of the disease for patients and society;
 - transformational nature of the potential results on innovation processes
- b) Demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem and/or in industrial processes.

When applicable, relevant aspects of **patient-centricity** to be considered, 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.

For topic 3

- a) Address an unmet public health need based on at least one of the below:
 - high burden of disease for patients and/or society
 - high economic impact of the disease for patients and society;
 - transformational nature of the potential results on innovation processes
- 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 and/or in industrial processes.

For topics 1, 2, 3, 4 and 5

Applicants should consider the following points in their proposals:

- If applicable, 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.
- As relevant, consider the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation in the context of secondary use of data.
- 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.



Note

At the end of each topic – i.e topic 1, 2, 3, 4 and 5 - there are examples of activities that could fall under the topic (indicative only) These are only suggestions and not prescriptive or limiting Applicants should refer to the text in the SRIA under each Specific Objective for full details on the scope covered by each topic



Expected outcomes for each topic

- Outcomes to be defined by the applicants, ensuring that they contribute to at least one of IHI JU's potential outputs linked to the relevant Specific Objective as set out in the IHI SRIA
- 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
- May cover the entire spectrum of care and be health technologies centred around disease areas and/or key themes such as prevention, personalised medicine, and chronic disease management. They may also include solutions for key enablers such digital data and solutions, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare, and implementation science

Expected outcomes – example for topic 1

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 science.



Strategic Research and Innovation Agenda



SPECIFIC OBJECTIVE 1:

Contribute towards a better understanding of the determinants of health and priority disease areas

CHALLENGE:

For many health conditions, we lack full understanding of the underlying mechanisms, including the predisposition to disease, how environmental and genetic factors affect the occurrence and course of the diseases, what affects treatment success, etc. Consequently, it is difficult to develop adequate prevention strategies, accurate and timely diagnostics, and targeted therapeutic interventions. In order to develop innovative interventions ranging from health promotion to treatment, a better knowledge and understanding of the biological mechanisms is paramount. By elucidating the mechanisms of diseases and factors contributing to health status, IHI can 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.

The Innovative Health Initiative will cover the

identification of new mechanisms underlying health status and disease development, bi-

omarker identification and validation as well

as elucidating potential new mechanisms for

therapeutic actions, including innovative methods of data exploitation. The scope will also

cover standardisation activities to facilitate the

development of new health technologies, bet-

ter identify individuals with disease predisposi-

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and assess the efficacy of targeted treatments.

POTENTIAL OUTPUTS (18):

 Increased understanding of health and disease mechanisms at a molecular level.

In the specific context of IHI as a cross-sectoral partnership, more efficient use of various re-

search tools or paradigms offered by emerg-

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research (with reproducible workflows, data

management and analysis, complex modelling

and in silico simulation) could be beneficial.

- Newly identified and validated biomarkers for disease interception, diagnosis, progression and treatment monitoring tested in real-world settings.
- Identification of common environmental factors, including social, with understanding of their impact on molecular mechanisms.
- Novel tools or hypotheses for new treatments tested preclinically and/or in early-stage clinical or in silico trials.
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^(**) Output: immediate use or uptake of R&I results: e.g. results of productive interactions between producers and users of R&I (short and medium term)

Expected impacts for each topic

- Contribute to one or more IHI JU's expected impacts linked to Specific Objective selected as set out in the IHI JU SRIA.
- Contribute to strengthening the competitiveness of the EU's health industry
- Contribute to relevant EU programmes, initiatives and policies



Expected impacts – example for topic 1

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 subpopulations;
- increased preparedness of EU healthcare systems for disease outbreaks.

b) contribute to strengthening the competitiveness of the EU's héalth 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 18 Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act21, where relevant.



Strategic Research and Innovation Agenda





- Validated ex-vivo and/or in-vivo solutions EXPECTED IMPACTS (19): for patient monitoring during and after treatment, including those based on artificial intelligence approaches, database exploitation, computational modelling, and innovative sensing approaches.
- Improved understanding of host-pathogen (including microbiota) interactions if applicable.
- Tools to improve tracking of, and preparedness for, infectious disease outbreaks.
- · Predictive models for the development of improved vaccines, taking into consideration the needs of specific populations like the elderly or children.

- · 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-effec-
- 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.

(%) Impact: wider benefit for society: e.g. social, economic and environmental impact (medium to long-term)



Dissemination, exploitation & communication

- Reserve budget for effective dissemination, exploitation & communication
- Describe the dissemination, exploitation and communication measures that are planned, and the target group(s) addressed, in particular:
 - Encourage the uptake of the results of the project through a strong communication and outreach plan
 - Allocating appropriate resources to explore synergies with other relevant initiatives and projects
 - Note 3A provisions (Availability, Accessibility and Affordability) do apply to all the topics (topics 1 to 5).



IHI Call 9 budget

Topic	Maximum EU contribution (EU funding envelope)	in-kind and cash contribution		
1	25 million	25 million		
2	100 million	100 million		
3	30 million	30 million		
4	24 million	24 million		
5	12 million	12 million		
191 Million EU Funding Public funding (50 %)		191 Million Private funding (50 %)		

50% matching is a target for Call 9 as 50% matching must be reached at overall Programme level



IHI Call 9 – budget per proposal

торіс	Maximum EU contribution (EU funding envelope)		in-kind and cash contribution		
1	8 million	+	8 million	-	16 million
2	15 million	+	15 million	=	30 Million
3	8 million	+	8 million	=	16 million
4	8 million	+	8 million	=	16 million
5	5 million	+	5 million	=	10 million





Proposal submission & evaluation



Proposal Template - Parts A, B & Annexes

- Part A of the proposal is administrative data that is entered in webforms through the Funding & Tenders Portal.
- Part B of the proposal is the narrative part that includes three sections:
 - Excellence
 - Impact
 - Quality and efficiency of the implementation
- Read instructions in proposal template very carefully
- Annexes:
 - Participant type
 - Budget details
 - Clinical studies template



Evaluation Criteria (1/2)

Excellence

- 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 science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.

Impact

- 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.



Evaluation Criteria (2/2)

Quality and efficiency of the implementation

- 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 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).



Tips for applicants

- Read all the call-relevant material, especially the introduction and the general elements to be considered for all topics and the relevant topic text
 - www.ihi.europa.eu/apply-funding/future-opportunities
 - FAQs on IHI call 9
- Read carefully the <u>Strategic Research and Innovation Agenda</u> for the Specific objective selected
- Form your consortium early
 - Always think "public-private partnership"
 - Include partners bringing in-kind contributions
- Ensure that all information requested in the call text and proposal template is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria
- Consider & plan for the potential regulatory impact of results
- Updated proposal template Part B and evaluation form
- Call deadline 29 April 2025



Finding project partners

You'll need to build or join a consortium!

- Network via the IHI Brokerage Platform:
 - https://ihicalldays2024.converve.io/
- Use EU Funding & Tenders portal partner search tool:
 - https://europa.eu/!QU87Nx
- Get in touch with your IHI national contact point:
 - https://europa.eu/!D7jyMy
- Network on social media:
 - be.linkedin.com/company/innovative-health-initiative



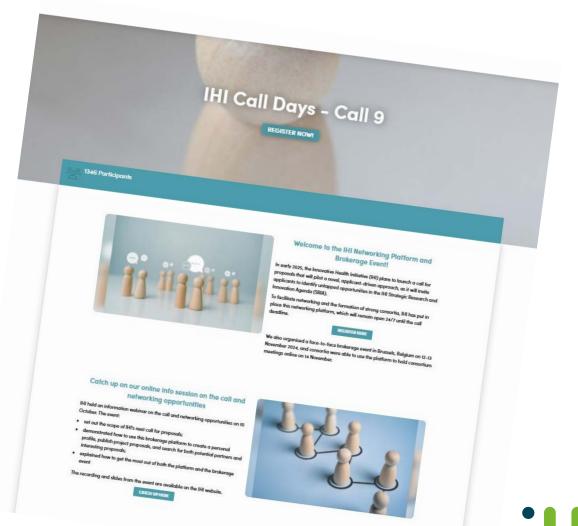
IHI Brokerage Platform

- Share proposals ideas
- Networking opportunities: making it easy to identify potential partners.
- Interactive scheduling: you can easily message other participants.
- **User-friendly interface**: designed with simplicity in mind, the platform ensures a smooth experience.



IHI Brokerage Platform

- 1357 Person Profiles.
- 1290 Companies Profiles
- 190 Proposals
- List of pitchers
- Presentation slides & recordings





IHI Brokerage Platform

How to get started?

Simply visit the platform at ihicalldays2024.converve.io

- 1. Create your person & company profile.
- 2. Share your proposal idea.
- 3. Start browsing and connecting with participants via messages.



#IHICallDays

innovative health initiative

Calls 9 & 10



15 Jan 10:30 Call 9: Rules & procedures

15 Jan 14:30 Call 10: Secondary use of data in the European Health Data Space

16 Jan 10:30 Call 10: Rules & procedures

Online event















Everything you need to know about IHI contributing partners

Register now

30.01.2025

Online Event

















Questions and answers

→ Use the Q&A function

