All information regarding future IHI Call topics is indicative and subject to change. Final information about future IHI Calls will be communicated after approval by the IHI Governing Board.

Topic 1: IHI European HealthCare Incubator Network

Expected outcomes

This call topic responds to the pressing need for a coordinated and collaborative approach to accelerating the research-to-market pathway and fostering innovation and competitiveness in the European healthcare sector. Accordingly, the action under this topic must contribute to all of the following outcomes:

- A **sustainable European HealthCare Incubator Network** (EHCIN) composed of incubators from the public sector (academia, foundations etc.) and industry (pharma, med tech, biotech) to consolidate and catalyse otherwise fragmented efforts and increase the reach of early-stage healthcare companies and academic players across Europe. By integrating tailored mentorship, tailored networking, resources and funding mechanisms, the network will identify high-potential innovations and establish clear pathways for scale-up and sustainable development of early-stage healthcare companies, supporting the next wave of European innovations.
- A **strong programme for de-risking pipelines and mentoring high potential startups,** with the objective of making start-ups more attractive as investment propositions, and capable of attracting essential scale-up finance through private or public investors. This should be achieved by leveraging the Network's unique access to multi-sectorial corporate expertise and mentorship from multiple large-cap companies with tailored funding.
- An **agile framework for funding promising startups** through the mechanism of Financial Support to Third Parties (FSTP).
- **Access to high-quality services and infrastructures**, provided by the consortium, to accelerate the most promising innovations.
- **A framework of collaboration** with other funding programmes such as the European Innovation Council (EIC) to raise selected start-ups' awareness of potential future additional opportunities for support.
- An 'industry quality seal' marking **industry-validated promising start-ups**, de-risked and connected to potential future funders and venture capital funds, that should enhance their ability to secure follow-on financing and successful further development.
- New **opportunities for strategic partnerships** between selected start-ups and partner companies, incubators, investors, venture capital funds, and other interested third parties.
- A portfolio of early-stage companies that have **improved business, market and technological readiness**. This is achieved through targeted access to expertise, infrastructure and services, mentorship, training, and FSTP-supported resources, culminating in sustainable innovations that can be implemented at scale.

The immediate and direct relationship between start-ups and the European HealthCare Incubator Network creates not only a support mechanism for start-ups, but also a coordinated platform delivering high value, non-financial industrial expertise that is not available through existing EU funding instruments.

Definitions for the purpose of this call topic:

Early-stage company

- Early-stage company / start-up refers to a new, fast-growing business that is typically in the early stages of development[1].

- The Technology Readiness Level (TRL) is a scale (from TRL 1 to TRL 9) used to assess the maturity of a technology or innovation. For the purpose of the topic, only early-stage companies at TRL 3 to TRL 5 are considered, meaning those in the early-stage development phase, where the technology is still being refined but has moved beyond basic concepts. The table below gives more specific examples.

Type of product	TRL 3	TRL 4	TRL 5
A medical device	Initial proof of concept demonstrated with a limited number of in vitro & in vivo trials including the expected device characteristics.	Proof of concept and safety of the device is demonstrated in vitro, ex vivo or in vivo conditions (non-GMP, Good Manufacturing Practice). System components integrated and tested regarding preliminary efficiency and reliability.	Pre-clinical studies include GLP (good laboratory practice), animal, and toxicity. GMP manufacturing process and quality controls identified. Classification of the device by appropriate regulatory body established. Accreditation when appropriate initiated.
A drug	Initial proof of concept demonstrated with a limited number of in vitro & in vivo models.	Proof of concept and safety of the candidate is demonstrated in a laboratory or animal model.	Pre-clinical studies including GLP animal safety & toxicity to support the Investigational New Drug (IND) application or similar EU process.

Incubator means an organisation that provides support and resources to early-stage companies to help them grow, develop their business models, and succeed. Incubators offer services like office and lab space, mentorship, training, and access to networks of investors and professional services.

Private or public funder means an investor who provides grants and/or capital to early-stage, high-growth potential companies in exchange for equity. A Venture Capital ('VC') investment as an example, offers a combination of funding and strategic support, such as business guidance and industry connections, to help new companies grow and achieve a significant return on investment. A relevant example of a public funder is the European Innovation Council Accelerator[2].

Scope

Specific Challenges

Europe has world-class research especially in the field of healthcare but continues to lag in commercialising its scientific output. This negatively impacts timely access to novel health technologies for European patients and healthcare systems, especially in areas of unmet healthcare need. Early-stage companies, which are the main engines of innovation, struggle due to structural barriers that inhibit innovation and scale-up. In general, early-stage companies often lack structured

[1] In line with the European Commission recommendation on the definition of innovative enterprises, innovative startups and innovative scaleups: https://research-and-innovation.ec.europa.eu/document/download/4e3cd140-47ed-4de2-be02-af1f344a2990_nl

[2] https://eic.ec.europa.eu/eic-funding-opportunities/eic-accelerator_en

support, impeding their development and survival. The EU is positioning itself as a strategic hub for innovative startups/ early-stage companies by launching several key initiatives and funding instruments to this end, such as the Start-up and Scale-up Strategy[3] and the Scale-up Europe Fund[4].

Additionally, Europe is rich in public incubators dedicated to healthcare start-ups, and many healthcare industry stakeholders have established dedicated incubators/venture accelerators.

However, the landscape of such initiatives, both public and private, is fragmented and not easily accessible to all early-stage companies across Europe, nor is it able to provide the necessary know-how and support at a scale that is necessary for generating a step change in bringing innovations to market in Europe and increasing Europe's competitiveness.

Consequently, the whole healthcare ecosystem is negatively impacted. Investors face difficulty identifying scalable ventures in a fragmented landscape. Industry lacks opportunities for early engagement with meaningful innovative projects that will bring novel therapies and medical technologies to patients. Additionally, regulators and policymakers must balance public safety with the need to reduce delays and complexity for innovators. This, in turn makes it very difficult for young and inexperienced innovators, who often lack relevant knowhow, to navigate the regulatory framework. Ultimately, this implies that European health systems and patients are missing out on timely access to innovative diagnostics and treatments.

Objectives

The overall aim of the call topic is to create a **European HealthCare Incubator Network** (EHCIN) that should address the above challenges by delivering a structured support framework to enable more effective progression of outputs of early-stage healthcare companies toward deployable innovations in the healthcare ecosystem. The EHCIN should create a unique, multi-sectorial network of business leaders and funders across the whole health industry and be exceptionally well placed to provide cross-industry business support and networking to promising startups. In practice, this should be achieved by providing both financial support (via FSTP) and direct interaction with large-cap pharmaceutical and medical technology industries/ companies.

The opportunities for start-ups to engage with major pharmaceutical and med-tech companies are unique within the EHCIN, while remaining fully complementary to other EU funding instruments (e.g., the EIC).

The applicants in their proposal should ensure that through its design, EHCIN will:

- **Provide early, industry-informed insights** into whether a start-up's concept or product has the potential to address an unmet clinical/ healthcare need and therefore represents a viable market opportunity.
- **Offer access to specialised mentorship and coaching**, including expertise from large-cap pharma and med-tech on pre-clinical development, regulatory pathways, market access considerations, and overall technology maturation.
- **Facilitate potential access to industrial capital, facilities, and infrastructural resources**.
- **Connect start-ups with high-quality early-stage innovators** across the ecosystem, stimulating collaboration and shared learning.

[3] https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/eu-startup-and-scaleup-strategy_en

[4] https://eic.ec.europa.eu/eic-fund/scaleup-europe-fund_en

- **Strengthen fundraising prospects** through association with leading industry partners as well as enhanced visibility to venture capital funds, major buyers, and other investors.

By fostering a cohesive, innovation-friendly ecosystem, the action should aim to foster retention of talent, reinforce Europe's technological leadership, and improve access to novel health technologies for patients and healthcare systems. The action generated from this topic should help to **bridge the first** '**valley of death**' in innovation[5], where promising technologies often fail due to lack of funding, know-how, and support mechanisms for reaching clinical efficacy and regulatory readiness.

The objectives of the topic are in response to IHI JU Strategic Research and Innovation Agenda (SRIA)[6] specific objective 2 - *Integrate fragmented health research and innovation efforts by bringing together health industry sectors and other stakeholders. This will enable the development of tools, data, platforms, technologies and processes that will in turn facilitate the prevention, diagnosis, treatment and management of diseases, especially in areas where there is an unmet public health need.*

The applicants are expected to address all the following strategic objectives in their proposal:

Objective 1 – Establishment and governance of a Europe-wide Incubator Network:
The European Healthcare Incubator Network should establish a lean and effective governance structure for the action with clear operational processes and collaboration mechanisms among the project partners and stakeholders (universities, industry, regulators, funders, etc), with the ultimate mission of guiding the selected start-ups and boosting the uptake of their innovative solutions into healthcare systems.

Activities to be performed in the context of this objective:

- Establish the **EHCIN Coordination Forum** (composition, terms of reference, meeting cadence) as the main governing and decision-making body of the consortium, including an even split between public and private partners.
- Establish an **Advisory Board (AB)** to provide advice on the network's activities including: the implementation of the eligibility and selection criteria, the nomination of experts in the FSTP evaluation committee, and the overall evaluation process for awarding the FSTP. The AB should include representatives from relevant European Commission Executive Agencies such as the European Innovation Council (EIC), and independent experts with relevant European-wide innovation expertise.
- Develop a formal EU incubator network partner map as well as a mechanism for onboarding further incubators into the EHCIN as relevant.
- Create and update throughout the duration of the action an integration plan detailing how existing incubators are connected and leveraged.

Objective 2 – SELECTION & MONITORING: Attract, identify, evaluate, fund and monitor a project portfolio of high-potential early-stage healthcare companies selected through open, competitive, widely published calls that conform to EU standards concerning transparency, equal treatment, conflict of interest and confidentiality.

[5] https://research-and-innovation.ec.europa.eu/document/download/2f76a0df-b09b-47c2-949c-800c30e4c530_en

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

Activities to be performed in the context of this objective:

- Prepare and implement the call logic, publish and launch the first call by month 6, and co-ordinate the evaluation and selection of third parties in line with the **'Financial Support to Third Parties (FSTP)**' section of this topic; publish and launch additional calls as needed.
- Implement objective criteria when an additional milestone-based follow-on grant could be made available to accelerate development, validation, and industrial uptake.
- Establish a standardised contract template for third-party engagements via FSTP (including the Intellectual Property (IP) considerations such as measures to safeguard it), milestone-based funding release schedules and clear oversight/audit protocols.
- Prepare a transparent onboarding workflow for early-stage companies funded through the project (timelines, governance guardrails).

Objective 3 – GROWTH CATALYST: Develop a comprehensive infrastructure support programme for early-stage companies that receive funding by providing mentoring; access to infrastructure, business development resources and regulatory navigation (CE marking, European Medicines Agency (EMA) processes, In Vitro Diagnostic Regulation / In Vitro Diagnostic Regulation (MDR/IVDR)); and training on commercial readiness ((pre)clinical validation, reimbursement strategies, business model development). By fostering early regulatory preparedness, the action should aim to improve time-to-market and increase the likelihood of regulatory acceptance of the outputs of the activities supported via FSTP.

Activities to be performed in the context of the objective:

- Create a mentoring programme for the FSTP recipients. The mentoring programme should be performed by expert consortium members. The applicants should identify a structure, mentor rota, matching process, milestones and evaluation for the mentoring programme. The mentoring programme is free of charge for the FSTP recipients, and additional to the FSTP funding.
- Provide regulatory navigation support (e.g. regulatory guidance on CE marking and clinical evidence generation, support with General Data Protection Regulation (GDPR) and ethical approvals, CE/ EMA pathway support, MDR/ IVDR training). Early engagement with regulators, such as EMA and national authorities, should be actively promoted and facilitated.
- Provide mentoring for (pre)clinical validation, go to market planning, reimbursement strategies and commercial considerations. Such mentoring should be delivered by relevant experts from the pre-identified industry consortium and contributing partners.
- Provide expertise related to securing investments and ensuring readiness for commercialisation and market deployment (market research, value proposition, business case and business model, prospects for growth, intellectual property protection, competitor analysis etc.)
- Provide access to infrastructures, facilities and specialised services, thereby strengthening selected start-ups' research and development capacity, accelerating technology maturation and validation, and supporting the translation of innovative ideas into robust, market-relevant solutions.
- Build up an infrastructure access catalogue (labs, equipment, shared services) and hybrid R&D options.
- Design and implement visibility, outreach and networking opportunities for the selected start-ups, to match them with relevant venture capital funds, big buyers, accelerators and other industry players within and outside the consortium, with the final objective of providing growth and/or exit opportunities to the selected start-ups.

- Establish a collaboration with relevant European Commission services/agencies, to enhance alignment across respective funding portfolios, for example channelling FSTP awarded start-ups towards subsequent fast track applications to EU funded initiatives and programmes, such as the European Innovation Council (EIC).

Objective 4 – SUSTAINING THE EUROPEAN HEALTHCARE INCUBATOR NETWORK GROWTH:
Develop the sustainability, impact measurement, and long-term viability of the platform to maintain ecosystem networking, expert guidance, and virtual incubation by delivering a strategy for sustaining the incubator network beyond the IHI JU funding period.

Activities to be performed in the context of this objective:

- Create a funding & collaboration map (VCs, corporate investors, public bodies) with regional/ broad reach to support start-ups' networking during the project's lifespan.
- Develop training modules on (pre)clinical validation and develop a business development toolkit (go to market plans, reimbursement strategies, commercial models).
- Industry quality seal: start-ups incubated through the action should receive, at the end of their participation in the action, a signal of validation and endorsement from the EHCIN, in recognition of the start-up's value and investment worthiness for the whole health industry sector. The 'quality seal' can be provided in the form of a letter of intent or any other form deemed appropriate by the applicants, insofar as the quality seal would increase the startup's visibility and credibility with potential investors and provide market validation that could help unlock future interest in the selected start-ups. This would not constitute a formal commitment or investment decision by the action's beneficiaries, but rather a form of industry endorsement signalling that the startup is credible, promising, and valuable to the broader sector.
- Develop a sustainability strategy for the European Healthcare Incubator Network beyond the funded period (business case, governance, revenue/ hosting model), with the objective of identifying scenarios to ensure long-term sustainability of the network and the continuous accessibility of the deliverables implemented in the project.
- Design project-wide key performance indicators (KPI) and implement a dashboard with agreed metrics by Category. Examples of Categories are:
  - Commercial and Economic Viability of the EHCIN,
  - Scientific and/or Technological Progress of the start-ups,
  - IP applications,
  - Talent and Human Capital Development,
  - Ecosystem Effects between start-ups, universities and industry.
- Develop annual impact and lessons-learned reports; go-to-market playbooks for incubated early-stage companies.
- Support an alumni network of start-ups that have progressed through EHCIN, designed to facilitate connections between the start-ups and potential investors and funding partners.
- Prepare training and knowledge transfer materials to ensure ongoing operation of the network.
- Develop, and validate a framework/ guidance to support early-stage engagement with regulators in a simpler and more accelerated way, including the development of recommendations for policy makers.

Financial Support to Third Parties (FSTP)

Beneficiaries may provide financial support to third parties.

In addition to providing structured access to industry expertise and complementing existing EU and national funding instruments, the IHI European Healthcare Incubator Network would offer **milestone-based financial support**, governed by the EHCIN Coordination Forum.

Applicants should provide as a key activity of the proposed action financial support to early-stage companies via the mechanism of Financial Support to Third Party (FSTP). This mechanism should allow the necessary financial support for early-stage companies to perform research and innovation activities with sufficient agility while limiting the administrative burden. This will effectively boost the progress of high potential third parties (start-ups) working on enabling technologies that will support innovation in areas of unmet healthcare need.

IHI JU estimates that to achieve all outcomes and impacts of this topic at least 75% of the IHI JU funding supplemented with Financial Contribution (FC) from the pre-identified industry consortium and/or contributing partners should be allocated to the purpose of financial support to third parties selected through dedicated calls.

Scope of the FSTP call/s

The FSTP open calls should target European early-stage companies developing transformative healthcare technologies at **TRL3–TRL5** to tackle unmet public health needs, including but not limited to new modalities or new screening/platform /technologies /early clinical validation, AI/ML for drug discovery, quantum, advanced biologics, next gen screening technologies, novel delivery systems, enabling computational tools, other transformative platform technologies - that can be applied across multiple indications or therapeutic areas.

The FSTP must be used exclusively to support TRL 3–5 start-ups in the advancement of their core innovative technologies. Such funding must not, under any circumstances, be used directly or indirectly for ancillary, non-core, or unrelated purposes.

Maximum amount per third party:

The maximum amount to be granted to each third party is EUR 2 000 000 (EUR 1 000 000 + EUR 1 000 000 as detailed below).

The programme should provide funding through a two-stage grant structure: an initial grant followed by a **potential** follow-on grant.

- **Initial Grant:**
  Via a competitive FSTP call, each startup could receive a milestone-based grant ranging from EUR 100 000 to EUR 1 000 000. Funding is disbursed only when agreed technical and development milestones are met.

- **Follow-on Grant:**
  Those startups receiving an initial grant which demonstrate **exceptional potential and strategic relevance**—in line with the criteria defined below—could unlock an additional conditional grant. This **follow-on grant** also may range from EUR 100 000 to EUR 1 000 000, is also tied to milestones, and aimed to accelerate further development, validation, and industrial adoption.

The maximum funding available to each start-up is up to EUR 1 000 000 for the initial grant, with the possibility of an additional EUR 1 000 000 follow-on grant, bringing the total potential support to a maximum EUR 2 000 000 per start-up. This is necessary to achieve the objectives of the third parties (start-ups) funded via FSTP which would otherwise be impossible or overly difficult to reach.
It reflects the financial needs of early-stage healthcare innovators, enabling subprojects to deliver meaningful, scalable and sustainable impact across the European healthcare landscape while supporting validation, maturation, and attracting follow-on investment. The funding level is aligned with the scope and complexity of subprojects advancing technologies that require significant resources for regulatory preparation, clinical validation, and business development.
This support is essential to strengthen proof-of-concept translation and enable progress toward scale-up and market readiness, including high-cost activities such as preclinical studies and model development.

Mechanisms of selection and award of the FSTP to third parties

The EHCIN Coordination Forum should select and fund third parties through FSTP based on excellence, meaningful impact and avoiding duplication.

Accordingly, the applicants should provide as part of their proposal the following information:

- specify how FSTP will be managed,
- provide a list of the different types of activities for which a third party may receive financial support and describe results to be obtained.
- Detail the role of the Advisory Board in line with the tasks indicated above.
- Detail how it will organise the call/s to select the third party and lay out the cadence of calls. **Note** that the timing of the call/s should allow the completion of the awarded subprojects within the lifetime of the main action.
- Describe the organisation of the team launching and implementing the FSTP call
- Detail how the principles of transparency, equal treatment, non-conflict of interest and confidentiality will be respected.
- Clearly delineate / detail the calls logic including:
    1) implementation of the eligibility and selection criteria indicated below (including contribution to the achievement of the general objectives of IHI JU and consideration for the scale of innovation and the strategic importance of the supported technologies, quality of the proposed plan of activity and alignment with the funding request);
    2) award procedure;
    3) eligible costs under IHI;
    4) the expert selection and evaluation process; and
    5) maximum funding per call. It should detail how the principles listed above will be respected.
- Specify how it will advertise the call/s including the following requirements:
    1) the call should at least be published on the action website and EU Funding and Tenders portal for a minimum of 2 months;
    2) the results of the call should be published at least on the EHCIN public website. In particular: the name and country of the third parties, the dates, the nature of the subprojects funded and their duration.

Eligibility criteria

These eligibility criteria apply to early-stage companies applying for Financial Support to Third Parties (FSTP) under this topic. All of the following conditions must be met for an application to proceed to merit-based assessment.

- The applicant is an early-stage company (start-up) legally established in an EU Member State or Horizon Europe Associated Country.
- The applicant's core technology or solution is declared to operate at Technology Readiness Level (TRL) 3, 4, or 5 at the time of submission, as defined in the call topic text.
- The applicant has NOT previously received FSTP funding under this action.
- The applicant is NOT receiving other EU funding for the proposed subproject.
- The applicant has NOT received an investment from any consortium member over the past 3 years (counted from the FSTP call application deadline)

***Selection/award criteria*:**

Applications passing the eligibility gate should be assessed and ranked on the following criteria

- Scientific and Technical Excellence
- Unmet Healthcare Need
- Innovation and Differentiation
- Regulatory Strategy & Path to Market
- Team capability & Investment Readiness
- Compatibility with industry in-kind offering
- Contribution to the achievement of the general objective of IHI JU[7]

Selection criteria for the additional follow-on grant:

- Successful completion of initial FSTP grant
- Achievement of pre-defined technical milestones from initial grant
- Clear justification that additional funding will materially accelerate outcomes
- Demonstrated advancement along the agreed TRL pathway
- Demonstrated exceptional potential and strategic relevance

[7] Article 115 of COUNCIL REGULATION (EU) 2021/2085:

Additional objectives of the Innovative Health Joint Undertaking

1. In addition to the objectives set out in Articles 4 and 5, the Innovative Health Initiative Joint Undertaking shall reach the following general objectives by 2030:

a) contribute towards the creation of a Union-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, in particular by launching at least 30 large-scale cross-sectoral projects, focusing on health innovations;

b) foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least five examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment or management of diseases affecting the Union population, including contribution to Europe's Beating Cancer Plan;

drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.

Evaluation

The applicants should include in their proposal the establishment of an independent expert evaluation committee composed of expert representatives nominated and selected by the EHCIN in consultation with the Advisory Board to assess applications under the FSTP scheme in a transparent, objective and fair manner, based on clear selection criteria and appropriate safeguards against conflicts of interest.

Please note that applicants should provide as part of the full proposal the relevant FSTP annex.

Form of Financial Support to third parties:

- The FSTP will take the form of a grant.
- No additional cascade funding is allowed, i.e. the third party receiving a financial support must not allocate or transfer the financial support to another entity (partially or in full).
- The indicative duration of the subprojects is up to 36 months. Nonetheless, this does not preclude submission and selection of proposals requesting other durations to allow for proper level of funding for maturing of business plans and solutions. However, the duration of the subprojects will not exceed the duration of the Grant Agreement.
- The FSTP will be reimbursed/paid to the third party on a milestones-based approach:

  A milestone-based disbursement combined with a technical and financial reporting scheme will ensure accountability and the efficient use of resources. Specifically, the applicants should describe in the proposal the technical and financial reporting frequency (which should at minimum be the same as those of the grant agreement) as well as the payment scheme it will design for the payment to the third-party. The payment scheme should be designed carefully to avoid any cashflow shortage and take into account the timing of payments from IHI JU. The call texts will have to be submitted to IHI JU for approval prior to launch.
- Applicants should also detail the procedures regarding the nature and frequency of controls to ensure the third-party respects the costs eligibility criteria and other compliance obligations and how they will support the third party, ensuring it is informed of the reporting and compliance requirements, particularly the cost eligibility criteria.
- The beneficiaries should be able to provide evidence of the FSTP disbursements, in particular extracts from their accounts and extracts from the third-party accounts as well as the bank statements of both the beneficiaries and the third-party showing the financial support amount.

Additional guiding principles:

1. **Access to External Partnerships for Start-ups Awarded Funding** - Start-ups (TRL 3 to 5) that are awarded funding through the EHCIN should be permitted to initiate partnerships within the broader innovation ecosystem—including with pharmaceutical companies, venture capital funds, and other relevant stakeholders subsequent to the finalisation of EHCIN grant funding.
   These partnerships may be structured on a non-dilutive or dilutive basis, as appropriate to support the start-up's development and commercialisation pathway.

2. **Eligibility of Start-ups hosted by participating Incubators** - A start-up hosted by a participating incubator should remain eligible to participate in FSTP calls, provided that respective hosting costs are not financed through EU funding (they can be part of the in-kind provided and thereby part of the project budget and reported costs).

3. **Equal Rights and Opportunities for All Industry** - In all cases, industry inside and outside consortium should have equal rights and opportunities to negotiate access rights, collaboration arrangements, and other partnership structures.

Expected impacts

The action under this topic is expected to achieve the following impacts and contribute to the following EU policies/initiatives:

- Deliver innovative, early technology solutions that contribute to addressing strategic unmet public health needs across multiple therapy areas to improve prevention, early diagnosis, and treatment
- Leverage the unique network and scale of IHI JU members to create a pipeline to support innovative startups in the health industry, fully integrated into European initiatives in support of start-ups and entrepreneurship.
- Drive early cross-sector health R&D and innovation to strengthen the European healthcare industry's global competitiveness, contributing to the EU Industrial Strategy and Pharmaceutical Strategy objectives.
- Create a sustainable network of European healthcare incubators to guide and support highly talented and innovative early-stage companies
- Harness digital health and data-sharing technologies (e.g., AI and big data) to enable interoperable health solutions, contributing to the European Health Data Space (EHDS) and improved evidence-based care.
- The action should generate a portfolio of early-stage companies that have undergone rigorous multi-industry validation, significantly increasing their credibility with investors, regulators, and healthcare systems. This 'industry quality seal' should enhance the selected startups' ability to secure follow-on financing.
- By integrating corporate expertise into a pan-European incubator network, the action should reduce fragmentation, support faster clinical and eventually commercial decision-making, and enable more innovators to navigate regulatory and reimbursement pathways successfully. This should contribute to the objectives of the EU to accelerate the translation of research into deployable health technologies. The Network should serve as a feeder mechanism into wider EU support structures, ensuring that promising companies can transition smoothly into later-stage funding and scale-up opportunities. This complementarity should maximise the added value of EU public funding while avoiding duplication and reinforcing Europe's position as a globally competitive hub for health innovation.

The action under this topic should synergise with relevant EU programmes and contribute to several key EU strategies and policies: Life Science strategy, Industrial strategy, Pharmaceutical strategy, Biotech Act, EU4Health Programme, Digital Europe Programme, Testing and Experimental Facility for Health AI and Robotic (TEF-Health), European Innovation Council (EIC), EU Competitive Compass, Choose Europe initiative, Startup and Scale-up strategy by the European Commission.

Additionally, the action under this topic should synergise with the forthcoming European Startup and Scaleup Hubs and, in particular, encourage connection into the EHCIN from the Call 'European Startup and Scaleup Hub Pilot Call – HORIZON-EIE-2026-02-CONNECT-01'.

Furthermore, the action has the potential to support Europe's Beating Cancer Plan, EU Mission on Cancer, Healthier Together – EU Non-Communicable diseases initiative, Joint Action for Cardiovascular Disease and Diabetes in Europe, or the Cardiovascular Health Plan.

Applicants should demonstrate in the proposal how these synergies will avoid duplication, ensure complementarity with existing EU efforts, and provide early-stage companies with continuity and scale-up pathways.

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

The fragmentation of Europe's early-stage health innovation landscape—across incubators, investors, national programmes, and regulatory actors—cannot be addressed by public initiatives alone. Achieving the expected outcomes of this topic requires the integrated, cross sector model uniquely enabled by an IHI Joint Undertaking action.

The positioning and added value of the IHI European Healthcare Incubator Network should be clearly articulated within the wider European innovation and funding landscape. Public and private collaboration is equally vital. Its distinctiveness lies in the provision of targeted industry in-kind support to a defined subset of start-ups developing enabling technologies (e.g. AI for biologics screening) with clear relevance to pharmaceutical and medical technology applications. This includes expertise and assets that cannot be replicated within public incubators or grant schemes, including access to infrastructure, clinical datasets, regulatory specialists, and corporate venture perspectives. These capabilities enable early-stage companies to receive actionable, market aligned guidance that significantly improves feasibility, derisks development, and accelerates time-to-market.

An IHI JU action brings these actors together under a shared governance model, ensuring alignment, mutual commitment, and faster translation of innovation.

Without this level of integration, efforts may remain fragmented. This model is uniquely positioned to deliver the coordination, ambition, and impact required to address these complex challenges in a stream-lined and accelerated manner bringing sustainable and continued investment in Europe.

Pre-Identified industry consortium

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following pharmaceutical and medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries (i.e. beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities with regard to such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall as project leader facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 35 000 000. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***
- The indicative in-kind and financial contribution from industry beneficiaries is EUR 10 696 000 (target). ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The allocation of the EUR 850 000 financial contribution (FC) from industry beneficiaries will be decided by the full consortium at the second stage when preparing the full proposal. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

- The indicative in-kind contribution from IHI JU contributing partners is EUR 4 328 750. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board***

JUSTIFICATION FOR LOWERING THE 45% THRESHOLD FOR THIS INDIVIDUAL ACTION

- The topic foresees a maximum of EUR 35 000 000 in IHI funding over **five years**, with the majority delivered through **cascade funding** (the Financial Support to Third Parties (FSTP) mechanism under Horizon Europe) to downstream innovators via calls targeting early-stage- healthcare companies. **75%** of the IHI funding is expected to be reserved for Financial Support to Third Parties, in line with the anticipated support needs of healthcare startups operating at- early Technology Readiness Levels (see below).
- The indicative in-kind and financial contribution from the pre-identified industry consortium is EUR 15 024 750 (30% of the total project budget – justification below)
- Industry and contributing partners contributions for this topic will primarily consist of advice and guidance on business development, market access and technical expertise, access to lab facilities, platforms and data, for the IKOP component. This is unlike other IHI actions which often include significant time spent by postdocs and specialists from industry partners contributing to the actual work packages.
- Article 119.3 SBA Regulation 2021/2085 states that '*contributions provided by participants to indirect actions funded by the Innovative Health Initiative Joint Undertaking shall amount to at least 45 % of an indirect action's eligible costs and costs of its related additional activities. When justified, the work programme may exceptionally allow a lower proportion of contributions at the level of an individual indirect action and its related additional activities.*'
- In line with the above-mentioned SBA provision, industry is investing significantly in IHI incubator activities and, as such, will seek to maximise relevant project-level IKAA, however, **providing 45%** or more of the requested eligible cost is **unlikely to be achieved**:
    - Some of the necessary resources contributed by companies and contributing partners (data, equipment, offices, general infrastructure) will not be considered as eligible costs in

accordance with article 6 of the Horizon Europe Model Grant Agreement[8] and therefore will not be reported.

- For all industry and contributing partners involved given the nature of the topic, it is not known in advance who the third parties are that will take part and hence it makes it challenging to predict upfront at individual company level the maximum in-kind levels that could be contributed to support them.

- Commitments from industry and contributing partners must represent at least **30%** of total project resources, which is likely to be matching the IHI funds reserved and required for the consortium partners eligible to receive funding for coordination, implementation, and support activities, but **insufficient** to match the cascade funding component and fully achieve the topic outcomes.

- Therefore, given its unique strategic importance, and systemic importance for the European innovation ecosystem, the 'European HealthCare Incubator Network Project' satisfies the conditions for a justified **exceptional** request for lowering the 45% threshold for an individual action.

- Expected budget distribution

Total Action	Industry and contributing partners contributions	IHI Funding	FSTP	Project coordination
50,024,750	15,024,750	35,000,000	26,250,000*	8,750,000

*75% of IHI funding + to be complemented with financial contributions from industry

Indicative duration of the action

The indicative duration of the action is **60** months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium and contributing partner(s) may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium

The preidentified industry consortium and contributing partners expect to contribute to the IHI JU project by providing the following expertise and assets that are essential to achieving the aims of the action and cannot be provided through public mechanisms alone.

- Technical and scientific knowledge across therapeutics, medical devices, diagnostics, digital health, and enabling technologies
- Specialised regulatory, legal and IP expertise.
- Commercial readiness and market access insight, ensuring that supported companies develop solutions aligned with real-world unmet needs and adoption pathways.
- Infrastructure, facilities, datasets, and platforms enabling early experimental validation, prototyping, and data-driven development.
- Corporate venture and investor-readiness support, enhancing visibility and credibility for startups seeking follow-on funding.

[8] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf

- Partnership opportunities, including testing environments, early pilots, and potential strategic collaborations or co-development agreements.
- Multi-corporate mentorship, ensuring that startups benefit from cross-industry perspectives rather than single-company viewpoints.

These contributions constitute the core added value of EHCIN and differentiate the action fundamentally from existing funding and acceleration programmes. Industry involvement will enable EHCIN to act as a European-level catalyst, delivering de-risked innovations with strong potential for scale-up and integration into healthcare systems.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium and contributing partners.

This may require mobilising the following expertise and/or resources:

Core Leadership & Operational, Financial, and Grant Management

- *Strategic Leadership & Stakeholder Engagement:* Expertise in overall strategy development, stakeholder management, and fundraising.
- *Operational & Administrative Management:* Capability to manage day-to-day operations, program execution, and logistics.
- *Third-Party Funding Management (FSTP):* Proven ability to select, fund and manage the full life cycle of third-party projects via FSTP. Sufficient operational and financial capacity will have to be clearly documented.
- *Community Building & Engagement:* Experience in organizing events, networking activities, training sessions, and expert workshops for early-stage companies.
- *Financial & Grant Management:* Proficiency in budget planning, grant administration, and financial reporting. Demonstrated track record in managing large financial budgets and public-private partnerships.
- *Startup Selection & Support:* Expertise in selecting, contracting, mentoring, and monitoring early-stage companies.

Technical & Business Support

- *Business Development & Commercialization:* Skills in corporate partnerships and commercialization strategy.
- *Investment & Funding Expertise*: Experience in due diligence, investment readiness, and investor network engagement.
- *Regulatory, Legal & IP Strategy:* Knowledge of regulatory frameworks, IP management, and contract negotiation.
- *Technology Expertise:* Competence in AI, data science, enabling technologies, and digital health solutions.
- *Public Health & Policy:* Understanding of public health impacts and policy development.

- *Technology tools:* Customer Relationship Management (CRM)/ portfolio management system; Data rooms for due diligence; Cloud computing resources; KPI tracking systems; Portfolio monitoring capabilities; Impact assessment framework

Physical Incubator Infrastructure (complementary to industry in-kind facilities)

- Flexible office/co-working spaces (hot-desking options).
- Meeting rooms and collaboration spaces.
- Wet lab facilities (for biotech-focused startups).
- IT infrastructure and cybersecurity advisory.
- Access to specialized lab facilities.

Experience in enabling key capabilities and partnerships

- *Pharma Partnership Development:* Ability to establish and maintain strategic collaborations with pharmaceutical companies; Access to industry experts and opportunities for technology validation.
- *Investor Network Management:* Strong connections with venture capital firms, corporate venture arms, and grant agencies; Expertise in facilitating funding opportunities for early-stage ventures.
- *Academic and Research Collaboration:* Partnerships with universities and research institutions for talent acquisition and intellectual property development; Capability to leverage academic resources for innovation.
- *Service Provider Ecosystem:* Established network of legal, accounting, Contract Research Organisations (CROs), and regulatory consultants; Ability to provide or broker specialized support services for startups.
- *Pan-European Networking:* Links to other incubators and innovation hubs across Europe for knowledge sharing and collaboration; Experience in fostering cross-border partnerships.
- *Health Incubator Program Expertise:* Proven track record in designing and operating MedTech and Pharma incubator programs; Ability to deliver structured support for early-stage health ventures.
- *Early-Stage Company Engagement:* Deep expertise in partnering with and mentoring early-stage companies; Capability to guide startups through commercialization and growth phases.
- *Sustainability& growth:* Deep expertise in shaping and implementing a roadmap to sustain long-term value beyond the project timelines

At the second stage, the applicant consortium selected at the first stage and the pre-identified industry consortium and contributing partners will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

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’ do not apply.

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Glossary

ACRONYM	MEANING
AB	Advisory Board
AI	Artificial Intelligence
CRM	Customer Relationship Management
CRO	Contract Research Organisations
EHCIN	European HealthCare Incubator Network
EHDS	European Health Data Space
EIC	European Innovation Council
EMA	European Medicines Agency
EU	European Union
FC	Financial Contribution
FSTP	Financial Support to Third Parties
GDPR	General Data Protection Regulation
IHI JU	Innovative Health Initiative
IKAA	in-kind contributions to additional activities
IKOP	in-kind contributions to operational activities
IND	Investigational New Drug
IP	Intellectual Property
IVDR	In Vitro Diagnostic Regulation
KPI	key performance indicators
MDR	In Vitro Diagnostic Regulation
R&D	Research and Development
TRL	Technology Readiness Level
VCs	Version Control System