EIT Health Call Document Flagships Call 2025

05 September 2024

Introduction

Europe is facing a turning point in healthcare. From an increase in infectious diseases, pandemic threats, antimicrobial resistance, to the rising costs of healthcare delivery, and social and healthcare systems typically slow to change and adapt, the time to act is now. In recognising this, EIT Health's Flagship concept was born in 2023 with the launch of the first EIT Health Flagship Call.

In 2025, the Call will address the **Digital Transformation of Healthcare (DTH)**. This Flagship concept aims to support the digital health transformation in Europe and will focus on the development of, and access to, health technologies and digital medical devices. It will finally focus on how patients, citizens, and healthcare professionals are trained to understand the importance and relevance of data sharing in informing and improving the continuum of care pathways.

Objectives and Scope

With the ambition to contribute to some of the top health priorities that have been identified at the EU level, EIT Health is calling for projects that are driving Innovation and Transformation in Healthcare, with a particular focus on the Digital Transformation of Healthcare.

Digital Transformation of Healthcare (DTH)

Advanced technology and data utilisation is driving the shift towards digital healthcare to improve the efficiency and effectiveness of medical services. This Flagship aims to support the digital health transformation in Europe by focusing on the development of, and access to, digital health solutions, and the implementation of the European Health Data Space by exploring the secondary use of data.

For 2025 specifically, funded activities under the DTH Flagship will focus on the development and market uptake of patient-centred digital health solutions. There will also be a focus on ensuring innovation adoption through the selection of modules to equip professionals with relevant knowledge and skills.

Innovation to Market Projects will focus on supporting the entry of digital medical devices, that are already CE-marked or awaiting CE approval, into one or more EU country market(s), by generating robust evidence of the solution's relevance in the target market and building commercial partnerships to drive market uptake.

The **DiGinnovation Programme** is specifically tailored for micro and small enterprises with CE-marked digital health solutions that are looking for support to achieve reimbursement coverage.

Modules towards EIT Labelled Certification to further enrich the EIT Health catalogue of courses that support the Flagship 'Digital Health Transformation', EIT Health is calling for high-quality content that will feed into modules on the EIT Health Academy.

EIT Health is looking for collaborators who will support the organisation and hosting of the **EIT Health Catapult** programme 2025. This is a competition and training programme to fast-track top life sciences and health tech start-ups and showcase them to leading experts and investors across Europe.

In a nutshell

An overall financial amount of up to 8,000,000 EUR (eight million Euros) is available for this Flagships Call 2025.

The call aims to fund **up to 7 Innovation projects**, distributed across Innovation to Market Projects and the DiGinnovation programme, covering different clinical areas and unmet needs.

Furthermore, the call intends to fund **up to 18 education modules** addressed to specific target audiences, offered through the EIT Health Academy.

Moreover, the call is also looking at funding one consortium that will be responsible for delivering the longest-standing initiative in the accelerator – The EIT Health Catapult Programme.

Please find below the list of activities that will be called in each Flagship:

Flagship	Activities	Funding stream
Digital Transformation of Healthcare	Innovation activities	DiGinnovation Programme Innovation to Market Projects
	Education activities	Modules towards EIT labelled certification
	Accelerator programme	EIT Health Catapult

Conditions to receive funding

This call follows the principle of equal opportunity and is therefore open to applications for funding from both EIT Health association members and applicants outside of the EIT Health Partnership.

To be eligible for funding, all applicants must be established in one of the Member States (MS) including their outermost regions, the Overseas Countries and Territories linked to the Member States[1] or in countries associated to Horizon Europe as well as certain low- and middle-income countries [2] [3] [4].

Individuals cannot apply for funding under this call.

Applicants who are not EIT Health members will only be eligible to receive funding after they have acceded to the relevant EIT Health legal framework.

The provisions of the Articles of Association and By-Laws of the EIT Health association (EIT Health e.V) will apply to partners of selected activity consortiums. All project participants **receiving funding on funded EIT Health projects** must adhere to the EIT Health Fees as decided by the Partnership Assembly. **Different membership fees apply depending on the size and nature of the organisation and the annual EIT Health funding requested** for that organisation as part of the project. For more information on the fee model please check our website section here.

[1] Entities from Overseas Countries and Territories (OCT) are eligible for funding under the same conditions as entities from the Member States to which the OCT in question is linked.

[2] UK entities will now be eligible to directly receive EIT funding, if selected as a part of a granted project consortia and will be treated as all other participants from Horizon Europe participating and associated countries. UK entities selected as part of prior calls for proposals (2023 and prior) will continue to be covered by the local UK reimbursement scheme. Further information on this topic can be found on the UK Research and Innovation website or by reaching out to the EIT Health Ireland-UK Co-location Centre.

[3] Switzerland is currently not an associated country of the Horizon Europe programme. As such, Swiss entities are not directly eligible to receive EIT funding, when part of a selected project consortia. Entities can receive up to €60,000 in EIT funding within the EIT Health Business Plan 2023-2025. However, for funding above €60,000 organisations need to refer to the Swiss national reimbursement scheme. In the current non-associated third country mode, researchers and innovators in Switzerland are funded directly by the Swiss Confederation if the complete project proposal has been positively evaluated. Further information is available on the State Secretariat for Education, Research and Innovation (SERI) of Switzerland or by reaching out to the EIT Health Germany-Switzerland Co-location Centre.

[4] Due to a decision by the Council of the European Union, published on and effective as of 15 December 2022, certain Hungarian "public trust foundations" are currently not eligible to receive funding under the Horizon Europe and Erasmus programmes. These Hungarian entities can still participate without receiving EIT funding, as an Associated partner, if allowed by the call conditions. Further information can be found on the EU Commission Funding and Tenders FAQ website. EU Commission Funding and Tenders FAQ website.

The European Commission is committed to promoting gender equality in innovation and technology. The EIT, as a body of the European Union and an integral part of Horizon Europe, plays a vital role in supporting the EU's objectives of creating sustainable economic growth and jobs by enabling entrepreneurs and innovators to turn their best ideas into products and services for Europe. EIT Health shares the EIT KIC gender diversity value statement through supporting well-being at work, compliance with domestic and EU regulations, attracting and retaining talents, economic benefits, excellence and quality, effectiveness and efficiency of innovations and technology and as a leverage for organisational change. Consequently, the gender requirements in Horizon Europe are of significant importance for all EIT Health-supported and funded activities.

EIT Health encourages the participation of entities from the EIT Regional Innovation Scheme (EIT RIS Regions) with the goal of improving the Knowledge Triangle integration, the innovation capacity of local ecosystems in RIS countries and regions, and attract new RIS Partners.

To uphold the principles of EIT Health financial sustainability, all activities selected in EIT Health's portfolio and receiving funding must commit to contributing to the long-term financial sustainability targets of EIT Health and will be required to enter into a Financial Sustainability agreement. This agreement establishes a framework for responsible financial management, where beneficiaries are obligated to sign the Financial Sustainability agreement, acknowledging their commitment to adhere to the specified EIT Health financial models and practices outlined here (Grant to options, Revenue Sharing, Revenue Sharing - EIT Health led). EIT Health Catapult programme will have a specific financial sustainability mechanism that will be owned by the KIC and based on sponsorship agreements.

The grant period for this call ends on 31 December 2025. The only exception to this rule is the support to EIT Health Catapult Programme, for which the budget for 2026 is conditioned to EIT validation of the EIT Health Business Plan in November 2025.

The maximum amount of financial support provided to individual entities within the 3-year duration of the Grant Agreement between EIT Health and EIT, namely 2023-2025 should not exceed 6,000,000 EUR (six million Euros).

Above and beyond the specific EIT Health rules of participation, all activities must comply with the relevant Horizon Europe and EIT financial and legal framework considerations.

In the case of any questions regarding eligibility, reach out to flagships@eithealth.eu.

Education activities

Specific conditions for Modules toward Labelled Certification

General Conditions

- The consortium must include at least two participants coming from two different and independent institutions.
- Each consortium must include participants residing in at least two eligible countries, participating through two different Co-Location Centres (CLCs).
- Each consortium must involve organisations from two sides of the Knowledge Triangle, e.g. industry and healthcare provider, higher education institution and industry, etc.
- Applications must commit to the EIT Health Competence Framework and EIT Health label / accreditation for non-degree programmes.
- Validated expertise in the Flagship topics and application for the European Union of Medical Specialists (UEMS) European Accreditation Council for Continuing Medical Education (EACCME) accreditation (where healthcare professionals are the target audience) are expected.
- The final recipients of funding must comply with the Intellectual Property Rights (IPR) rules under the MGA Article 16.

Description and strategic fit

To further enrich the EIT Health catalogue of courses that support the Flagship 'Digital Health Transformation', EIT Health is calling for high-quality content that will feed into modules on the EIT Health Academy.

What is called for:

- Course outline with clear expected learning outcomes mapped on selected competences from the EIT Health Competence Framework and EIT overarching learning outcomes (OLO's).
- Content developed on the above for a 4-week (up to 15/20 hours of study in total) online course, that will be hosted entirely on the EIT Health Academy. The Academy team will support selected consortia from the selection notification.
- Content toward assessment, for example, scenario-based assessment, multiple choice questions, etc.

What not to include in the proposals / not eligible:

- Learning management system (LMS) - LMS costs provided by EIT Health.

- Marketing and promotion costs - provided by EIT Health.

List of modules

The table below lists the sought after topics. EIT Health will select one module for each topic 1 to 16, and up to three modules for topic 17:

#	Module topic	Target audience	Expected outcome
1	**Quality assurance skills in biomanufacturing, biotech, medical devices, quality assurance, standards, quality assessment. General overview / basics of quality assurance in the industry.**	Post-graduate learners in pharmaceutical, biochemistry, bioengineering, etc.	Students taking the course will learn about quality assurance and its relevance in the industry workplace.
2	**Quality assurance skills in bioproduction, biotech, medical devices, quality assurance, standards, quality assessment. Advanced course on quality assurance in different departments across industries.**	Professionals working in bioproduction, biotech, medical devices.	Professionals taking the course will have an improved understanding of quality assurance, and they can engage with the quality assurance methodologies in their work practice.
3	**Basics of biomedicine**	Students in post-graduate education in STEM fields.	Students taking the course will • Gain an understanding of the biomedical field. • Get an overview of what the most novel implications and developments in biomedicine are. • Obtain an overview of biomedicine in industry.

#	Module topic	Target audience	Expected outcome
			• Receive insights on the career opportunities provided by biomedicine and bioproduction.
4	**Introductory course on the European Health Data Space (EHDS) Regulation**	Medical professionals, public health bodies, healthcare providers, healthcare industry, and start-ups. Will be of particular relevance to those working in Digital Health, Pharma and MedTech, Management positions, and IT departments.	Students taking the course will • Understand the main objectives of the EHDS Regulation, its rationale, scope, impact, and relationships with other EU regulations. • Learn about individual rights and GDPR specific to health data. • Understand the common infrastructure for MyHealth@EU. • Learn about the certification scheme for European Health Regulation (EHR) systems and associated standards. • Understand the labelling process for health and wellness apps. • Learn about the conditions and procedures for the secondary use of health data. • Provide a series of case studies and examples around different use cases within health systems and healthcare practices and activities.
5	**The future of health data management: Trends and new models for data platforms**	Policymakers, healthcare providers, health industry, and start-ups. Of particular interest to those working in management positions, IT departments, Digital Health, MedTech, and Pharma.	This course will provide an overview of the current different data management models and platform architectures, both vendor-specific and open-source solutions. Including the common terminology and technical standards in the healthcare sector. The course will cover the theory and practical case studies for the different models currently implemented across Europe and beyond. Attention will be paid to the concept of “Data-as-a-service" in healthcare.

#	Module topic	Target audience	Expected outcome
6	**European Health Data Space: Labelling health and wellness apps for MyHealth@EU**	Healthcare industry, start-ups, and public health bodies. In particular those in Digital Health, Pharma, MedTech.	Learners will: • Understand the criteria and standards for the labelling of health and wellness apps in the European. • Learn about the key regulatory and quality requirements specific to the European Health Data Space and MyHealth@EU. • Understand how labelling impacts market access and acceptance of health and wellness apps. • Develop strategies to leverage labelling for competitive advantage and user trust.
7	**European Health Data Space: Course on market access for Digital Medical Devices**	Healthcare industry, start-ups, and public health bodies. In particular those in Digital Health, Pharma, MedTech.	By the end of the course students will: • Understand the existing regulatory frameworks such as DiGA (Germany) and PECAN (France), and the key similarities and differences. • Learn how to manage the certification process of a digital health solution through these frameworks, including the administrative and evidence-generation. • Be able to implement the required quality assurance processes. • Develop strategies to leverage labelling for competitive advantage and user trust.
8	**How to design and implement Health Data Access Bodies across Europe**	Policymakers and public health bodies	This course will be based on case studies from existing health data hubs and workshops to exchange experiences. This course will provide participants with knowledge on the design and implementation of Health Data Access Bodies to ensure alignment with the aims and requirements of the European Health Data Space. It will cover data security, compliance, interoperability,

#	Module topic	Target audience	Expected outcome
			stakeholder engagement, ethical and legal issues, capacity building initiatives, and performance monitoring.
9	**European Health Data Space: Introduction to Privacy-Enhancing Technologies (PETs)**	Health industry, start-ups, public health bodies, healthcare providers, researchers and academia. Will be of particular interest to those in Digital Health, Pharma, and MedTech.	This course will give a comprehensive overview of the current and emerging Privacy-Enhancing Technologies (PET). It will cover the basic principles, functionalities, and application in the healthcare sector in the European regulatory framework (GDPR, EHDS, Data Act). Several scenarios for secondary use of health data and case studies will be covered for research and clinical studies, healthcare management, public health, care provision, and industry applications.
10	**Introduction to the European Artificial Intelligence Act**	Health industry, start-ups, public health bodies, healthcare providers, researchers and academia. Will be of particular interest to those in Digital Health, Pharma, and MedTech.	This course will equip participants with a thorough understanding of the Regulatory Framework and its implications for healthcare sector. Participants will gain insights into the Act's key provisions, compliance requirements, and the ethical considerations surrounding AI deployment. By the end of the course attendees will: • Understand Regulatory Framework, its structure and objectives, including the classification of AI systems and associated risks. • Be able to ensure organisational compliance and identify and implement measures to comply with the AI Act. • Understand how to mitigate the legal and operational risks. • Understand the ethical considerations of implementing AI and be able to integrate these into AI development and deployment,

#	Module topic	Target audience	Expected outcome
			ensuring fairness, transparency, and accountability. • Develop strategies for managing risks associated with AI. • Understand how to engage effectively with stakeholders to align AI initiatives with regulatory and societal expectations.
11	**Health Technology Assessment (HTA) 2025: Upcoming Regulation**	Health industry, start-ups, public health bodies, healthcare providers, researchers and academia. Will be of particular interest to those in Digital Health, Pharma, and MedTech.	This course will provide an overview of the Health Technology Assessment focussing on the 2025 updated European HTA Regulation. Participants will learn about the main developments related to HTA in Europe and its implications, considering the different points of view from stakeholders across the health ecosystem.
12	**Deep Tech Venture Builder (DTVB): Product Development and technologies**	DTVB applicants, individuals looking to upskill as part of their journey toward start-up creation.	Participants taking the course will learn about market research and validation, customer discovery and validation, regulatory basics and first strategy, developing minimal viable product (MVP) prototyping and testing. Among others, learners will be able to: • Identify the key steps in market research. • Define and validate the clinical need/ unmet need / Problem- Solution Fit. • Interrogate the assumptions and market research methodology. • Objectively validate the market research. • Stipulate the steps for customer discovery. • Validate the resulting customer discovery reports. • Plan the development and delivery of a minimum viable product (MVP).

#	Module topic	Target audience	Expected outcome
			• Develop a prototype of their deep tech product/ service. • Identify and choose an appropriate methodology to test the prototype. • Identify the main regulatory steps/ pathway and processes.
13	**Deep Tech Venture Builder (DTVB): Business Models and strategies**	DTVB applicants, individuals looking to upskill as part of their journey toward start-up creation.	Participants taking the course will learn about business model development, cost structure and financial planning, and strategic planning and roadmaps. Among others, learners will be able to: • Identify the key components of a business model. • Critique business models from multiple stakeholder perspectives. • Contribute to the development of a business model. • Identify the cost structure of the their venture. • Contribute to the development of financial plans to support the venture. • Identify the characteristics of good strategic planning. • Contribute to the development and review of strategic planning and roadmap documentation.
14	**Deep Tech Venture Builder (DTVB): Tech transfer strategies & impact assessment**	DTVB applicants, individuals looking to upskill in this domain, in their journey toward start-up creation.	Participants taking the course will be introduced to tech transfer, intellectual property (IP) management, and assessment of commercial potential. Among others, learners will be able to: • Identify the principal technology transfer models. • Assess which model tech transfer approach is best suited to their venture. • List the key steps and features of IP Management.

#	Module topic	Target audience	Expected outcome
			• Apply IP Management to their venture. • Contribute to commercial potential assessment for their venture.
15	**Deep Tech Venture Builder (DTVB): Product refinement and scaling**	DTVB applicants, individuals looking to upskill in this domain, in their journey toward start-up creation.	Participants taking the course will learn about obtaining user feedback and iteration, clinical trial design and strategy, introduction to industrialisation, and health tech innovations. Among others, learners will be able to: • Develop a full stakeholder map • Collate and compile user feedback • Prioritise the feedback based on business needs • Develop an iteration strategy using an appropriate methodology • Document and audit quality assurance measures • Defining their Clinical Trial Design and Strategy • Identifying their industrialisation pathway
16	**Deep Tech Venture Builder (DTVB): Market Access**	DTVB applicants, individuals looking to upskill in this domain, in their journey toward start-up creation.	Participants taking the course will learn about market assessment and go-to-market strategies, regulatory pathways and compliance (QMS), reimbursement and pricing strategies, branding and positioning, and building partnerships with industry and the ecosystem. Among others, learners will be able to: • Critically review market assessment and go to market strategies. • Determine the appropriate regulatory pathway for their venture. • Develop compliance documentation and processes for their venture. • Contribute to reimbursement and pricing strategy development.

#	Module topic	Target audience	Expected outcome
			• Develop a brand and brand positioning plan.
17	**Innovation Adoption**	To be determined by applicants based on identified barriers to adoption (can be healthcare professionals, citizens, patients).	Development of training required by innovation owners to support the innovation adoption. Thus, EIT Health aims to boost adoption of innovation, be it technology development (such as an introduction on the market of digital health applications or medical devices) or service development (such as an introduction of innovative clinical pathways, patients' journeys, support to shared decision making). Applicants must refrain from product or service placement. The education / training interventions must be generic (applicable to a family of products or services, not specific to a brand name product or service).

EIT Health Quality Assurance and Accreditation

The EIT Health Quality Assurance and Accreditation process involves a straightforward, high-quality learning and teaching self-assessment. This system, based on the principles and requirements set by the EIT, places a strong emphasis on Innovation and Entrepreneurship Education. Tailored specifically to the healthcare sector, the EIT Health Quality Assurance and Accreditation system utilises the EIT Health Competency Framework as its foundation. This framework comprises 8 competencies, 5 of which are sector-agnostic (1-5) and 3 are healthcare-related (6-8). The table below provides a description of each of the 8 competencies.

The Framework's purpose is to ensure that the modules meet real market and educational needs and are equipped with appropriate teaching methods to achieve the previously defined learning objectives. It also aims to help consortia define the competencies addressed by the modules and their intended learning outcomes. Consequently, when applying for a Module in this call, applicants must select 3 competencies, with at least one being healthcare related (Health technology management, Digital health, Health systems).

The EIT Health Quality Assurance and Accreditation process encourages reflection on the quality of teaching and learning, with the ultimate goal of making a significant impact in the sector by upskilling and reskilling its workforce.

To undergo the quality assurance and accreditation process, consortia fill out a comprehensive accreditation form and submit supporting evidence. Although administered by EIT Health, quality assurance and accreditation applications are reviewed by a panel of three external subject matter experts.

#	Competency	Description
1	Innovation and Entrepreneurship	The ability to recognise, develop and act on entrepreneurial and innovation opportunities in a range of organisation settings, and to transform them into value for others.
2	Problem-Solving	The ability to analyse and understand the problem space, generate new ideas, assess their validity, and co-create solutions to meet unmet needs.
3	Critical Thinking	The ability to assess facts and evidence to drive decision-making, including constructive questioning of the status quo.
4	Leadership	The ability to be an effective leader, and to mobilise resources efficiently to enable change management and accomplish a goal based on responsible and innovative management practice.
5	Stakeholder engagement and interdisciplinary skills	The ability to drive interpersonal communication, translating complex ideas for diverse audiences, collaborating with diverse stakeholders, including patients, healthcare providers, payers, and regulatory bodies. This competency involves building partnerships to advance healthcare innovation and outcomes, leveraging collaborative networks for mutual benefit.
6	Health Technology Management	The ability to use emerging technologies in innovation processes. This competency underlines the necessity to a commitment to lifelong learning and professional growth in the dynamic field of healthcare.
7	Digital Health	The ability to develop, use and leverage digital tools to enhance healthcare delivery, patient engagement, and outcomes ensuring compliance with data privacy regulations and ethical standards.
8	Health Systems	The ability to analyse the health systems, appraise current and future sustainability challenges, and develop appropriate responses using system approaches to improve healthcare

#	Competency	Description
		outcomes, patient-centred innovation and enhance sustainability of systems (with concepts such as net-zero industry and value-based healthcare) while understanding and navigating the complex regulatory landscape in healthcare.

Consortium

- The consortium must include at least two participants coming from two different and independent institutions.
- Each consortium must include participants residing in at least two eligible countries, participating through two different Co-Location Centres (CLCs).
- Each consortium must involve organisations from two sides of the Knowledge Triangle, e.g. industry and healthcare provider, or higher education institution and industry, etc.
- The consortium must be complete at the time of submission.

Budget

- Funding per module: up to 50,000 EUR (fifty thousand Euros).
- Reimbursement rate: 70%

Financial sustainability and revenue generation

- As this activity is an EIT Health-driven and administered activity, the financial sustainability requirement lays with EIT Health.
- The consortiums will be requested to sign a Revenue Sharing Agreement with EIT Health upon selection. Please find the agreement template here.
- EIT Health will distribute and generate revenues from the final modules to ensure their sustainability beyond the funding period. Revenues will be shared with members of the respective selected consortium once the grant is offset by said revenues.

Duration of the activity

- The grant covers the activity until the delivery of the module(s) by latest 12 December 2025.
- The work on production of the content for the modules will start one month after selection notification, (allowing for a one month stand still period, see Education and

Catapult activities timeline). However, costs for work carried out from 1 January 2025 are eligible as part of the grant award.

- Work must be completed by 31 December 2025. There will be no extension possibility. Selected consortia must commit to the timelines as outlined in the application form and the EIT Health Academy annex.

Impact

- All modules toward EIT Labelled certification must address a European audience.

Implementation of the activity

- EIT Health leads this activity and will ensure recruitment marketing campaigns.
- The selected consortia will be expected to deliver the below outputs, deliverables and milestones.

Expected deliverables	Detail
Key performance Indicators (KPIs)	EIT Health will promote and distribute the courses developed and hosted on the EIT Health Academy. Hence, EIT Health is accountable for the following KPIs, to which content developed by selected consortia will contribute. • EIT08.1: Participants in non- labelled education and training • EITHE08.2: EIT RIS Participants in nonlabelled education and training. • KIC04: Number of professionals trained • KIC04.1: Number of healthcare professionals trained by EIT Health (non-degree) education programmes
Outputs	• OUT 01: Module to be developed and shared with KIC • OUT 02: Content-based assessment method
Milestones	• MS 01: (Activity) Availability of the modules content. • MS 02: (Critical) Availability of content-based method and assessment
Deliverables	• DEL 01: Curriculum of the learning pathway. Visualisation of potential journeys. • DEL 02: Definition of content-based assessment.

	• DEL 03: Report to identify the contribution of the non-academic Partner/s in the curriculum development.

- KPIs will be managed and reported by EIT Health. However, it is important that proposals acknowledge the KPIs since they are an expected outcome of courses in the EIT Health catalogue. Selected consortia are welcome to make recommendations for dissemination of the course, based on their needs assessment and course design.
- Content will be hosted on the EIT Health Academy. No content from the final product/course/programme on the EIT Health Academy (whole or part) can be used by any member of a contributing selected consortium without prior written consent by EIT Health.
- Selected consortiums will be supported by the EIT Health Academy team to validate the learner journey through curriculum development and storyboarding workshops ensuring optimal instructional design and learning experience on the EIT Health Academy. For more information, please see here.
- The modules shall be submitted to an accreditation institution - UEMS EACCME where target audience are healthcare professionals; EIT Health Labelling and Accreditation system for all.

Ethics

- Each consortium must complete the mandatory Ethical, Legal and Social Implications self-assessment checklist related to Horizon Europe in the EIT Health application system. Please see Horizon Europe guidance here, if needed.

EIT Health Catapult

Specific conditions for EIT Health Catapult activities

General conditions

- Each consortium must have at least one EIT Health member of the association as part of the consortium (Core or Associate Partner).
- Each consortium must include participants residing in at least two eligible countries, participating through two different Co-Location Centres (CLCs).
- Each consortium must contribute to the European Green Deal and the Sustainable Development Goals (SDGs). Therefore, they should add at least one customised KPI that

proves how they contribute to the reduction of the environmental impact of their activity and at least 2 SDGs that the activity will contribute to.

- Each consortium must contribute to the EIT and EIT Health Dissemination and Promotion, and must follow the communication, dissemination, open science and visibility rules, including branding guidelines and obligations (set out in MGA Article 17). A communication, dissemination and outreach plan is required for each activity, including those providing financial support to third parties.
- The final recipients of funding must comply with the Intellectual Property Right (IPR) rules under the MGA Article 16.

Description and strategic fit

The EIT Health Catapult is a training program for Health-Tech and Life Sciences start-ups. Through dedicated sessions, up to 30 ambitious start-ups optimise their business plan, strengthen their pitch deck and present themselves in front of international investors and corporates. At the end of the training, 9 finalists, selected by an independent expert jury of investors, join the world's leading health market community for a live on-stage competition at a major Health-Tech conference in Europe.

EIT Health Catapult gives the European health disruptors the needed visibility, stamp of excellence and boost. The EIT Health Catapult organises its activities along 2 thematic focus areas: Health-Tech (including MedTech and Digital Health) and Life Sciences (previously BioTech). The programme involves start-ups active across a broad portfolio of disciplines ranging from patient-centred solutions to professional solution concepts, platform technologies, clinical data science, health devices and therapies. Commercialisation of these best business concepts will contribute to reach the overall goals of EIT Health of **better health of citizens** through the reach of the innovations, contributing to a **sustainable health economy in Europe** through the creation of jobs and enterprises, overall **strengthening the European healthcare system.**

The EIT Health Catapult programme is built on a well-tested concept that has been refined over nine previous editions. The programme is organised into three defined stages:

Regional Selections: In this stage, the top start-ups from each region (EIT Health CLC regions) are chosen across two categories—Life Sciences and Health-Tech (which includes Med-Tech and Digital Health). The two leading Health-Tech start-ups and the top Life Sciences start-up from each region advance to the semi-final stage.

Semi-finals: Training and Selection Days: the best European start-ups in each category are selected by an international panel of healthcare investors. This stage includes 2-3 days of online training with mentors and pitch trainers. On pitch day, 10 start-ups from Life Sciences and 20 from Health-Tech present in front of top-level investors and industry experts, with the top 9 (3 in Life Sciences, 6 in Health-Tech) moving on to the final. At this stage an in-person get-together is organised to connect start-ups with investors, industry, hospitals and other

stakeholders. In addition, an online platform to showcase the current participants of the programme to investors and the European healthcare ecosystem is set up and managed.

International Finals: The final pitch stage takes place during a major health related event in Europe. An international jury of investors selects one winner per category. Each winner receives prize money from EIT Health. Additionally, the audience can vote to award one finalist with the Audience Award and industry partners award the industry in-kind prizes (i.e., technical cloud infrastructure, opportunity to pilot their solution in a clinical environment, exposure to relevant departments, etc.).

The programme offers the following value proposition to entrepreneurs:

- 360° TRAINING: optimise their business plan and strengthen their ability to present their project in a convincing manner in front of top-level investors and industry experts.
- VISIBILITY: opportunity to pitch in front of major seed or series A investors & industry leaders active in the field.
- PEER-TO-PEER CONNECTIONS: connect with other innovative healthcare start-ups.
- NETWORKING/PARTNERING: get privileged access to the high-class network of EIT Health.
- PRIZE MONEY: one winner in each category will receive a cash prize of up to 30,000 EUR (thirty thousand Euros); In addition, one start-up is selected to receive an Audience Award.
- COST COVERAGES/OTHER PRIZES: receive multiple benefits such as review of the business plan, pitch training, participation at relevant events, T&A.
- SPONSOR Prizes: get access to sponsor services such as technical cloud infrastructure, opportunity to pilot their solution in a clinical environment, exposure to relevant departments, etc.

The EIT Health Catapult Programme has historically been pivotal in achieving the Accelerator's goals aligned with the EIT Health Strategic Agenda. The selected consortia will be responsible for delivering the planned programme outcomes while preserving the integrity and legacy of this essential programme.

Consortium

- The consortium must include at least two participants coming from two different and independent institutions.
- Each consortium must include participants residing in at least two eligible countries, participating through two different Co-Location Centres (CLCs).
- Each consortium must have at least one EIT Health member of the association as part of the consortium (Core or Associate Partner).
- The consortium must be complete at the time of submission.

- This activity necessitates partners who not only possess specific know-how and contacts but also demonstrate a track record of successfully executing similar programs.

Budget

- The total budget of the programme shall not exceed 380,000 EUR (three hundred eighty thousand Euros) including EIT Health costs.
- The following costs will be covered by EIT Health and should not be included in the proposed consortium budget:
    - Sub-contracting of experts (legal, mentors, pitch trainers, evaluators, jury members, etc.);
    - Sub-granting to Start-ups (T&A and prize money);
    - Costs to run the call for start-ups and the regional selections.
- Co-Funding: The recommended, though not mandatory, co-funding contribution for this activity is 20%.

Financial sustainability and revenue generation

As this activity is an EIT Health-driven and administered activity, the financial sustainability requirement lays with EIT Health. As with previous editions, the KIC will aim to secure the financial sustainability of the activity be engaging in sponsorship agreements with interested promoters.

Duration of the activity

- The grant covers the activity from 1 May 2025 until 31 July 2026.
- The programme is launched in 2025 and its continuation into 2026 is conditional to EIT validation of the EIT Health Business Plan 2026-2028 in November 2025.
- There will be a stand still period of one month after selection notification. This means no work should be undertaken during this period. However, costs for work carried out from 1 January 2025 are eligible as part of the grant award.

Impact

The following key performance indicators (KPIs) are mandatory:

Key performance Indicators (KPIs)	Description
KIC04	Number of Professionals Trained in EIT Health funded KAVAs.

EITHE03.1	Start-ups and scale-ups supported by KICs
EITHE06.1	Investment attracted by KIC supported start-ups and scale-up

Implementation of the activity

EIT Health is the leader of this activity and will ensure start-up recruitment campaigns in collaboration with the consortium and set up the necessary application process.

EIT Health will also manage:

- Regional selections: each CLC will run a regional selection of start-ups. A list of selected start-ups (semi-finalists) will be provided to the consortium.
- Development of Prize Alliance – Industry prizes to complement cash prizes (Sponsorships)
- Provide legal framework (compliant procurement, contracts, participants agreement, etc.)
- Payment of prizes to the winning start-ups

The awarded consortium is expected to execute the below work packages, adding additional work packages to reach the overall objectives if desired.

Throughout the programme, Partners are encouraged to leverage their networks to involve experts, mentors, investors, industry partners, and other stakeholders. In-kind contributions to support these activities are highly valued and appreciated.

The consortium may propose the budget for each work package, except for WP3, which must adhere to the specified range of between 150,000 EUR (one hundred fifty thousand Euros) and 180,000 EUR (one hundred eighty thousand Euros).

Work package 1: Project Management

The objective of this work package is to ensure the effective coordination and management of the EIT Health Catapult Programme. This includes overseeing all operational aspects, enhancing the programme based on past experiences, and fostering strong engagement with all stakeholders to ensure successful outcomes.

Work package 2: Training & Capacity building

This work package aims to deliver comprehensive, customised mentoring support to selected start-ups during the semi-final stage. The focus will be on connecting start-ups with industry experts for real-world insights, offering pitch training, and facilitating introductions to potential investors. The training is designed to equip participants with the knowledge, skills,

and resources necessary to advance their projects and achieve success in their respective fields.

By carefully aligning mentors and experts with each start-up's unique challenges and objectives, the partners can provide targeted guidance that maximises the start-up's potential. This personalised approach ensures that mentoring is both relevant and impactful, helping start-ups overcome obstacles, refine their strategies, and accelerate their growth.

Work package 3: Events and Platform

To effectively nurture and accelerate start-up growth within the EIT Health Catapult programme, this work package emphasises a strategic blend of online and in-person events, supported by a robust digital platform.

Partners are responsible for organising and managing the semi-finals, which include virtual training sessions for life sciences and Health-Tech start-ups, online pitching events, and a digital platform designed to showcase fundraising ventures to the healthcare ecosystem, including investors.

Additionally, Partners will run two major in-person events: a "Get-together" after the semi-finals presenting a networking opportunity to connect start-ups, experts, and investors, and the Finals at a major European Health-Tech conference scheduled for May-June 2026. For the Finals, Partners must provide comprehensive support, including tickets, stage time, personnel costs, and efforts to maximise the visibility of participating start-ups.

The budget for this work package is between 150,000 EUR (one hundred fifty thousand Euros) and 180,000 EUR (one hundred eighty thousand Euros).

DELIVERABLES		OUTPUTS	
Code	**Description**	**Code**	**Description**
DEL01	Programme Guidelines	OUT01	Training & Capacity building
DEL02	Nominees for Semifinal	OUT02	Virtual Semi-final Events (including recording of Pitch Videos)
DEL03	Mentoring report	OUT03	Final Pitch Event
DEL04	Nominees for Finals	OUT04	Start-ups connected to growth investors
DEL05	Programme Report for EIT Health Catapult	OUT05	Catapult Promotion and Marketing

Ethics

Each consortium must complete the mandatory Ethical, Legal and Social Implications self-assessment checklist related to Horizon Europe in the EIT Health application system. Please see Horizon Europe guidance here, if needed.

Innovation activities

General conditions

- The consortium must include at least two participants coming from two different and independent institutions.
- Each consortium must have at least one EIT Health member of the association as part of the consortium (Core or Associate Partner).
- Each consortium must include participants residing in at least two eligible countries, participating through two different Co-Location Centres (CLCs).
- Each consortium must involve organisations from two sides of the Knowledge Triangle, e.g. industry and healthcare provider, higher education institution and industry, etc.
- Each consortium must contribute to the European Green Deal and the Sustainable Development Goals (SDGs). Therefore, they should add at least one customised KPI that proves how they contribute to the reduction of the environmental impact of their activity and at least 2 SDGs that the activity will contribute to.
- Each consortium must contribute to the EIT and EIT Health Dissemination and Promotion, and must follow the communication, dissemination, open science and visibility rules, including branding guidelines and obligations (set out in MGA Article 17). A communication, dissemination and outreach plan is required for each activity, including those providing financial support to third parties.
- The final recipients of funding must comply with the Intellectual Property Right (IPR) rules under the MGA Article 16.

Specific conditions for Innovation to Market Projects in DTH

Description and strategic fit

With the rise of digital health, Europe is still behind in terms of ease of evaluation, reimbursement, and adoption to the market of Digital Medical Devices (DMDs)[5].

Through this call, EIT Health aims to support the transformation, harmonisation and strengthening of the use of DMDs across European healthcare systems. We are calling for collaborative SME- or industry-led projects with a duration of maximum 10 months, that focus on new market entry and commercial piloting activities for patient-centred DMDs to facilitate and accelerate their implementation and wider adoption across EU markets.

[5] https://www.europarl.europa.eu/RegData/etudes/STUD/2021/695465/IPOL_STU(2021)695465_EN.pdf

Digital Medical Devices are health technologies falling into the definition of medical devices as outlined in the Regulation (EU) 2017/745[6] and which main function is based on digital technologies intended to support one or more of the following medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, or;
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

These devices could include software[7] intended to be used alone or in combination with hardware (e.g. scanners, sensors, monitors, etc.), and include static and self-learning algorithms (e.g. artificial intelligence, machine learning).

DMDs can be used by patients, caregivers, healthcare professionals and health system users in the broadest sense.

They do not include:

- Devices that are not intended to support medical purposes (e.g. wellness apps);
- Software qualified as an accessory for a hardware (intended to drive or influence the use of a hardware without having or performing a medical purpose on its own, or creating information on its own for one or more of the medical purposes described in the definition of a medical device regulation)[8];
- Administrative software.

EIT Health seeks proposals for Innovation to Market projects (max. 10 months long) for DMDs that have either already obtained CE approval or are awaiting CE approval (in this case, a CE mark dossier must have been submitted to a notified body at least 6 months prior to the proposal submission), and that are aiming to generate further evidence to enter new European markets. The focus here is on generating robust data to support health economics arguments, improve market access conditions, and strengthen the commercial viability of providers of digital health solutions in these markets.

[6] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[7] Software as defined in the MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR - October 2019 - page 5

[8] Also considered software driving or influencing the use of the device in the MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR - October 2019 - page 5

The proposed digital health solution must be at an Innovation Maturity Level (IML) of between IML 7 (Validation of Solution) and IML 8 (Approval & Launch) at the time of the proposal submission and be preparing for entry into a new market within the activity timeframe.

To expedite commercial studies and market entry conditions for DMD solutions, it is recommended that consortiums leverage existing health data, particularly from health registries and biobanks, where applicable. These activities should be part of the initiatives outlined below and must be feasible within the project's 10-month duration.

In addition, EIT Health strongly encourages applications for solutions that are able to demonstrate their contribution to the green transition of healthcare systems (i.e., in the form of energy and resource efficiency, emissions reduction, waste management, or sustainable procurement, as outlined in the EU Green Deal targets) and that incorporate strategies to promote gender equity and inclusivity (for example, by considering the differential impact of health innovations on various genders, or ensuring diversity within project teams and target populations).

Innovation to Market Projects

Innovation to Market Projects may request funding for the following types of activities:

- Commercialisation pilots with one or several potential partners (e.g. health care providers, medical device and health technology companies, etc.) to test the implementation of the solution on a small scale and generate the necessary evidence in order to secure commercial commitments from pre-identified interested partners and deploy the product into the target market.
- Product adaptations for the target market: conduct product testing and gather user feedback on solution usability, and work on product adaptations for the local target market (e.g. language, user interface, systems integrations, etc.) before a larger scale launch.
- Business model validation and go-to-market activities (e.g. market analysis, establishing commercial or distribution networks, pricing model, etc.) to ensure the deployment of a commercially sustainable solution in the new target market(s).

The activities are expected to lead to the product's commercialisation in the new target market(s) **within a maximum of one year after the EIT Health funding period**.

Consortium

- The consortium must include at least two participants coming from two different and independent institutions.
- Each consortium must have at least one EIT Health member of the association as part of the consortium (Core or Associate Partner).

- Each consortium must include participants residing in at least two eligible countries, participating through two different Co-Location Centres (CLCs).
- Each consortium must involve organisations from two sides of the Knowledge Triangle, e.g. industry and healthcare provider, higher education institution and industry, etc.
- Every consortium must include a designated "commercialising entity" listed in the participants section of the application form.
- The commercialising entity can be a start-up or micro-small enterprise, a medium or large-sized industry player, a healthcare provider, or any type of organisation that will be responsible for bringing the product to market and commercialising it.

The following requirements and definitions shall apply in the case of micro and small enterprises applying as a commercialising entity:

- The entity is a for-profit micro or small enterprise according to the EU definition,
- The entity must have at least 4 paid FTEs (Full Time Equivalent) working at the time of the proposal submission. The entity must have a CEO working full-time in the company at the time of the proposal submission, where full-time refers to the legally mandated number of hours for a full-time occupation in the country where the entity is incorporated.
- The entity cannot have publicly traded shares or gone through an IPO.

Budget

- The activity must request a minimum of 500,000 EUR (five hundred thousand Euros) EIT Health funding.
- The maximum grant that can be requested by the consortium is 1,000,000 EUR (one million Euros) for the total duration of the activity.
- A co-funding rate of 30% for the whole duration of the activity is required.

Financial sustainability and revenue generation

The commercialising entity is required to formulate a proposal that aligns with the stipulated requirements outlined in this call. Intellectual Property is owned by the consortium.

Two distinct, pre-defined financial sustainability models that cater to the diverse nature of the commercial entities may be implemented: "**Grant to Options**" and "**Revenue Sharing**".

The "Grant to Options" model is designated for micro and small enterprises, while the "Revenue Sharing" model is intended for medium enterprises, large companies, or any organisational entity responsible for introducing the product to the market that does not fall under the definition of a micro and small enterprise. Please find further information about the "Grant to Options" model here and about the "Revenue Sharing" model here.

The feasibility of implementing the appropriate financial sustainability model with the commercialising entity of the project will be assessed during the Due Diligence stage, and the

final agreement must be signed at the time of project contracting. In addition, as described below in the Application Process, the feasibility of the implementation of relevant Grant to Options Agreements is validated by EIT Health before project approval.

Duration of the activity

- The maximum duration of EIT Health financial support is 10 months.
- The grant covers the activity until 31 December 2025, at the latest.
- The work will start one month after selection notification, (allowing for a one month stand still period, see Innovation activities timeline in the Application Process section). However, costs for work carried out from 1 March 2025 are eligible as part of the grant award.
- Work must be completed by 31 December 2025. There will be no extension possibility. Selected consortia must commit to the timelines as outlined in this document and the application form

Impact KPIs

The following key performance indicators (KPIs) are mandatory:

Key performance Indicators (KPIs)	Description
KIC13	Health impact is expected to be 150,000 European citizens and/or patients benefitting from the solution commercialised through the activity within three years after activity completion (independently from health conditions and range of applications)
EITHE01.1	The activity must aim at protecting innovative solutions through filing of patents, trademarks, registered designs, copyrights, etc.
EITHE02.4	The activity must aim at introducing and scaling products to the market during the activity duration or within 1 year after the EIT Health financial support ends. The activity must prioritise EU markets over other markets.
Custom KPI	Each consortium must contribute to the European Green Deal and the Sustainable Development Goals (SDGs). Therefore, at least one customised KPI should be added that proves how the project will contribute to the reduction of the environmental impact of its activity and at least two SDGs that the activity will contribute to.

Key performance Indicators (KPIs)	Description
Custom KPI	Each consortium must contribute to promoting gender equality and inclusivity in healthcare innovation and technology. Therefore, at least one customised KPI should be added that proves how the project intends to do this.

All points described above are expected to be demonstrated through dedicated KPIs, milestones and/or deliverables at the proposal stage and shall be documented by annual reporting. Please find here the list of KPIs available and the reporting requirements.

Ethics

- Each consortium must complete the mandatory Ethical, Legal and Social Implications self-assessment checklist related to Horizon Europe in the EIT Health application system. Please see Horizon Europe guidance here, if needed.

Activity summary

	Innovation to Market Projects
Goal	Preparing for entry into one or more new EU country market(s), with the aim of conducting solution pilots in partnership with interested commercial partners, buyers or payers to validate the implementation of the solution and the business model.
Product Requirements	Start: 7-8 | IML End: 8-9 (more on IMLs here) Solutions must already be CE-marked or have submitted their CE mark dossier to a notified body at least 6 months prior to the proposal submission.
Activity Examples	Usability Tests Product Adaptation Stakeholder Engagement Business Model and Go-to-market Strategy (e.g., Pricing model) Distribution and Supply Chain Management Data analysis / health economics

	No technology development activities
Duration	Max. 10 months projects, or until December 31, 2025
Funding	Min. €500K and up to €1M may be requested Min. 30% co-funding rate required
End Result	Projects are expected to reach product commercialisation stage and be generating initial revenues in the new market within a maximum of 1 year after the EIT Health funding period.

Specific conditions for DiGinnovation programme

Description and strategic fit

The DiGinnovation programme selects the top digital health micro and small enterprises as part of a consortium that will improve healthcare systems by accelerating the uptake of digital medical devices by healthcare professionals and patients and **expediting market launch of the innovation while easing the reimbursement process**.

The focus of this programme is on supporting patient-centred Digital Medical Devices on their way to reach reimbursement in a European healthcare system. **Digital Medical Devices** (DMDs) are health technologies falling into the definition of medical devices as outlined in the Regulation (EU) 2017/745[9] and which main function is based on digital technologies intended to support one or more of the following medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; and / or,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

[9] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

These devices could include software[10] intended to be used alone or in combination with hardware (e.g., scanners, sensors, monitors, etc), and include static and self-learning algorithms (e.g., artificial intelligence, machine learning).

DMDs can be used by patients, caregivers, healthcare professionals and health system users in the broadest sense.

They do not include:

- Devices that are not intended to support medical purposes (e.g. wellness apps).
- Software qualified as an accessory for a hardware (intended to drive or influence the use of a hardware without having or performing a medical purpose on its own or creating information on its own for one or more of the medical purposes described in the definition of a medical device regulation[11]).
- Administrative software.

The proposed digital health solution must be at an **Innovation Maturity Level (IML) of between IML 7 (Validation of Solution) and IML 8 (Approval & Launch)** at the time of the proposal submission to advance to IML9 (Clinical Use) maximum 1 year after the project end date.

The proposals must target one or more specific European country market(s) with a fast-track reimbursement scheme or must provide a clear business plan to enter another market in a fast way or with a private payor. The solution must meet the requirements of reimbursable applications and digital medical devices in the targeted country.

The solution must have CE-mark at the time of submission, and be classified as I-IIa or, in the case of France as the targeted market, also IIb medical-grade solution under Medical Device Regulation (MDR) 2017/745 and the Regulation (EU) 2023/607.

In addition, EIT Health strongly encourages applications for solutions that demonstrate their value to the green transition of healthcare systems (i.e., in the form of energy and resource efficiency, emissions reduction, waste management, or sustainable procurement, as outlined in the EU Green Deal targets) and that incorporate strategies to promote gender equity and inclusivity (for example, by considering the differential impact of health innovations on various genders, or ensuring diversity within project teams and target populations).

Consortium

- The consortium must include at least two participants coming from two different and independent institutions.

[10] Software as defined in the MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR - October 2019 - page 5
[11] Also considered software driving or influencing the use of the device in the MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR - October 2019 - page 5

- Each consortium must have at least one EIT Health member of the association as part of the consortium (Core or Associate Partner).
- Each consortium must include participants residing in at least two eligible countries, participating through two different Co-Location Centres (CLCs).
- Each consortium must involve organisations from two sides of the Knowledge Triangle, e.g. industry and healthcare provider, higher education institution and industry, etc.
- The consortium must be complete at the time of submission.
- Every consortium must include a designated “commercialising entity” listed in the participants section of the application form.
- The lead partner and commercialising entity is a micro or small enterprise.

The following requirements and definitions shall apply to micro and small enterprises applying as a commercialisation entity:

- The entity is a for-profit micro or small enterprise according to the EU definition,
- The entity must have at least 4 paid FTEs (Full Time Equivalent) working at the time of the proposal submission. The entity must have a CEO working full-time in the company at the time of the proposal submission, where full-time refers to the legally mandated number of hours for a full-time occupation in the country where the entity is incorporated.
- The entity cannot have publicly traded shares or gone through an IPO.

Budget

- The maximum grant that can be requested by the consortium is 350,000 EUR (three hundred fifty thousand Euros) for the total duration of the activity, of which a minimum grant of 150,000 EUR (one hundred fifty thousand Euros) must be requested by the micro or small enterprise.
- The maximum funding rate is 70% among the whole activity’s duration (30% co-funding required).

Financial sustainability and revenue generation

The commercial entity is required to formulate a proposal that aligns with the stipulated requirements outlined in this call. Intellectual Property is owned by the consortium.

The "Grant to Options" model is designated as the financial sustainable model for micro and small enterprises responsible for introducing the product or service to the market. Please find further information about the “Grant to Options” model here.

The feasibility of implementing the appropriate financial sustainability model with the commercialising entity of the project will be assessed during the Due Diligence stage, and the final agreement must be signed at the time of project contracting. In addition, as described below in the Application Process, the implementation of all Grant to Options Agreements is evaluated by EIT Health before project approval.

Duration of the activity

- The maximum duration of EIT Health financial support is 10 months.
- The grant covers the activity until 31 December 2025, at the latest.
- The work will start one month after selection notification, (allowing for a one month stand still period, see Innovation activities timeline in the Application Process section). However, costs for work carried out from 1 March 2025 are eligible as part of the grant award.
- Work must be completed by 31 December 2025. There will be no extension possibility. Selected consortia must commit to the timelines as outlined in this document and the application form.

Impact KPIs

The following key performance indicators (KPIs) are mandatory:

Key performance Indicators (KPIs)	Description
KIC13	Health impact is expected to be 150,000 European citizens and/or patients benefitting from the solution developed in the activity within three years after activity completion (independently from health conditions and range of applications)
EITHE01.1	The activity must aim at protecting innovative solutions through filing of patents, trademarks, registered designs, copyrights, etc.
EITHE02.4	The activity must aim at introducing and scaling products to the market during the activity duration or within 1 year after the EIT Health financial support ends. The activity must prioritise EU markets over other markets.
Custom KPI	Each consortium must contribute to the European Green Deal and the Sustainable Development Goals (SDGs). Therefore, at least one customised KPI should be added that proves how the project will contribute to the reduction of the environmental impact of its activity and at least two SDGs that the activity will contribute to.
Custom KPI	Each consortium must contribute to promoting gender equality and inclusivity in healthcare innovation and technology. Therefore, at least one customised KPI should be added that proves how the project intends to do this.

All points described above are expected to be demonstrated through dedicated KPIs, milestones and/or deliverables at the proposal stage and shall be documented by annual reporting. Please find here the list of KPIs available and the reporting requirements.

Ethics

- Each consortium must complete the mandatory Ethical, Legal and Social Implications self-assessment checklist related to Horizon Europe in the EIT Health application system. Please see Horizon Europe guidance here, if needed.

Activity summary

	DiGinnovation Programme
Goal	To ease the reimbursement pathway, expedite the market launch and accelerate the uptake of digital medical devices by healthcare professionals and patients in Europe.
Product Requirements	**IML Start:** 7-8 | **IML End:** 9 (more on IMLs here) Solutions must already be CE-marked at the time of submission. The solution must meet the requirements of reimbursable applications and digital medical devices in the targeted country. The solution must be classified as I-IIa or, in the case of France as the targeted market, also IIb medical-grade solution.
Activity Examples	Study design for evidence generation Stakeholder Engagement Training for Healthcare professionals Patient Engagement Activities to include the innovation into clinical workflows Compliance with Regulatory Requirements Pricing and Business Model Go-to-market Strategy No technology development activities
Duration	Max. 9 months projects, or until 31 December 2025

Funding	Max. €350K Grant may be requested by the consortium Min. €150K Grant must be requested by the micro or small enterprise Min. 30% co-funding rate required
End Result	Projects are expected to reach product commercialisation and reimbursement of the Digital Medical Device within a maximum of 1 year after the EIT Health funding period.

Application Process

How to apply

The application will be made through the EIT Health Application Platform.

New applicants will need to register on the application platform here.

If the applicant is already an EIT Health member or has registered as an External Project Partner in a previous call or calls on the previous EIT Health application platform PLAZA, the corresponding data for the **organisation** will be available in the current application platform. However, the **applicant** will still need to create a new account as an **organisation representative** and link themselves to their **organisation**.

The approval of this link might take up to 48 hours and extra information on the organisation profile might be requested.

Proposal Submission deadline is set for **5 November 2024, 16.00 CET**. In order to avoid disappointment, we strongly advise applicants to familiarise themselves with EIT Health Application platform before beginning their application, and to **begin the application process on the EIT Health Application platform at least 24 hours in advance of the deadline**.

The application timelines for the different activities are detailed in the table below.

Innovation to Market Projects, and the DiGinnovation Programme timeline

Evaluation Process step	START DATE	END DATE
Call open	5 September 2024	
Call closed	5 November 2024	
Eligibility check outcome notification	11 November 2024	
Remote evaluation	11 November 2024	22 November 2024
Remote evaluation outcome notification (& Invitations to Hearings, if applicable)	28 November 2024	
Due diligence	2 December 2024	
Hearings	13 January 2025	15 January 2025
ELSI Evaluation	16 January 2025	31 January 2025

Evaluation Process step	START DATE	END DATE
Final selection outcome notification	5 February 2025	
Stand Still period	5 February 2025	5 March 2025
Project start	6 March 2025	6 March 2025

Education and Catapult activities timeline

Evaluation Process step	START DATE	END DATE
Call open	5 September 2024	5 November 2024
Call closed	5 November 2024	5 November 2024
Eligibility check outcome notification	11 November 2024	11 November 2024
Invitation to pitch	13 November 2024	14 November 2024
Online Pitching	20 November 2024	26 November 2024
ELSI Evaluation	27 November 2024	3 December 2024
Selection notification	10 December 2024	10 December 2024
Stand still period	10 December 2024	10 January 2025
Project start	10 January 2025	10 January 2025

Evaluation process overview

The selection process of this call will consist of a single proposal submission for all types of activities.

In order to be selected for funding, applications must score **at least 70/100** at each of the different evaluation steps (remote evaluation, hearings, and due diligence).

Following submission, all applications will undergo an eligibility check. All applications must satisfy the eligibility requirements before proceeding to the next step. Please see the relevant section for the general and specific conditions of each activity. The evaluation process for education activities and innovation activities differs.

The Innovation to Market and DiGinnovation programme activities will first undergo a remote evaluation subject to passing eligibility checks. Up to 15 Innovation to Market applications, and up to 6 DiGinnovation applications that score 70/100 or more in the remote review will be invited to participate in online hearings.

Applications for Innovation to Market and DiGinnovation programme activities will go through a Due Diligence process to assess the Financial Sustainability proposed for each project. This process will begin before the Hearings. The Due Diligence process is different for applications opting for a Grant to Options Agreement and Revenue Sharing Agreements.

Small and micro enterprises (SME) following the Grant to Options Agreement must score at least 70/100 at the Due Diligence evaluation to be considered for funding. Applications from SMEs that that do not pass the Due Diligence evaluation will not receive funding.

Entities following a Revenue Sharing Agreement must also participate in a Due Diligence process. Due Diligence for Revenue Sharing applications will assess the entity's alignment with EIT Health's strategic goals, and potential for impact. The Due Diligence process for entities on a Revenue Sharing Agreement does not produce a required minimum score. The decision to grant funding to entities on a Revenue Sharing Agreement will be based on the quality evaluation at the Hearings stage.

For Education activities and Catapult activities, all applications will be invited to an online pitch, subject to passing the eligibility checks. Applications will then be selected based on a ranking of scores following the online pitches which will determine the final selection.

Notifications for all applications will be sent to applicants by email form the EIT Health Application system.

Selection process in detail

The selection process aims to ensure that applicants provide information for evaluation only at the necessary moment in the selection funnel, while strengthening proposals to maximise the success and impact of activities ultimately welcomed into the EIT Health portfolio.

Eligibility check

Consortia will be invited to submit a full proposal form (accessible through EIT Health's application platform), as applicable, as well as general information on their activity.

The minimum requirements for applying, including eligibility criteria, are specified in the previous section.

An eligibility check will be performed against the relevant general and specific conditions stated in the above sections to validate the application's compliance with the requirements

outlined in this Call. This will yield a yes/no decision on the progression of the proposals in the evaluation process.

Upon completion of the eligibility check, observations on the project and consortium partners may be communicated to the Hearings evaluators.

Online Pitching

Education activities

Following submission, all proposals for education activities that pass the eligibility checks will be invited to present their proposals at an online pitch. This will involve a presentation and question and answers session in front of a panel of experts, details on the organisation of the pitches will be communicated to eligible applicants in a timely manner.

Following the online pitches, experts will produce a final score out of 100. Projects that score 70/100 or more will be awarded EIT Health funding. Please see the Evaluation Criteria for description of the criteria in which projects will be assessed during the online pitches.

Remote Evaluation

Innovation to Market and DiGinnovation activities

Eligible proposals for Innovation to Market and DiGinnovation activities will be evaluated by external evaluators based on the below criteria (see Evaluation Criteria section). Evaluators are instructed to check for conflict of interest and to inform the EIT Health Headquarters, if necessary, before evaluation of the proposal proceeds.

A maximum of 100 points will be awarded by each evaluator during the remote evaluation. The final remote evaluation score will be the average of all remote evaluators' scores.

The results of the remote evaluations will be issued to the activity leaders by email in the specified dates.

Hearings

Innovation to Market and DiGinnovation activities

This phase will consist of an online external evaluation that will take the form of an online presentation and questions and answers from an external panel of experts. Details on the organisation of the Hearings will be timely communicated to shortlisted applicants.

Due Diligence

Innovation to Market and DiGinnovation activities

All entities applying as commercialising entities to Innovation to Market Projects, or the DiGinnovation Programme must go through a Due Diligence process. This process will assess the financial viability and fit with the requirements of the relevant financial sustainability model (Grant to Options or Revenue Sharing). Please refer to the Financial sustainability and revenue generation section for Innovation to Market and DiGinnovation activities.

EIT Health will select **up to 15 commercialising entities from Innovation to Market** project applications, and **up to 6 commercialising entities from DiGinnovation** project applications to undergo Due Diligence. To be considered for the Due Diligence process, projects must score a minimum of 70/100 at the remote evaluation stage. Companies that fail to participate or pass Due Diligence will not be awarded funding from EIT Health.

During the Due Diligence process, EIT Health, and in the case of small and micro enterprises, EIT Health's contractors, will communicate directly with entities during this process. The aim is for EIT Health to gain a comprehensive understanding of each applying entity and to finalise the Due Diligence.

Submitted documents will be treated as confidential. They will only be accessible to relevant EIT Health staff and/or independent third parties bound by confidentiality provisions. It is expected that companies will collaborate with EIT Health by providing relevant information and documentation in a timely fashion to facilitate the Due Diligence. The documentation will be requested during the period from 11 - 22 November 2024. Failing to provide the documentation within the given deadline will result in disqualification and exclude the application from progressing further in the process.

Due Diligence for the Grant to Options Agreement

For small and micro enterprises (SMEs) following the Grant to Options Agreement, the Due Diligence process comprises of a review by external Due Diligence consultants, and a review by investment specialists within EIT Health and external specialists. The process involves the following activities:

- Additional document request
- Team interviews
- Review by external consultants
- Review by EIT Health investment specialists
- Alignment meetings between EIT Health senior management and external consultants.

Documentation is expected to be in English (except for the registration certificate). The below list explains which documents must be included for SMEs. The EIT Health application platform provides further details on what is required.

- Business plan (including, but not limited to, product/technology description, IP strategy, clinical/regulatory strategy, market analysis, business strategy, competitive analysis, value creation plan to exit, team and track record)

- CVs of the founder, managerial team and board members
- Business supporting documents:
    - Legal Self-Assessment Certificate and documentation upon request.
    - Supporting documents regarding IP, technology ownership, partnerships, exclusivity rights, regulatory approvals.
- Financial supporting documents:
    - Historic financial information.
    - Financial projections, ownership structure and value creation plan, in one Excel document, with the financial summary using a specific template. See the supporting documents for the template to complete for small and micro enterprises.
    - Explanations to the projections and year-to-date financial traction.
    - Financial agreements, historical changes of cap table and valuation calculations.
    - Governance structure.

The Grant to Options Due Diligence process produces a score based on a set of evaluative criteria that is based on the financial sustainability requirements of EIT Health. The table below provides further detail on the evaluative criteria on which the Due Diligence conclusions for SMEs will be drawn.

The outcome of the Due Diligence evaluation for SMEs will be a score out of 100. Only applications that achieve a Due Diligence score of 70 or more, and a quality score from the hearings stage of 70 or more will be considered for EIT Health funding.

Due Diligence criteria
1. Product • **Product scalability.** The product must be scalable in an economically viable manner. • **Technology maturity.** The technology used must be of sufficient maturity to be applied to a commercial product within a reasonable timescale. • **Regulation strategy.** A clear and realistic strategy must be in place to ensure the product is compliant with all required regulations. • **Product commercialisation strategy.** The small and micro enterprise must have a clear and feasible strategy to commercialise its product.

Due Diligence criteria
• **Product design.** The product design must be innovative, with features that enhance functionality and usability. It must add significant value to the healthcare system and/or patients by addressing gaps and improving efficiency. • **Product portfolio strategy.** The small and micro enterprise must have a promising and feasible strategy to expand its portfolio, demonstrating plans for growth and diversification.
2. Market assessment • **Market competition.** The small and micro enterprise and product must have a reasonable lead on the relevant competition in the market to as part of its commercialisation strategy. • **Market demand.** There must be a clearly identified demand from the market for the product. • **Market size and growth.** There must be a considerable growing market for the small and micro enterprise to service and operate in.
3. Management team • **Experience and capability.** The management team should possess relevant experience and demonstrated capability to support the small and micro enterprise's future growth.
4. Business model • **Revenue model.** The small and micro enterprise should plan for a feasible revenue model that is scalable, realistic and sustainable. • **Partnerships.** Partnerships or validated partnership opportunities validated by qualified documentation • **Business milestones.** Milestones planned should provide added value to the small and micro enterprise and its current and future shareholders. • **Risk assessment.** Due Diligence will look for an effective risk assessment, and effective risk mitigation strategies.
5. Governance

Due Diligence criteria
• **Governance and ownership structure.** Clear and effective governance and ownership structures should be in place that will not pose a risk to realising the EIT Health financial sustainability mechanism. • **Legal.** The small and micro enterprise's legal self-assessment should indicate no significant issues or concerns, ensuring compliance and minimising potential legal risks.
6. Financials and Sustainability • **Financial Projections.** The Profit and Loss (P&L) statement should demonstrate a healthy and realistic financial performance, with a clear trend of revenue growth and profitability. It should reflect efficient cost management and provide evidence of sustainable financial practices that support the small and micro enterprise's long-term viability and growth objectives. • **Potential to realise the EIT Health financial sustainability mechanism.** Due Diligence will look for a realistic value creation plan for the small and micro enterprise factoring in investor/commercial appetite.

Due Diligence for the Revenue Sharing Agreement

For entities using the Revenue Sharing Agreement, the Due Diligence process consists of the following steps:

- Additional document request
- Team interviews
- Review by EIT Health investment specialists
- Alignment meetings between EIT Health investment specialists and senior management.

The below list shows what documentation will be required from commercialising entities following the Revenue Sharing Agreement:

- Project proposal
- Partner organisation overview
- Financial projections (using the provided template) and supporting evidence (such as market research or data)
- Implementation plan
- Risk assessment

- Any other relevant supporting materials

The outcome of the Revenue Sharing Agreement Due Diligence process will be a set of recommendations to include in the Revenue Sharing Agreement. Only applications that achieve a quality score from the hearings stage of 70 or more will be considered for EIT Health funding.

ELSI review

The ELSI review will aim to ensure that all elements in the proposal linked to critical ethical, legal and social considerations are well defined and addressed, thereby helping to de-risk the EIT Health portfolio.

Final notification

Depending on the available budget for the next period, a final list of activities will be proposed for funding.

Evaluation criteria

For all activities at each of the respective quality evaluation stages (remote review and hearings), evaluation will be based on the following criteria:

Evaluation Criteria
Activity Excellence and Strategic Fit (20%) 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 approach, including the underlying concepts, models, assumptions, and interdisciplinary approaches.
Impact and Sustainability (40%) 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 of the project, including to the EU Green Deal and Sustainable Development Goals (SDGs). Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities, when applicable (DiGinnovation and 'Innovation to Market' activities only) Credibility of the potential business model and strategies identified, for Innovation activities. The robustness of the financial projections and future scalability of the business model will be assessed as part of the project's contribution to EIT Health's financial

sustainability mechanisms when applicable (DiGinnovation and 'Innovation to Market' activities only).

Implementation and Feasibility (40%)

Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall.

Capacity and role of each participant, and the extent to which the consortium as a whole brings together the necessary expertise.

Contracting

Activities that are accepted for funding must execute a set of legal agreements (see the list below).

It is expected that the contracting phase will last approximately three months. Release of funding is contingent on execution of all agreements, but activities will be able to claim costs retroactively from the notification date which is the earliest date that activities can start.

The legal documents that will need to be signed are the following:

- **Internal Agreement (IA)** which is transposing the provisions of the Partnership agreement between EIT and EIT Health and the **Financial Support Agreement (FSA)** which is outlining the conditions for receiving financial support from EIT Health.
- **Project Grant Agreement (PGA)** which is the basis to govern the relationship between the EIT Health and the consortium in one specific activity as well as the relationship amongst the parties in this activity.
- **Financial Sustainability Agreement (FSA)** is the agreement between EIT Health and the commercialising entity that governs the financial sustainability model (either "Grant to Option" or "Revenue Sharing" model) implemented in the activity.

Further information on contracting as well as pre-financing rates and timing of (balance) payments can be found in the Implementation Handbook.

Monitoring

All activities are subject to a formal review once a year.

The process serves to either fast-track, support, redirect, or stop the activity in cases of improper implementation or severe underperformance.

The review is a go/no-go point for the continuation of the activity and its EIT funding.

Post-funding monitoring will also be required for up to five years after activity closure to capture impact which exceeds the activity lifetime and contributes to the EIT Health Strategic Agenda and Horizon Europe indicators.

Post-funding monitoring will, in most cases, be in a light format. However, capture of EIT Core KPIs in post-funding years is given special attention. Additionally, post-funding monitoring will help to identify potential success stories and capture key learnings to be shared with the wider community.

EIT Health monitoring principles and obligations are governed by the Horizon Europe MGA, Annex 5 general-mga_horizon-euratom_en.pdf (europa.eu).

Confidentiality and conflict of interest

All proposals submitted through the application platform are accessible only to EIT Health staff members for the processing of the application, and the Master Contact of each Partner, as well as the persons designated during the proposal phase.

During the selection process, proposals are shared with assigned external evaluators, who are contractually bound to confidentiality. Additionally, EIT Health may give access to documentation provided during the Due Diligence phase to external advisors to support the assessment.

Furthermore, EIT Health may give access to the submitted data to sub-contractors who are tasked with maintaining the application platform and the Plaza system.

All such third parties are also bound by confidentiality provisions.

EIT Health staff are bound by the policy on conflicts of interest.

Staff of EIT Health Partners are not involved in the evaluation process of the proposals. Furthermore, members of the EIT Health Managing Boards (Supervisory Board) cannot be involved in activities.

Applicants and potential beneficiaries of the EIT grant in selected activities must avoid any conflict of interest and comply with the principles of transparency, non-discrimination, and sound financial management. (Régulation EU 2021/695) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0695

Grounds for appeal and appeal procedure

The appeal process can be publicly found here: https://eithealth.eu/appeals-procedure/

Applicants may appeal the process for the selection of their own proposal(s). The only grounds for appeal are:

- Process errors
- Technical problems beyond the control of applicants, e.g., the technical failure of the electronic submission system
- Human/technical errors made by EIT Health staff
- If you consider that you have been adversely affected by a particular decision not following EIT Health's Code of Conduct.

What does not constitute grounds for appeal:

- Scores awarded in the course of the evaluation process, unless if these go against EIT Health's Code of Conduct

Appeal process:

- Applicants should send their appeals in writing to appeals@eithealth.eu as soon as they identify an error, but no later than 21 days after the error occurred,
- EIT Health assesses the claim and deliver a first response,
- If there are grounds for appeal, the staff will attempt to remedy the consequences, e.g., if a technical error of EIT Health prevented the submission of a proposal or application, a late submission may still be accepted as eligible,
- The Head of Compliance, and where applicable, Supervisory Board is notified about the matter if:
    - the applicant does not accept a rejection of the appeal, or
    - there are grounds for appeal, but the problem cannot be remedied any more without disrupting the process.

Where to get help

Call webinar Q&A – 19 September 2024, 15.00 - 16.00 CET
Prospective applicants are invited to attend an online webinar Q&A to hear more about the call and ask questions. Access the webinar by: **EIT Health Flagships Call 2025 Webinar and Q&A**

EIT Health has pan-EU representation via eight Co-Location Centers (CLCs), and an InnoStars office, all of which operate as strong clusters of relevant actors, collaborating in a thriving ecosystem. For support in the preparation and submission of proposals, or to find out how to participate, please contact your Co-Location Center (CLC) / InnoStars.

More information here: https://eithealth.eu/in-your-region/

For applications by non-Partners without CLC affiliation, please contact support in the regions according to the table below:

Hub	Affiliated countries
Austria	Austria
Belgium-Netherlands	Belgium, Luxembourg, Netherlands, Israel
France	France
Germany-Switzerland	Germany, Switzerland
InnoStars	Italy, Bulgaria, Croatia, Cyprus, Malta, Czechia, Poland, Portugal, Romania, Slovakia, Slovenia, Greece, Hungary, Albania, Bosnia and Herzegovina, North Macedonia, Montenegro, Serbia, Turkey, Moldova, Ukraine, Georgia, Armenia, Latvia, Lithuania
Scandinavia	Denmark, Estonia, Finland, Sweden, Iceland, Norway, Faroe Islands
Spain	Spain
Ireland-UK	Ireland, United Kingdom

For further support, please refer to our **Frequently Asked Questions** document which can be found on the our Flagships Hub.