EIT Health Call Document Flagships Call 2024

10 January 2024

Change log

ID	Date	Description of Change	Location
1	30/10/2024	Removal of EIT Health membership requirements	Throughout

Introduction

Europe is facing a turning point in healthcare. From an increase in infectious diseases, pandemic threats, and 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 2024, the Call will address the following flagships:

- **New models to deliver healthcare (NMDH)**: This Flagship aims to support the delivery of new models to deliver healthcare utilising evidence-based approaches leveraged by robust analysis of patient experiences, as well as clinical and economic data. The Flagship is focusing on the concept of value-based healthcare, where success is measured through patients' outcomes and the shift of healthcare from treatment to prevention.

- **Digital Transformation of Healthcare (DTH)**: This Flagship aims to support the digital health transformation in Europe and will focus on the development of, and access to, digital medical devices. It will also support the implementation of the European Health Data Space through exploring the secondary use of data. 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.

Note: The IPCEI Flagship, initially channelled through the so-called European Initiative in Health, led by 16 Member States and supported by the European Commission, will be extended to a wider topic called "The Re-Industrialisation of Europe". This Flagship aims at addressing the dual imperative of

(i) equipping Europe with a strong, innovative, and export-friendly healthcare industry that can meet the challenges posed by the future of medical care and,
(ii) developing lasting and innovative European manufacturing capabilities regarding critical products, notably pharmaceuticals

This Flagship will have a dedicated call for activities that will be announced in due course.

Objectives and Scope

With the ambition to contribute to some of the top health priorities that have been identified at EU level, EIT Health is calling for activities in Innovation and Transformation through funding different activities/programmes in each Flagship.

New models to deliver healthcare (NMDH)

The selected activities will deliver innovative solutions that provide compelling evidence, based on patient reported outcomes and real-world data, which can convince payors that the value brought to the patient justifies the evolution of the reimbursement models, thereby promoting the incorporation of innovative solutions and services into new markets. EIT Health welcome consortiums including healthcare service providers and their corresponding payors, steered by industry providers that have reached commercialisation stage to apply to **Service Development activities**.

Several transversal activities will support innovators and change agents along their entire innovation journey. The online **EIT Health Academy** and, more specifically, the High Value Care track, will provide ongoing support and learning modules towards upskilling graduates and professionals. To strengthen this track, EIT Health welcome consortiums who could deliver Flagship-related content courses that will contribute to the **EIT Labelled fellowship on advanced high value care principles**.

Digital Transformation of Healthcare (DTH)

EIT Health welcome applications from consortiums who have reached Proof of Value or Initial Clinical Trials (IML 5-6) stage within the **Technology Development activities**. These activities aim to validate regulatory approvals of **digital medical devices.** It is strongly recommended, if applicable, that such activities leverage **existing health registries or biobanks,** to expedite the clinical validation of their solutions and market access.

Further start-ups and scale-ups with CE-marked, patient-centered DMDs (level IML7 - Validation of Solution and IML8 - Approval & Launch) are invited to apply to the **DiGinnovation Programme**, that is aimed at supporting the activity to achieve reimbursement coverage (IML9 - Clinical Use).

Several transversal activities will support innovators and change agents along their entire innovation and transformation journey. While **Innovation Days** (i-Days) kick-off the mindset to foster changes among the earliest entrepreneurs, who can also enhance their skills within a **Master Degree programme**, the online **EIT Health Academy** will provide ongoing support and learning modules upskilling Master and PhD level learners as well as healthcare and medical professionals in digital health topics through the **Labelled Fellowship Programme.** Further, **non-degree education** modules will be set-up and delivered through the **EIT Health Academy** that aim at raising awareness and attracting talents to the healthcare sector, in addition to training professionals in the technical competencies needed in a digitally transformed health system.

In a nutshell

An overall financial amount of 11 M EUR is available for this Flagships Call 2024.

The call aims at funding **up to nine Technology and Service Development activities**, distributed across shorter (9 months) and longer activities (18 months), covering different clinical areas and unmet needs.

Furthermore, the call intends to fund **up to four Education-related programmes** (leading up to 14 activities that will be selected) using different formats and addressed to specific target audiences, with a focus on online modules combined with face-to-face activities offered through the EIT Health Academy and other labelled activities.
Please find below the list of activities that will be called in each Flagship:

FLAGSHIP	Activities*
New models to deliver healthcare	EIT Health Innovation Days Series (i-Days) Modules towards a Labelled Fellowship Programme Service Development activity
Digital Transformation of Healthcare	EIT Health Innovation Days Series (i-Days) Master Degree Programme Modules towards EIT Labelled Certification Modules towards a Labelled Fellowship Programme Technology development activity DiGinnovation programme

* In pink: Technology and Service Development activities, in green: Education-related programmes

Eligibility Criteria

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.

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 of funded EIT Health projects must adhere to the EIT Health Fee Model. For more information on the fee model please check our website section here.

The European Commission is committed to promoting gender equality in innovation and technology. The EIT, as a body of the European Union and 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

[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.

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.

The involvement of an EIT Health KIC member is recommended and highly preferable.

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 (except for the i-Days programme). 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).

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 EUR 6,000,000.

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

General conditions to participate in the call

At short proposal stage (when applicable)

- The consortium must include at least two participants coming from two different and independent institutions[5] [6].
- For the Education programmes (if applicable), commitment to ECTS delivery, validated expertise in the Flagship topics and application for UEMS EACCME accreditation (where healthcare professionals are target audience) is expected. EIT Health is mindful of national variability in terms of re-accreditation of masters programmes. Relevant flexibility will be addressed in the consortium, including the validation of the students' recruitment dates.

[5] Not applicable for the Master Degree activity and the DiGinnovation programme.

[6] For the Education programmes, it is preferred that the final consortium is already established at short proposal stage, as required in the specifics for the activity. For Fellowships, the presence of the non-academic partner may be confirmed at the second stage.

At full proposal/single proposal stage

- Each consortium must include participants residing in at least two eligible countries, participating through two different Co-Location Centres (CLCs)[5].
- Each consortium must involve organisations from two sides of the Knowledge Triangle, e.g., industry and healthcare provider; higher education institution and industry, etc[7].
- Each consortium must contribute to the European Green Deal and the Sustainable Development Goals (SDGs). Therefore, they should add at least one CUST 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[8].
- Each consortium, except consortiums applying to Education programmes, 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[9].
- 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.
- The final recipients of funding must comply with the IPR rules under the MGA Article 16.

Specific conditions for EIT Health Innovation Days (i-Days) – New Cities

Strategic fit

EIT Health is calling for up to 5 new host Cities to enrich its Innovation Days (i-Days) Series, which are challenge-based learning events that train participants in innovation and entrepreneurship, design thinking methods, and pitching. The events aim to inspire creativity and collaboration while encouraging a new generation of health innovators.

The EIT Health i-Days Series is a network of cities delivering the above-mentioned events, and a coordination work package for operational support is provided to all i-Days cities. The coordination work package is administered by EIT Health and led, in close collaboration, by an Education and Academic Lead, who will walk i-Days hosts through the EIT Health i-Days handbook and online consortium meetings, and provide general guidance. In collaboration with the KIC, EIT Health is inviting institutions to join the existing i-Days host consortium, of around 10 cities, and the broader network that goes beyond 20 cities.

The call for i-Days Events Delivery Work Package is structured into three phases:

[7] Not applicable for Master Degree activity.
[8] Above mentioned CUST KPI is not required for education proposals.
[9] Not applicable to Education programmes

A) Challenges definition. Challenges shall be based on UN SDG3-related targets (3.1. to 3.9) and relate to one or both of the Flagships (Digital Transformation of Health and/or New Models to Deliver Healthcare).
B) Educational event planning and student recruitment.
C) Event delivery. All i-Days are expected to take place in 2024 and in 2025 between mid-October and mid-November.

We are calling for new cities where EIT Health has not funded these events previously. The list of already awarded cities can be found here.

The programme must enrol a minimum of 65 learners per i-Days city.

Target Audience: The i-Days main target should be undergraduate, Master and PhD students with an interest in healthcare innovation. Participation does not require any prerequisite skills or prior experience in innovation, entrepreneurship or healthcare, making the event highly accessible. In addition to the main target, young professionals without innovation, entrepreneurship or healthcare experience but interested in healthcare innovation can be targeted.

i-Days Format & delivery timelines: The learning format can be in-person (preferred), online, or blended. Each i-Days event must take place within the same four-week period. In-person i-Days events should last for one or two days, while online or blended i-Days can be spread out over four to five days to facilitate scalability. The format and duration of i-Days events must be adhered to, to ensure the finalists can register and participate in the EU finals smoothly. For the same reason, even if registration of already-formed teams are accepted, ideas addressing the specific challenges should be designed from scratch during the i-Days events, and not come from other programmes or previous work.

Winners of the local i-Days events will be invited to participate in the European semifinals and finals that takes place at the end of the year during the EIT Health "Career Path event: From Students to Innovators", where, in addition to benefiting from a whole learning programme, the i-Days winners from all the European i-Days cities gather at EU level to pitch and compete for prizes aimed at supporting them to continue their entrepreneurial learning process.

Knowledge Triangle Integration: It is strongly recommended that entrepreneurs, (industry) professionals, citizens and patients participate, to support/mentor students in the learning process and facilitate the Knowledge Triangle integration.

Letters of commitment and interest from the stakeholders involved, sponsors or Higher Education hierarchy are expected and strongly encouraged.

Registration & data sharing: Participants' registration will be led by EIT Health via EIT Health's platform, and access to participants' data will be shared with respective i-Days hosts prior to the event, in compliance with GDPR rules. After each local i-Days event, EIT Health must receive confirmation of attendance of enrolled parties from i-Days hosts.

Assessment: The student's programme assessment will be led by EIT Health. They will provide a questionnaire, based on EntreComp framework, which demonstrates the variation in levels of confidence, performance, skills, knowledge and/or behaviour towards entrepreneurship and business creation around the i-Days event. This evaluation is a requirement to report on participant KPIs and for EIT Health to issue EIT Health Certificates of Completion to eligible participants.

Marketing & Communication: Under EIT Health coordination, each i-Days event should follow the general Marketing and Communication guidelines for the overall i-Days Series programme, while developing its own objectives and action plan to reach the KPIs, which will be submitted as a deliverable. This means, that although the i-Days Series Marketing is centralised and managed by EIT Health, individual i-Days hosts are expected to promote and market their local i-Days event using the materials provided.

EIT Health i-Days Series Consortium: All new i-Days hosts will be invited to join regular meetings of the i-Days Series Consortium, where updates, content material, and other resources of common interest are shared. All i-Days participants will also be invited to join the EIT Health Innovator's Community.

Consortium

- Consortiums applying to host a new i-Days event must include at least one academic organisation to lead the implementation of the i-Days event, and at least one non-academic organisation (preferably industrial company).
- Involvement of start-ups, healthcare professionals, and patient associations is strongly recommended.
- As EIT Health aims to continuously increase its geographical coverage of the i-Days Series, it will only fund one i-Days event per European city. We highly encourage the participation of cities from countries where currently no i-Days events are taking place. Please check the i-Days link for previous i-Days cities and the i-Days website for the most recent cities.

Budget

We are calling for consortiums to create new i-Days in up to 5 new cities.

Maximum budget per city:

1st year (2024): up to 12 K EUR

2nd year (2025): up to 8 K EUR

Financial sustainability and revenue generation

Each i-Day must outline a well-defined sustainability strategy to continue the education programme beyond EIT Health funding.

An advanced sponsoring action plan is expected to illustrate how the grant will be replaced by committed sponsors. Letters from potential or committed sponsors are also expected. i-Days events are the only exception to the financial sustainability conditions requirement that the grant must be offset by revenues in addition to a revenue sharing model.

Duration of the activity

Funding is for a period of two years. However, after the two-year period, the consortiums could opt to enter the Recognition Scheme. For more information on the Recognition Scheme see following section: Specific conditions for Innovation Days – Recognition Scheme.

Impact

The impact consists of participants in the i-Days event: a minimum 65 learners, of which 10 should come from the RIS region.

Implementation of the activity

- The selected cities will contribute to expected outputs, deliverables and milestones which are listed here that will already be pre-filled in the EIT Health Application Platform.
- All selected new i-Days hosts will collaborate with an EIT Health Education Lead, who will monitor progress of the activity and support them to ensure the required information is structured according to the specific reporting guidelines to facilitate the coordination of the network and the deliverables.

Specific conditions for Innovation Days – Recognition Scheme

EIT Health is inviting those self-sustainable i-Days cities who have previously received EIT Health funding to apply to continue being members of the i-Days network through the Recognition Scheme. The list of eligible cities can be found here.

The Recognition Scheme aims to recognise the successful evolution of a programme and further develop EIT Health's relationship with the educational programmes by establishing a win-win approach for the programme and EIT Health.

A dedicated Education Lead, in collaboration with an Academic & Educational Lead (WP 1), will support, develop, and enhance the organisation of these educational events, addressing the methodological perspective, overall coordination and measurement of impact to enable further strengthening of the activity.

Benefits offered by the Recognition Scheme for programmes include:

- Registration platform for participants
- Promotion on the EIT Health web site and other promotional channels
- Access to marketing material templates
- EIT Health certificates of participation
- Participants can join the EIT Health Alumni Network Innovator's Community
- Survey data on students' entrepreneurial mindset
- The programme gains visibility with the EIT Health marketing, gains potential lead generation to strengthen ongoing sustainability and does not have to assume operational registration tasks.

A previously funded programme can help EIT Health gain further reach and impact, including continued growth of the EIT Health Alumni Network Innovator's Community, engaging students with further opportunities, programme participants measurements and KPI targets. The main KPI exchanged among the city host and EIT Health is a minimum of 50 learners, of which 10 participants should come from the RIS regions.

EIT Health will cover travel and accommodation costs for the winning i-Day cities team selected in the Recognition Scheme (a maximum of 4 students per team) in 2024 and 2025. EIT Health will administer the grant for travel and accommodation directly with students. i-Days will seek sustainability strategies, such as sponsorship, for student travel in future editions. As this is a post-funding activity, funding will only cover participation of students to the annual Finals event, as outlined above.

Specific conditions for Master Degree Programmes in DTH

Strategic fit

EIT Health is calling for four Higher Education Institutions eager to join a consortium led by EIT Health with the goal of incorporating Entrepreneurship and Innovation Education elements into their existing master's programmes, equivalent to 30 ECTS. The consortium's ultimate aim is to design and implement a comprehensive set of activities focused on Innovation and Entrepreneurship education in a collaborative fashion.

The already-existing programmes from the applicants should be fully-accredited Master of Science Degrees, consisting of 60-90 ECTS credits maximum, with a primary focus on healthcare.

Collectively, the consortium will work to create and execute an integrated and innovative 'learning-by-doing' curriculum, that places a strong emphasis on aligning with the Knowledge Triangle Integration. This curriculum will interconnect all the activities mentioned in the table (see below), cultivating an entrepreneurial mindset, and promoting start-up creation.

Each selected organisation will be involved in the development and delivery of the following activities. Tasks and responsibilities will be discussed and distributed across the consortium upon masters' selection:

Activity*	**Format**	**ECTS**	**Expected academic semester**
Citizen and Patient Activities in accordance with ELSI Principles	Online	2 ECTS	1st academic semester
Residential School A (Flagship-related: New models to deliver Healthcare)	Blended	5 ECTS	2nd academic semester
Residential School B (Flagship-related: Digital Transformation of Healthcare)	Blended	5 ECTS	2nd academic semester
Business Lab	Online	3 ECTS	3rd academic semester

*For more information about each activity and the learners' journey, please check the glossary here.
*Learners are expected to attend one Residential school only.

In addition to the Innovation & Entrepreneurship activities mentioned in the above table, the 30 ECTS plug-in will incorporate an already existing EIT Health introductory online course, with a focus on Innovation, Entrepreneurship, and Leadership, equivalent to 5 ECTS (1st semester).
In adherence to the EIT Label requirements for Degree Programmes, the plug-in will also feature a mandatory, activity-based internship, equivalent to 15 ECTS (between the 3rd and 4th semester).

As the consortium lead, EIT Health, is also responsible for the enrolment to the already existing online module with a focus on Innovation, Entrepreneurship, and Leadership (5 ECTs) and the provision and allocation of the mandatory internships (15 ECTs).

Consortium

- Applications from Higher Education Institutions from the RIS Region is highly encouraged.
- During the development phase, the consortium will jointly engage non-academic partners to actively participate in curriculum development and implementation, as well as to become part of the consortium.

Budget

For information, once the Higher Education Institutions are selected and join the EIT Health Consortium, EIT Health will invest the following funding for respective activities.

Funding is available for 2024 – 2025 and will be allocated yearly across different activities, for example (non-exhaustive list):

Tasks	Available grant in 2024	Available grant in 2025
Programme's set-up and accreditation request	22 K EUR	12 K EUR
Residential School A (1st implementation, 2025)	10 K EUR	90 K EUR
Residential School B (1st implementation, 2025)	10 K EUR	90 K EUR
Business lab (1st implementation, in Winter 2025)	10 K EUR	35 K EUR
Online modules toward Patients & Citizens Activity[10]	27 K EUR	NA

Financial sustainability and revenue generation

- As this activity is led, coordinated and administered by EIT Health, the financial sustainability requirement lays with the KIC (EIT Health). Intellectual Property is owned by the consortium.
- The consortium members will be requested to sign a Revenue Sharing agreement with EIT Health. EIT Health is mindful of national variability in terms of the price for ECTS. Relevant fees will be market validated. Please find the agreement template here.
- EIT Health will generate revenues from the final activity to ensure the activities are sustained beyond the funding period. Revenues will be shared with members of the consortium once the grant is offset by said revenues.

[10] Content of the modules will be implemented on the EIT Health Academy in 2024.

Duration of the activity

All programmes will receive funding for the next 4 years, starting in 2024 with preparation, labelling and, for those master programmes that achieve accreditation in the same year, first recruitment:

- The first year serves as a development phase (to obtain the EIT Label and consolidate syllabus, consortium agreement, etc. See list of milestones here.
- For those programmes that successfully achieve accreditation, the first cohort of students must be enrolled in late 2024 (September – October, depending on Partners' academic calendar) or in the following semester or earliest entrance date. This will be validated and agreed within the Consortium. Again, EIT Health is mindful of national variability in terms of re-accreditation of masters. Relevant flexibility will be addressed in the consortium, including the validation of the students' recruitment dates.

The selected master programmes will be invited to establish a consortium and collaborative framework with EIT Health. Within this structure, each of the selected master programmes, in conjunction with EIT Health, will work towards ensuring the long-term sustainability of the programme beyond the grant period. The specific terms of this collaboration are outlined in a Consortium Agreement that delineates roles and responsibilities extending beyond funding.

Impact

- Once the programme is kicked off, each participating university must commit to enrol a minimum of 20 EU and/or non-EU students from the cohorts of their existing master programmes in 2024, 25 students in 2025, and 30 students in both 2026 and 2027.
- Additionally, each participating university must be willing to provide training to students from the other consortium member universities and grant the corresponding ECTS credits to the enrolled students.
- The selected consortium will contribute to expected outputs, deliverables and milestones which are listed here that will already be pre-filled in the EIT Health Application Platform.

Implementation of the activity

- From an administrative standpoint, EIT Health will lead and coordinate the consortium. Therefore, EIT Health, in collaboration with the consortium members, will oversee the following responsibilities:
  - Preparation and Submission of the EIT Label for Degree Programme Application (2024, development year).
  - Establishment of internship processes through the WorkinHealth Foundation.
  - Coordination of consortium meetings, including the programme's Kick-off in Q2 2024.
  - Coordination & implementation of shared activities such as the students' yearly Kick-Off in 1st semester and the yearly Graduation Celebration after the 4th semester.
  - Management of marketing and awareness initiatives handling registration, data collection and management.

  - Management of 30 ECTS related payments, fee collection, and revenue distribution.
  - Performance, mid-term, cost and final reporting and budget management.
  - Providing support for Master programmes and students.
- EIT Health will oversee marketing, recruitment, so the budget for Partners is expected to be allocated solely to personnel time, curriculum development, accreditation, and content production.
- Content is expected to be hosted on the EIT Health Academy. Selected consortiums will be supported by the EIT Health Academy team to validate the learner journey through curriculum development workshops, ensuring optimal instructional design and learning experience on the EIT Health Academy platform. For more information, please see here.

Specific conditions for Modules towards a labelled Fellowship Programme in NMDH

Strategic fit

Background: EIT Health will launch its first EIT Labelled Fellowship Programme in 2024. Labelled Fellowships are personalised online learning pathways for individuals to acquire theoretical and practical knowledge, and develop skills they can apply in a professional environment. Over 9 to 12 months, participants need to collect 30 ECTs by completing the journey depicted here.

For this activity, EIT Health is calling for organisations to participate in a consortium. This will be led by EIT Health, who will handle all administration, and selected organisations will be expected to focus on delivering their expertise and repurposed academic content, and participate in its assessment. Several modules (for example, Innovation, Entrepreneurship and Leadership) for the programme have been selected in the previous Flagship call, and EIT Health is now calling for an additional Flagship-related module in the Flagship topic “New Models to Deliver Healthcare” (NMDH). To further understand how contents should be linked, please refer here to consult the learning journey for the Fellowships.

What we are calling for: We are calling for a repurposed, already existing module made of several independent courses, for an equivalent of minimum 30 ECTS in the field of NMDH and, in accordance with the implementation matrix, nine domains of the ‘Implementing of Value-Based Healthcare in Europe’ paper.

The consortium should offer at least 30 ECTS of NMDH-related content, divided into different independent courses. Learners will need to take 17-22 ECTS of these courses, but we ask consortiums to offer at least 30 ECTs, to allow learners have the possibility to choose courses. These courses should be repurposed, that is they should come from already existing high-quality content, and should aim at upskilling/reskilling learners in the field of NMDH. The distribution of ECTS per course and the number of courses can be defined by the consortium, as long as it offers flexibility on the learner’s journey. For example, course. "X" 5 ECTs, course. "Y" 10 ECTs, course. "Z" 5 ECTs, course. "A" 5 ECTs, course "B" 5 ECTs. Courses offering less than 5 ECTs are discouraged as they don´t ease the uptake of new content and skills deep enough. The module should be offered by Consortiums in different, optional, and independent set of courses and

learners should be able to take any NMDH-related course or combination of courses according to their personalised learner journey.

Therefore, the NMDH-related module shall work independently and avoid, as much as possible, interdependency and series (course 1, course 2, etc.), to maximise the personalised progress of individual learners. Content-based assessment should be developed and applied by the Consortiums for each course.

The selected module will be hosted on the EIT Health Academy, where the full Fellowship journey is taking place, following its instructional design guidance.

Consortium

The consortium applying for this call must include a minimum of two Higher Education Institutions (HEI), from two, different eligible member states, whereby:

- One HEI must belong to a RIS region.
- There must also be at least one non-academic or industry partner that is expected to contribute to the curriculum of the repurposed courses, as well as assessment supervisors.

Active contribution from non-academic/industry partners is important, as a highly integrated, innovative “learning-by-doing" curriculum is a key principle of the EIT Labelled Fellowship. Participants should work both individually and in teams, with an interdisciplinary approach and typically focussing on authentic challenges articulated by industry and business partners and/or other non-academic partners.

Budget

- The maximum EIT Health grant that is available for the NMDH Flagship pathway is 200 K EUR.
- Please note that work must start in 2024, upon selection communication.
- EIT Health provides the LMS platform through the EIT Health Academy, challenges definition, and recruitment/marketing related costs. Proposals shall present full budgets for the whole granting period.

Financial sustainability and revenue generation

- As this activity is an EIT Health led, coordinated and administered activity, the financial sustainability requirement lays with the KIC (EIT Health). Intellectual Property is owned by the consortium.
- The consortiums will be requested to sign a Revenue Sharing agreement with EIT Health. Please find the agreement template here.
- The KIC will generate revenues from the final activity to ensure the activities are sustained beyond the funding period. Revenues will be shared with members of the 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).

- (Repurposed) courses should be available by the end of 2024, for implementation and launch of the Labelled Fellowship in NMDH in early 2025.
- The selected proposal will join the existing Labelled Fellowships consortium with a consortium agreement in place defining the continuation of the activity in the post-funding period.

Implementation of the activity

- The selected consortium will contribute to expected outputs, deliverables and milestones which are listed here that will already be pre-filled in the EIT Health Application Platform.
- KPIs will be managed and reported by EIT Health. However, it is important that proposals acknowledge them since they are an expected outcome of the personalised learner journeys.
- Additionally, as part of the labelling monitoring, EIT will monitor the ´EIT Label graduates employed´ and its ´Career growth´. Therefore, EIT Health shall structure relevant data collection around the topic information until the end of 2025.
- Content is expected to be hosted on the EIT Health Academy.
- Selected consortiums will be supported by the EIT Health Academy team to validate the learner journey through curriculum development workshops ensuring optimal instructional design and learning experience on the EIT Health Academy platform. For more information, please see here.

Specific conditions for Modules towards a Labelled Fellowship Programme in DTH

Strategic fit

Background: EIT Health will launch its first EIT Labelled Fellowship Programme in 2024. Labelled Fellowships are personalised online learning pathways for individuals to acquire theoretical and practical knowledge, and develop skills they can apply in a professional environment. Over 9 to 12 months, participants need to collect 30 ECTs by completing the journey depicted here.

For this activity, EIT Health is calling for Partners to participate in a consortium. This will be led by EIT Health, who will handle all administration, and selected organisations will be expected to focus on delivering their expertise and repurposed academic content, and participate in its assessment. Several modules (for example, Innovation, Entrepreneurship and Leadership) for the programme have been selected in the previous Flagship call, and EIT Health are now calling for additional Flagship-related courses to enrich and strengthen the personalisation of the learning experience. The selected courses should enhance and diversify the already selected / existing Flagship-related modules. To further understand how contents should be linked, please refer here.

What we are calling for: We are calling for repurposed, already existing, online courses for an equivalent of minimum 15 ECTS that supplement the existing curriculum that is already selected.

Please refer here for the detailed curriculum of the already selected courses. The modules will be hosted in EIT Health Academy, following its instructional design guidance.

These modules should come from excellent, high-quality courses that already exist in organisations (Partners or non-Partners), and can be repurposed to cater to the Labelled Fellowship Programme needs. The repurposed modules are expected to offer ECTS credits as part of the requirements of the EIT Labelled educational programme.

We are calling for online courses in the topics below, aimed at enhancing the already existing module:

- Modules in Facilitating the uptake of Digital Medical Devices.
- Modules in Harnessing the Full Potential of Health Data for Innovation.

Target Learner:

- Master and Doctoral level learners having completed, or not completed their studies.
- Professionals willing to upskill/reskill themselves in the related Flagship related fields. First learners will be recruited to start their Fellowship journey in 2024.

Consortium

Consortiums are expected to demonstrate expertise in the field of their chosen topic, and also consider that the content should not overlap with the existing curriculum of the current selected Fellowship programme.

The consortium applying for this call must include a minimum of two Higher Education Institutions (HEI), from two, different eligible countries, whereby:

- One HEI must belong to an RIS region.
- There must also be at least one non-academic or industry partner that is expected to contribute to the curriculum of the repurposed course.

Active contribution from non-academic/industry partners is important, as a highly integrated, innovative “learning-by-doing" curriculum is a key principle of the EIT Labelled Fellowship. Participants should work both individually and in teams, with an interdisciplinary approach and typically focussing on authentic challenges articulated by industry and business partners and/or other non-academic partners.

Budget

- The maximum grant available for this activity is 100 K EUR for each topic.
- Please note that work must start in 2024, upon selection communication.
- EIT Health provides the LMS platform through the EIT Health Academy, challenges definition and recruitment/marketing related costs. Proposals shall present full budgets for the whole granting period.

Financial sustainability and revenue generation

- As this activity is an EIT Health led, administered and coordinated, the financial sustainability requirement lays with the KIC (EIT Health). Intellectual Property is owned by the consortium.
- The consortiums will be requested to sign a Revenue Sharing agreement with EIT Health. Please find the agreement template here.
- The KIC will generate revenues from the final activity to ensure the activities are sustained beyond the funding period. Revenues will be shared with members of the 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).
- (Repurposed) courses should be available by the end of 2024.
- The selected proposal will join the existing Labelled Fellowships consortium with a consortium agreement in place defining the continuation of the activity in the post-funding period.

Implementation of the activity

- The selected consortium will contribute to expected outputs, deliverables and milestones which are listed here that will already be pre-filled in the EIT Health Application Platform.
- KPIs will be managed and reported by EIT Health. However, it is important that proposals acknowledge them since they are an expected outcome of the personalised learner journeys.
- Additionally, as part of the labelling monitoring, EIT will monitor the ´EIT Label graduates employed´ and its ´Career growth´. Therefore, EIT Health shall structure relevant data collection around the topic information until the end of 2025.
- Content is expected to be hosted on the EIT Health Academy.
- Selected consortiums will be supported by the EIT Health Academy team to validate the learner journey through curriculum development workshops ensuring optimal instructional design and learning experience on the EIT Health Academy platform. For more information, please see here.

Specific conditions for Modules toward Labelled Certification in DTH

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.

The following topics are sought after. EIT Health will select one module per topic:

1. **Quality assurance skills** in biomanufacturing, biotech, medical devices, quality assurance, standards, quality assessment. General overview/ basics of quality assurance in the industry.
    - Target audience:

        - Post-graduate learners in pharmaceutical, biochemistry, bioengineering, etc.
    - Expected outcome:
        - 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.
    - Target audience:
        - Professionals working in bioproduction, biotech, medical devices.
    - Expected outcome:
        - 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**
    - Target audience: students in post-graduate education in STEM fields.
    - Expected outcome: Students taking the course will:
        - Understand what the biomedical field is.
        - Get an overview of what the most novel implications and developments are.
        - Receive an overview of the industrial implications.
        - Be given well-rounded insights on future professional perspectives: panorama of relevant jobs for students in biomedicine / bioproduction
4. **Regulatory Affairs for students**
    - Target audience:
        - Learners in post-graduate pharmaceutical, biochemistry, bioengineering, etc. General overview/basics of regulatory affairs in the healthcare industry.
    - Expected outcome:
        - Students taking the course will learn about regulatory affairs and its relevance in the industry workplace.
5. **Regulatory Affairs for professionals**
    - Target audience:
        - Professionals working in bioproduction, biotech, medical devices. Advance course on regulatory affairs for employees of healthcare providers, healthcare industry companies.
          To be noted, EIT Health already has modules on regulatory affairs for healthcare professionals (medical professions). This module is directed at other professionals in the healthcare sector.
    - Expected outcome:
        - Professionals working in bioproduction, biotech, medical devices. Advance course on regulatory affairs for employees of healthcare providers, healthcare industry companies.
        - Professionals taking the course will eventually have improved understanding of regulatory that allows them to modify their work practice.

6. **EHDS explained to computer science engineers**
    - Target audience:

        - Computer scientists and engineers. The aim is to attract data/ computer scientists to the healthcare sector.
    - Expected outcome:
        - By taking the course, data/computer scientists will:
            - Be able to describe the EHDS European Health Data Space Initiative, background, problems it aims to solve, etc.
            - Understand the relevance of their skills and how data/computer science and analysis can be applied to the management of healthcare population data.
        - The EHDS effort was launched to harmonise all pan-European healthcare systems and facilitate access and sharing of data to promote medical advancements. Considering this, EIT Health has developed a platform intended to bring together all European biobanks (BBMRI-ERIC accredited and not). A website for accessing information on samples availability, disease areas, access to national legislation and contacts of virtually all European biobanks will be available early January 2024. Applicants can utilise this resource as relevant.

Budget

- 50 K EUR is available for each module.
- One module for each of the six topics listed above will be selected.

Financial sustainability and revenue generation

- As this activity is an EIT Health-driven and administered activity, the financial sustainability requirement lays with EIT Health. Intellectual Property is owned by the consortium.
- The consortiums will be requested to sign a Revenue Sharing agreement with EIT Health. Please find the agreement template here.
- EIT Health will 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) and the expected duration of each is 4 weeks.
- The activity may take place at any time within the 12 months from the selection communication.
- The work on production of the content for the modules must start in 2024, upon selection communication.

Implementation of the activity

- The selected consortium will contribute to expected outputs, deliverables and milestones which are listed here that will already be pre-filled in the EIT Health Application Platform.

- EIT Health leads this activity and will ensure recruitment marketing campaigns.
- 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.
- Content is expected to be hosted on the EIT Health Academy.
- Selected consortiums will be supported by the EIT Health Academy team to validate the learner journey through curriculum development workshops ensuring optimal instructional design and learning experience on the EIT Health Academy platform. For more information please see here.
- The modules shall be submitted to an accreditation institution (UEMS, EACCME) upon content readiness.

Specific conditions for Technology Development activities in DTH

Strategic fit

With the rise of digital health, Europe is still behind in terms of ease of evaluation, reimbursement, and adoption of Digital Medical Devices (DMD)[11].

Through this call, EIT Health aims to support the transformation, harmonisation and strengthening of the use of DMD. We are looking for collaborative SME or industry led projects that focus on validation, certification, and market access of patient-centred DMD solutions in Europe to facilitate market entry and wider adoption.

Digital Medical Devices are health technologies falling into the definition of medical devices as outlined in the Regulation (EU) 2017/745[12] 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,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

[11] https://www.europarl.europa.eu/RegData/etudes/STUD/2021/695465/IPOL_STU(2021)695465_EN.pdf
[12] 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[13] intended to be used alone or in combination with hardware (e.g. scanners, sensors, monitors…), 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)[14];
- Administrative software's.

In case of devices that combine software and hardware components that require further development, the EIT Health grant should be dedicated to the software component development exclusively.

To speed up clinical trial development and market access of the DMD solutions, it is encouraged, where applicable, that the consortiums leverage existing health registries and biobanks.

The solution or technology maturity level must be between IML5 (Proof of Value), and IML6 (Initial Clinical Trials) at proposal submission and planned to advance through IML7 (Validation of Solution) and IML8 (Approval & Launch) within the activity timeframe. For more information on IMLs (Innovation Maturity Levels please check **here)**

The activities are expected to reach the product's commercialisation stage a maximum one year after the EIT Health funding period.

Consortium

At short proposal submission stage

- The commercialising entity of the product developed in the activity proposal must be part of the consortium and listed in the participants section of the application form,
- The commercialising entity is an SME, a large-size industry, or any type of organisation that will be responsible for bringing the product to market,

[13] 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
[14] 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 following 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 2 paid FTEs working at the time of the short proposal submission,
    - The entity must have a CEO working full-time in the company at the time of the short proposal submission.

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.
- 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 micro and small enterprise. Please find further information about the “Grant to Options” model here and about the “Revenue Sharing” model here.

Funding rate

- The maximum funding rate is 70% for the whole duration of the activity.

Budget

- The activity must request a minimum of 500K EUR EIT Health funding.
- The maximum grant that can be requested by the consortium is 1 M EUR for the total duration of the activity.

Duration of the activity

- The maximum duration of EIT Health financial support is 18 months and will last until 31 December 2025, at the latest.

Ethics

- A dossier of relevant Ethics Committee approvals must be submitted by all clinical centres involved in trial implementation within the first month after the notification of acceptance of the activity in the EIT Health portfolio (if not done earlier).
- Approval by at least one Ethical Committee is expected within 4 months following the notification of acceptance of the activity into EIT Health portfolio (for multi-centric studies, Ethics Committee approval must be in place for at least one centre).
- Activity can only commence once Ethics Committee approval is obtained.

Impact

- 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).
- The activity must aim at protecting innovative solutions through filing of patents, trademarks, registered designs, copyrights, etc.
- 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.

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

Specific conditions for Service Development activities in NMDH

Strategic fit

With the goal to build more resilient healthcare systems that operate on value, not on volume, EIT Health is calling for collaborative activities that aim to promote the market uptake of innovative products and services by assessing the quality of the healthcare service improvement. The ultimate goal of those activities is to generate sufficient evidence of added value to patients that will convince payors to reimburse based on value.

The activity aims at measuring the impact of the improved/new service approach, including Patient-Reported Experience Measures (PREMs) and Patient-Reported Outcome Measures (PROMs), together with process, clinical and other outcomes during a testing/piloting phase. The early involvement of payors is key, as securing dialogue as early as possible on outcomes to be measured, expected results definition, and timelines to incorporate those services, will speed up the adoption of the innovations paid for by these organisations.

EIT Health aims to support pan-European solutions that can be replicated. Therefore, the activity should focus on large scale implementation in different regions/countries from where the test/pilot takes place. Although this upscaling is expected within one year after the end of the activity, having healthcare providers and their payors involved in the current activity as a learning opportunity is highly recommended.

The commercialising entity must take care of the large-scale implementation of the approach.

The technology to be used in the proposal should be readily available in the market, and if needed, with CE mark granted. Only platform integration developments to capture/incorporate/ analyse patient outcomes into the IT systems are envisioned.

Consortium

At short proposal submission stage

- The commercialising entity of the service developed in the activity's proposal must be part of the consortium and listed in the participants section of the application form,
- The commercialising entity is an SME, large-size industry, or any type of organisation that will be responsible for bringing the product to the market,
- The following 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 2 paid FTEs working at the time of the short proposal submission,
    - The entity must have a CEO working full-time in the company at the time of the short proposal submission.
- The clinical partners must come from at least two different countries. They must be part of the consortium and listed in the participants section of the application form.

At full proposal submission stage, the consortiums must include

- Two healthcare providers and two payors from the same country as the healthcare providers: one should provide the healthcare services that the other will purchase,
- A partner taking care of the IT platform integration,
- A partner with health economics expertise capable of supporting the development of the required evidence.

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.
- 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 micro and small enterprise. Please find further information about the "Grant to Options" model here and about the "Revenue Sharing" model here.

Funding rate

- The maximum funding rate is 70% for the whole duration of the activity.

Budget

- The activity must request a minimum of 500K EUR EIT Health funding.

- The maximum grant that can be requested by the consortium is 1.15 M EUR for the total duration of the activity.

Duration of the activity

- The maximum duration of the EIT Health financial support is 18 months and will last until 31 December 2025 at the latest.

Ethics

- A dossier of relevant Ethics Committee approvals must be submitted by all clinical centres involved in trial implementation within the first month after the notification of acceptance of the activity in the EIT Health portfolio (if not done earlier).
- Approval by at least one Ethical Committee is expected within 4 months following the notification of acceptance of the activity into EIT Health portfolio (for multi-centric studies, Ethics Committee approval must be in place for at least one centre).
- Activity can only commence once Ethics Committee approval is obtained.

Impact

- Health impact is expected to be 150,000 European citizens and/or patients benefitting from the solution developed in activity within three years after activity completion (independently from health conditions and range of applications).
- The activity must aim at protecting innovative solutions through filing of patents, trademarks, registered designs, copyrights, etc.
- The activity must aim at scaling services 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.

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

Specific conditions for DiGinnovation programme

Strategic fit

The DiGinnovation programme selects the top digital health micro and small enterprises and links them with international entities to create a consortium that will improve healthcare systems by accelerating the uptake of digital health apps by healthcare professionals and patients, and expediting market launch of the innovation while easing the reimbursement process.

The focus of this programme is on patient-centred Digital Medical Devices & Diagnostics. **Digital Medical Devices** are health technologies falling into the definition of medical devices as outlined

in the Regulation (EU) 2017/745[15] 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,
- 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[16] intended to be used alone or in combination with hardware (e.g. scanners, sensors, monitors…), 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)[17];
- Administrative software's.

The lead partner of the activity is a micro or small enterprise according to the EU definition.

The proposal must target one specific European market and the solution must meet the requirements of reimbursable applications in the targeted country.

The solution must have CE approval at the time of submission, and 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.

[15] 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

[16] 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

[17] 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

Consortium

At short proposal stage

- The commercialising entity of the product, i.e., the micro or small enterprise, is listed in the participants section of the application form,
- The following 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 2 paid FTEs working at the time of the short proposal submission,
    - The entity must have a CEO working full-time in the company at the time of the short proposal submission.
- The micro or small enterprise applies alone. Consortium is only expected at the full proposal stage.

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.

Funding rate

- The maximum funding rate is 70% among the whole activity’s duration.

Budget

- The maximum grant that can be requested by the consortium is 350 K EUR for the total duration of the activity, of which a minimum of 150 K EUR must be requested by the micro or small enterprise.

Duration of the activity

- The maximum duration of the EIT Health financial support is 9 months and will last until 31 December 2025 at the latest.

Ethics

- A dossier of relevant Ethics Committee approvals must be submitted by all clinical centres involved in trial implementation within the first month after the notification of acceptance of the activity in the EIT Health portfolio (if not done earlier).

- Approval by at least one Ethical Committee is expected within 4 months following the notification of acceptance of the activity into EIT Health portfolio (for multi-centric studies, Ethics Committee approval must be in place for at least one centre).
- Activity can only commence once Ethics Committee approval is obtained.

Impact

- Health impact is expected to be 150,000 European citizens and/or patients benefitting from the solution developed in activity within three years after activity completion (independently from health conditions and range of applications).
- The activity must aim at protecting innovative solutions through filing of patents, trademarks, registered designs, copyrights, etc.
- 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.

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

Application Process

Cut off and distribution of activities

The Flagships Call will consist of a one-year long call with two application deadlines, known as cut-off dates: **28 February 2024** and **18 September 2024.**

- **The cut-off dates are the deadlines for short proposals and/or single proposal submission.**
- It is important to note that not all activities called within the Flagship framework will be called at both cut-offs.

Flagship	Activities	Application Deadline	Application type
New models to deliver healthcare	EIT Health Innovation Days Series (i-Days)	28 February 2024	Single stage submission
	Modules towards a Labelled Fellowship Programme		Two-stage submissions
	Service Development activity		Two-stage submissions
Digital Transformation of Healthcare	EIT Health Innovation Days Series (i-Days)		Single stage submission
	Master Degree Programme		Single stage submission
	Modules towards EIT Labelled Certification		Two-stage submissions

	Modules towards a Labelled Fellowship Programme		Two-stage submissions
	Technology development activity		Two-stage submissions
	DiGinnovation programme	18 September 2024	Two-stage submissions

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

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

If the applicant is already an EIT Health member, or has registered as an External project Partner in previous Call(s) on our platform PLAZA, the corresponding data for the organisation will be available in the application platform.

However, the applicant will still need to create a new account as an individual 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.

Selection process in details

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.

A quality threshold of minimum 70% of the maximum obtainable points applies at the relevant selection steps.

The selection process will vary according to the single stage or two-stage submission evaluation.

Single stage submission

For single stage submissions the selection process is planned to last one month. The selection phases and corresponding dates are outlined below. Please consider that for the single stage evaluation process the number of steps is reduced.

Two-stage submission

For two-stage (Short + Full proposal) submissions, the selection process is expected to last up to 4.5 months from the short proposal submission to the final selection notification. The selection phases and corresponding dates are outlined below.

	Single-stage submission	Two-stage submission	DiGinnovation
Submission date of short/single proposal	28 February 2024	28 February 2024	18 September 2024
Filtering notification and invitation to pre-selection evaluation	1 March 2024	21 March 2024	10 October 2024
Pre-selection evaluation	---	10-12 April 2024	22-23 October 2024
Pre-selection notification	---	22 April 2024	31 October 2024
Support Programme	---	23 April-13 June 2024	04 November-19 December 2024
Submission date of full proposal	---	13 June 2024	19 December 2024
Final selection evaluation - Hearings if applicable	---	26-28 June 2024	---
Final selection notification	21 March 2024	11 July 2024	23 January 2025

Filtering

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

For single stage submissions, all details are expected at the submission date.

In the two-stage submission process, the activity plan may not be fully finalised, and the consortiums may not be complete at the short proposal stage.

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

In addition to eligibility checking, EIT Health will perform a high-level assessment of general alignment of the proposal with the Flagships call based on strategic fit, potential future impact, and activity feasibility.

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

Pre-selection

Pre-selection is only applicable to the two-stage evaluation approach.

Proposals that pass the filtering step will go through a pre-selection evaluation consisting of an online pitch in front of external evaluators.

Pre-selection evaluations will be based on the following criteria:

Evaluation criteria
Activity Excellence and Strategic Fit (50%) Clarity and pertinence of the activity'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%) Pathways to achieve expected outcomes and impacts identified with plausible planning Identified measures to maximise expected outcomes and impact Initial idea of the potential business model identified, to be refined during proposal preparation[18]
Implementation and Feasibility (10%) Quality and effectiveness of the initial idea plan

[18] Only for Technology and Service Development activities, as well as DiGinnovation programme.

Capacity and role of each participant identified

Complementary expertise identified

Depending on the available budget per call, a certain number of proposals will be invited to the next phase.

EIT Health will apply a ratio of three invited consortiums for one finally selected consortium.

Support programme

The support programme is only applicable to the two-stage evaluation approach.

The support programme provides an opportunity for each invited consortium to work further on their activity plan, complete their team, and strengthen their ideas through mentoring and coaching.

The support programme is a service offered by EIT Health to all pre-selected applicants to enhance the quality of their proposals. It applies to all types of proposals that will go through the two stage evaluation process.

It is mandatory to take part, except for consortiums who have already been through the programme, e.g., from participation in previous calls.

More details on the programme content will be communicated to invited teams in due course.

Full proposals are expected to be submitted at the end of the support programme. The full proposal must incorporate relevant feedback, learnings, recommendations, and improvements gathered within the support programme, with the goal of producing a high-quality proposal for the final selection phase and facilitate the evaluation process.

Due diligence

All micro and small enterprises acting as commercialising entities and applying to Technology or Service Development activities or DiGinnovation programme must go through a due diligence process to assess the company potential.

Companies that fail to pass due diligence will be removed from the selection process. The due diligence process will happen in parallel with the support programme.

It is expected that the companies will collaborate with EIT Health by providing relevant information and documentation that enables the due diligence process and the valuation analysis, as needed.

Documentation is expected to be in English (except for the registration certificate) and must include, among others:

- 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)

- Historic financial information
- Financial projections in Excel, with the financial summary using a specific template (to be provided)
- Cap table
- Legal Self-Assessment Certificate and documentation upon request

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 (see "Independent" paragraph below). It is expected that EIT Health and/or the independent third party supporting/performing the due diligence and valuation analysis, may communicate directly with the micro and small enterprises during this process to gain further clarity on the situation, to finalise the due diligence and/or valuation analysis.

Final selection

The final selection phase will be facilitated for all consortiums who submit complete full proposals and complete single stage proposals.

This phase will consist of an external evaluation and an Ethical, Legal and Social Issues (ELSI) review, as further outlined in this section.

External evaluation

The external evaluation will take the form of a remote review for all calls, except for Technology and Service Development activities, for which the external evaluation will involve Hearings.

Details on the organisation of the Hearings will be timely communicated to shortlisted applicants. 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 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

Defined idea of the potential business model identified; for non-EIT Health led and coordinated activities. The robustness of the financial projections and scalable business models will be assessed as a reference to the potential financial contribution for EIT Health future re-investment
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

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.

Contracting

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

Finalisation of the terms and conditions of such agreements will commence immediately after notification.

No activity funding will be released prior to execution of all agreements, but activities will be able to claim their costs retroactively from the notification date – the earliest Activity start date.

Sets of legal documents to be executed:

a) **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.
b) **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.
c) **Financial sustainability agreement** 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

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

To further support our applicants, our glossary provides brief definitions of the technical terms and key concepts used throughout the text.

Summary - Activities and Timeline

Table with activity maximum funding amount and duration:

Cut Off	Flagship	Type of activity	Duration of the activity	Max Grant (€)
Cut off 1	NMDH/DTH	Innovation Days (i-Days) - New cities	one event in 2024 and one event in 2025	20 K
Cut off 1	NMDH/DTH	Innovation Days (i-Days) – Recognition Scheme		Non applicable
Cut off 1	DTH	Master's Degree Programmes	4 years	See budget table in the specific conditions
Cut off 1	NMDH	Modules towards a labelled Fellowship Programme	9-12 months	200 K (for 30 ECTs equivalent)
Cut off 1	DTH	Modules towards a labelled Fellowship Programme	9-12 months	100 K (for 15 ECTs equivalent)
Cut off 1	DTH	Modules towards EIT labelled certification	12 months	50 K (per module)
Cut off 1	DTH	Technology development Projects	18 months	1 M
Cut off 1	NMDH	Service development Projects	18 months	1,15 M
Cut off 2	DTH	DiGinnovation programme	9 months	350 K

Type of activities	NMDH	DTH	Single/Short Proposal submission	Selection Process	Pre-selection	Pre-selection notification	Full Proposal submission	Final Selection	Final selection notification
Innovation Days (I-Days) new cities + recognition scheme	X	X	28 February 2024	Single proposal	Non applicable	Non applicable	Non applicable	Remote review	21 March 2024
Master's Degree Programmes		X	28 February 2024	Single proposal	Non applicable	Non applicable	Non applicable	Remote review	21 March 2024
Modules towards a labelled Fellowship Programme	X	X	28 February 2024	Short proposal + Full proposal	Pitching Days	22 April 2024	13 June 2024	Remote review	11 July 2024
Modules towards EIT labelled certification		X	28 February 2024	Short proposal + Full proposal	Pitching Days	22 April 2024	13 June 2024	Remote review	11 July 2024
Technology development Projects		X	28 February 2024	Short proposal + Full proposal	Pitching Days	22 April 2024	13 June 2024	Hearings	11 July 2024
Service development Projects	X		28 February 2024	Short proposal + Full proposal	Pitching Days	22 April 2024	13 June 2024	Hearings	11 July 2024
DiGinnovation programme		X	18 September 2024	Short proposal + Full proposal	Pitching Days	31 October 2024	12 December 2024	Remote review	23 January 2025

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