30 June 2022

EIT Health Flagships Call outline

EIT Health's outline for the call relating to the flagships is opening on **Thursday, 30 June 2022. It entails the main principles of the calls for activities regarding each flagship.**

The detailed call for flagships will be published on **Thursday, 15 September 2022**.

> **Please Note: Any content in this outline call is subject to change before the final call document is released on 15 September 2022.**

1. Overview

1.1. About EIT Health

Our network

EIT Health is a vibrant community of some of the world's leading healthcare innovators, supported by the European Institute of Innovation and Technology (EIT), an independent EU body strengthening Europe's ability to innovate. The EIT is an integral part of Horizon Europe, the EU's framework programme for research, and innovation.

Working across borders, EIT Health harnesses the brightest minds from business, research, education, and healthcare delivery to answer some of Europe's biggest health challenges.

EIT Health's world-leading consortium of approximately 150 best-in-class Partners was created with the understanding that bringing together such diverse perspectives and abilities can drive the kind of healthcare innovations that improve people's lives. It has now become Europe's largest innovation network, bringing together experts from across Europe to find solutions to the most pressing societal challenges.

EIT Health already represents a unique network of complementary Partners, who are proactively combining and applying their assets and strengths (along common interests) to generate truly innovative solutions addressing the challenges of healthy and active ageing.

Strengths and key assets are mapped for:

- Identifying and closing competence gaps
- Connecting with major innovation hubs, within and outside of the EU, to share best practises
- Scaling up proven concepts on a European level.

It is the main role of EIT Health's eight Regional Innovation Hubs (RIH) to engage and support Partners in the development of high-impact projects, and to develop their ecosystems, integrating Partners' assets across the Knowledge Innovation Community (KIC).

EIT Health is also eager to keep on welcoming new Partners who can help strengthen and extend our powerful network.

Our strategy

By 2030, EIT Health aims to be Europe's leading health innovation platform, facilitating longer, healthier lives and more sustainable healthcare systems.

A strategically built-up and well managed portfolio orients the different activities in innovation, business creation and education towards common targets. It does this while ensuring that the entire organisation "lives" its objectives by incorporating our strategy across our activities.

Underpinning this, are our three strategic objectives with the primary one being to directly improve the quality of life for 480 million Europeans. Please refer to our Strategic Agenda 2021-2027 for more information.

Our impact

EIT Health aims to support activities that will transform the way healthcare is delivered in Europe. We will do so by changing lives, and continually making new advancements in healthcare delivery, putting patients are at the front and centre of their care.

EIT Health defines societal impact as socio-economic impact along its three strategic objectives:

- Better health for all
- Competitive health economy
- Sustainable health systems.

Please refer to the Impact Section of our Strategic Agenda for more information.

1.2. Flagships Concept

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 has been born.

Our flagship concept will contribute to some of the top health priorities that have been identified at EU level. This at the highest level is about building a European Health Union, where countries work together to improve prevention, treatment, and outcomes for all citizens. EIT Health will leverage its extensive network of talent and expertise and address these through a series of bespoke programmes of activities and initiatives.

What is a flagship?

- A flagship will present a problem focused approach, much narrower than previous focused areas, and calls will be built around defined societal needs and clear business cases for Partners
- There will be clear alignment with EU policy priorities across the healthcare landscape
- EIT Health and its Partners will be working together on four clearly defined challenges to create a higher impact
- Through the process of an annual joint assessment, EIT Health will incorporate Partners feedback to ensure that the flagships topics are still relevant and that they remain patient centric and Partner-led in their design and delivery
- The introduction of a shared funding model between EIT Health, Partners and other public sources ensures that the model is built on an approach of sustainable value
- A revised and improved call process, where flagships follow a standardised process to ensure alignment across all the activities that EIT Health launches calls for
- Using a cross-pillar approach, Innovation, Education and Business Creation activities will be selected during the flagship calls and their respective deadlines, referred to as cut-offs.

Following engagement with our Partners, four areas of interest have been identified which will be our primary focus for 2023:

New models to deliver healthcare

As society continues to evolve, so do our healthcare systems. This flagship will look at how we might start to define new models to deliver healthcare and implement robust analysis of databases that are already in place. At the centre of this will be the concept of value-based healthcare, where success measures are based on patient outcomes and the shift from treatment to prevention.

Facilitating the uptake of Digital Medical Devices[1]

This flagship aims to support the digital health transformation in Europe and will focus on the development of, and access to, digital health medical devices. It will also explore how we transform, harmonise, and strengthen the use of Digital Medical Devices (DMD) around:

  (i)   The prescription and reimbursement in EU countries for already certified medical devices
  (ii) The harmonisation of clinical trial protocol design to ensure the replicability and consistency of medical outcomes between member states for faster reimbursement.

Harnessing the full potential of health data for Innovation

This flagship will support the implementation of the European Health Data Space. The flagship will enable us to unleash the full potential of health data for innovation by exploring the secondary use of data. And moreover, for the development of technologies or solutions that deliver outcomes that matter to patients. It will also look at how we train and develop patients, citizens, and healthcare professionals to understand the importance and relevance of data sharing in informing and improving the continuum of care pathways.

Supporting the deployment of Important Projects of Common European Interest in Health (IPCEI) to address market failures

16 countries have committed to enable the deployment of Important Projects of Common European Interest (IPCEI) to: address potential market failures impeding innovation, and improve the quality of, and access to, patient healthcare.

These will contribute to an EU-wide coordinated strategy through two waves of projects. The first wave will focus on the following areas:
- innovating and greening production technologies and processes for medicines and or drug

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[1] **Definition of Digital Medical Device:** *The European Commission's definition* of **digital health and care** *refers to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring, and management of health-related issues, and to monitor and manage lifestyle-habits that impact health. Digital health and care are innovative and can improve access to care and the quality of that care, as well as to increase the overall efficiency of the health sector.*

*EIT Health decided to use the denomination of **Digital Medical Devices (DMD)** for its flagship as this terminology is broad in its scope. We suggest narrowing down the definition by identifying four distinct categories: Digital Diagnostics, Digital Therapeutics, Digital Management in Healthcare and Digital Analytics in Healthcare. Differentiating DMDs into these four categories allows for better specifications of rules and regulations applicable to each category, which in turn, permits to better structure evidence requirements and the health data legal landscape as well as analysis of the socio-economic and business environment.*

In Innovation projects, the focus will be primarily put on patient centred DMDs (that fall under the reimbursement requirements).

products
- innovation in antimicrobial resistance and rare diseases
- emerging health threats where complementary to HERA
- developing cell and gene therapies, including production processes and technologies.

The second wave will address market failures in digital health, MedTech, and medical devices.

This flagship will focus on three key areas:

(i)   Equipping Europe with a strong, innovative, and export-friendly healthcare industry that can meet the challenges of delivering healthcare in the future

(ii)   Creating a single vision for developing lasting and innovative European manufacturing capabilities regarding critical products, most notably, pharmaceuticals

(iii)   Fostering a state-of-the-art quality and accessible healthcare through the development of new products and services with a high research and innovation content.

As the IPCEI in health is an independent programme, the flagship will support activities at a different time within the year.

A dedicated call for activities will be launched once the agreement between EIT Health and the coordinator of the programme is fully set-up.

2. Flagships Call for cross-pillar activities

2.1. Main principles

EIT Health is launching a call for cross-pillar activities for each of the flagships described above, except "Support to IPCEI" which will have its own specific call and timeline.

We are mainly calling for Education and Innovation activities (see below). The table below provides an overview of the activities that will be called for, for each flagship:

New models to deliver healthcare	Facilitating the uptake of Digital Medical Devices	Harnessing the full potential of health data for innovation
Winter / Summer School	Winter / Summer School	Winter / Summer School
Modules towards a labelled Fellowship programme	Modules towards a labelled Fellowship Programme	Modules towards a labelled Fellowship Programme
Modules on advanced high value care principles	Start-up and Partner driven projects	EIT labelled certification for non-degree education: Training module for professionals
Service Quality Assessment Call for projects	DiGinnovation – Fast Track Start-up driven projects	EIT labelled certification for non-degree education: Training module for patients and citizens
Bootcamp in Value-based healthcare for mature start-ups		Start-up and Partner-driven projects (registry based)

Activities highlighted in **green** fall under **Education** pillar.

Activities highlighted in **pink** fall under **Innovation** pillar.

Activities highlighted in **blue** fall under **Business Creation** pillar.

Most activities selected in the call framework will also benefit from services provided by the EIT Health Business Creation pillar, such as:

- Mentoring and Coaching Network support (MCN)
- Ulabs support (Ulabs)

- Bridgehead programme
- Finance Booster programme

For both, Bridgehead, MCN, and Ulabs, EIT Health will integrate a section in the final flagship call document that will specifically ask Partners to apply as:

- Catalysers with a thematic focus of the flagship
- Experts/mentors/coaches/evaluators with a thematic focus of the flagship
- ULabs/LLs[2]/TB[3]s with a thematic focus of the flagship.

More detail on this call for interest will be fully included in the final version of the call document which will be issued on 15 September 2022.

NB: all grant amounts described in the following parts of this document are indicative and subject to our Supervisory Board, Partner Assembly, and EIT's validation.

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[2] Living Labs
[3] Test beds

2.2. Call for activities within the flagship "New models to deliver healthcare"

Europe's healthcare systems are unsustainable[4]. The cost of delivering care keeps rising faster than gross domestic product (GDP), while at the same time evidence shows that not all healthcare spending coincides with improved outcomes for patients. This is not likely to improve as we have an ageing population, an increasing prevalence of chronic diseases,[5] and new pandemic health threats.

The situation must change. We must define and measure the outcomes that truly matter to patients and align this with the incentives for payors to finance based on those outcomes, and for providers and innovators to deliver those outcomes.

At EIT Health, we are determined to support the transformation of healthcare systems in Europe through the "New models to deliver healthcare" flagship. EIT Health, together with its Partners, aims to foster healthcare system transformation to overcome not only contractual but also cultural, social and mindset barriers. To address this unavoidable need for change, new models with enough transition time and sufficient understanding and involvement from all parties to turn it in the right direction, will be built.

The models should rely on the seamless integration of EIT Health's offer. They will consist of educational programmes, business model iteration services and support programmes, and innovation projects that fit into a comprehensive innovator's journey. This will start from increasing awareness of learners about value-based healthcare concepts, as well as citizens and patient engagement, and then will identify healthcare inequities and efficiency disparities which will be solved through innovative approaches that maximise the value brought for the patient, while considering healthcare systems sustainability. They will then validate those and pilot and scale the new models on their way to receiving reimbursement. In parallel, high-level public affairs activities will be implemented to foster alignment of regional or national and EU landscapes towards the creation of an environment that is amenable to value-based healthcare.

To increase awareness about the flagship, students will learn about value-based concepts via the **Winter and Summer Schools,** and graduates and professionals will be able to upskill through the dedicated **EIT Labelled fellowship.** Some of the learners and fellows could also create or join teams to solve the pressing needs identified, and when already incorporated and mature, their start-ups (with a CE marked product) will be able to join other commercialising entities from selected innovation projects to get support and guidance in value-based business model creation through a **Value-based healthcare Bootcamp**. This will prepare them for the next steps in the innovation journey, supporting them to develop robust business models capable of convincing payors of the needed transformation, while making healthcare systems stronger and more resilient.

Consortia including healthcare service providers and their corresponding payors, steered by industry providers, that have reached commercialisation stage will be welcomed to apply to

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[4] https://www.europarl.europa.eu/cmsdata/150781/Full%20version%20all%20presentations.pdf

[5] https://apps.who.int/iris/bitstream/handle/10665/329382/Policy-brief-1997-8073-2019-3-eng.pdf

Service Quality Assessment Innovation projects. These projects will aim to generate the needed evidence to convince the payors that the value brought to the patient is worth changing the reimbursement model. To prepare those consortia in advance of the project's implementation stage, a **Value-based healthcare support programme** will be offered, aimed at learning from both the successes and failures of other members of the EIT Health network on their journey towards achieving high value care.

Several transversal activities will support innovators along their entire innovation journey: the online **EIT Health Academy** platform and more specifically, the High Value Care track available through the platform, will provide ongoing support and learning modules. This will be complemented with a **living repositorium of mature and early-stage cases** aimed at achieving the desired transformation from all over Europe and offering the opportunity to connect with those pioneers. Additionally, the consortia will benefit from individualised support from the **Mentoring and Coaching Network** that links the teams to a network of experts, who will be particularly addressing the value-based healthcare contracting hurdles; **U-Labs and Test Beds** that connects teams with user validation labs and can work with them to organise and execute a validation study of their solution; and other training and mentoring opportunities linked to the topic, such as the **Citizen and Patient Bootcamp.**

EIT Health aims to act as neutral platform to favour the discussions at regional, national and EU level that will support this change. For instance, the EIT Health Think Tank might further build on the publication "Implementing Value Based Health Care in Europe: Handbook for Pioneers" to foster dialogue and gain new insights as relevant.

In the sections below, a more detailed explanation of the activities and services within the "New models to deliver healthcare flagship" offer is provided.

Call for Winter / Summer School

Need: To train talented individuals on value-based healthcare concepts under Innovation and Entrepreneurship education approaches during their graduate studies.

Short programme description: The programmes is designed with the ambition of creating a reference programme for short courses in Innovation and Entrepreneurship education – carving a path towards start-up creation for aspiring entrepreneurs. I & E (Innovation and Entrepreneurship) elements are central and are delivered with a hands-on approach. It covers a min of five European Credit Transfer and Accumulation System (ECTS) points.

Target audience: Graduates (Bachelor, Master, PhD level)

Timeline: two to three weeks Winter / Summer School format, to be delivered once each year, funded for three years before the programme becomes self-sustainable.

EIT Grant per activity: Max 160K€ for year 1, 115K€ for year 2 and 70K€ for year 3 (please see the 3.3 for explanation on the co-funding principles). EIT Health assumes costs for marketing and prizes on Mentoring & Coaching Network access for winning teams.

Specific characteristics:

- The Winter / Summer School exposes learners to innovation and entrepreneurship in a dynamic and hands-on short course, preparing them to continue on a path toward further I & E pursuits
- The delivery of a Winter / Summer School aims at covering 5 ECTS
- Minimum 2 HEI – one of them leading the consortium and/or one from RIS region. At least one non-academic Partner.
- A Winter / Summer School includes:
  1. Development of the Winter / Summer School track, including: • arranging consortium meetings; • developing education content (including developing challenges, which shall be based on UN SDG3 related targets 3.1. to 3.9); • sourcing coaches, mentors and speakers; • arranging hosting logistics (agenda, venues, supporting technology, etc.).
  2. Delivery of a two-to-three-week Winter / Summer School track for a minimum of 70 students, including: • Online, pre-learning, levelling course: Delivery of an online, pre-learning course is encouraged to facilitate Winter / Summer School participants starting off at the same level, allowing them to make the most of the learning experience. • Support for the ideation and development of group projects. • Real-life health challenges. • Presentations and meetings with relevant stakeholders, experts and role models. • Organisation and implementation of learning sessions, case studies. • Final pitch and winner selection, delivered in collaboration within the KIC.
- A dedicated Education Lead will collaborate closely with the Winter / Summer School Tracks Activity Leads to support the coordination of the Winter / Summer School Series. The Education Lead will focus their support on areas such as: marketing, registration, recruitment, learner monitoring, monitoring of implementation, a final closing event and facilitating synergies between tracks.

Mandatory KPIs:

- EITHE08.1: Participants in (non-degree) education and training (minimum 70 /year).
- EITHE08.2EITRIS: Number of EIT RIS Participants with (non-degree) education and training (minimum 12).
- KIC09: Programme Attractiveness and Demand (minimum of three applicants per available spot).

Tag: value-based healthcare, high value care

Call for modules towards a labelled fellowship programme

Need: To enable personalised learning pathways aimed at skilling, upskilling and reskilling Master and PhD-level students and graduates, healthcare and medical professionals in the field of value-based healthcare transformation.

Short programme description: Modules toward EIT Labelled Fellowship Programme

Target audience: Master students, PhD students, healthcare professionals

Timeline: Up to 12 months (TBC)

EIT Grant per activity: Max 300K€ (please see the §3.3 for explanation on the co-funding principles).

Specific characteristics:

- Call to contributing institutions for existing courses addressing the specific need and target audience
- To be noted, per EIT Label Framework, the EIT Labelled Fellowships programme must be administered and managed by EIT KICs. Hence, EIT Health calls for modules that will feed into the EIT Labelled Fellowship journey.

Mandatory KPIs:

- Labelled Fellows (new KPI)

Tag: value-based healthcare, high value care

Call for modules on advanced high value care principles

Need: To dive deeper on value-based healthcare concepts towards high value care implementation aimed at skilling, upskilling and reskilling Master and PhD-level students and graduates, healthcare and medical professionals in the field of value-based healthcare transformation

Short programme description: Modules on advanced high value care principles

Target audience: Individuals and professionals working in healthcare

Timeline: Max. 8 weeks programme.

EIT Grant per activity: Max 50K€ (please see the §3.3 for explanation on the co-funding principles)

Specific characteristics:

- Topics to be covered:
    - Outcomes
    - IT Platform – integration
    - Establishment and nurturing of learning communities
    - Rewards - incentives
    - Value-based healthcare contracts
    - Citizen and patient involvement and engagement
    - Ethical, Legal, Social, Implications (ELSI) importance
    - Holistic perspective – patient journey and added value
- The applicants can suggest additional content based on the HVC expertise. Such topics could be for instance:
    - the use of patient registries or real-world data
    - federated networks approach for benchmarking
    - health technology assessment
    - Digital Medical Devices fast-track reimbursement based on value

Mandatory KPIs:

- EITHE08.1: Participants in (non-degree) education and training

Tag: Value-Based healthcare, high value care

Call for Service Quality Assessment Innovation projects

Need: Contribute to restructuring the healthcare delivery towards measurable outcomes that have high impact and matter most to patients by setting standards for measuring the right outcomes and incentivising the health care industry to pay for outcomes rather than services.

Short programme description: Collaborative projects that aim to assess the quality of the healthcare service improvement, brought by innovative technologies, services or models, to generate sufficient evidence to convince payors to reimburse based on value. The value is understood as a compound of clinical, process and patient perceived value (improving health outcomes that matter most to patients).

Target audience:

- Healthcare service delivery institutions willing to embark in the value-based healthcare journey together with their payors.
- Technology providers (mature start-ups (CE marked) or industrial players) that want to generate convincing data to back their products or services aiming at value-based business models.

Timeline: Up to 30 months (EIT Health grant support), end date no later than December 2025.

EIT grant per activity: Max 2M€ (please see the §3.3 for explanation on the co-funding principles)

Specific characteristics:

- Collaborative project with the involvement of healthcare provider, payer, industry from a minimum of two countries from two different Regional Innovation Hubs.
- At the <u>final proposal stage</u>, the consortia must have at least:
    - ο Two healthcare providers and two payors from the same country as the healthcare provider: one should provide the healthcare services that the other will purchase
    - ο a Partner taking care of the IT platform integration
    - ο a commercialising entity taking care of the replicability of the approach in third countries and beyond
    - ο a Partner with health economics expertise capable to support the development of the required evidence.
- A dossier for the relevant ethics committee approvals to facilitate assessment study submitted and approval foreseen before project start (for multicentric studies, ethics committee approval in place for at least one centre before project start).

- No technology development. The technology to be used should be readily available, in the market, if needed with CE mark granted. Only platform integration developments to capture/incorporate/analyse patient outcomes into the IT systems are envisioned.
- Encouraged (but not mandatory) use of existing patient's registries to potentially speed up patient recruitment, baseline measures or control groups.
- Only in the case that marketed innovations are expected, they should be considered no later than one year following completion of project.

Mandatory KPIs:

- EITHE01.1: Designed/Tested Innovation (within framework of project)
- Health Outcomes KPIs:
    o One Patient Reported Outcome Measure (PROM)
    o One Clinical Outcome
    o One Process Outcome [6]
- KPI13: Number of citizens/patients that benefitted from solutions developed or implemented in EIT Health activity or number of patients touched by the product/service launched on the market
- **Tags:** Biotech diagnostics, MedTech, digital health, digital medical devices, Value-Based healthcare, high value care.

Call for Value-based Healthcare Bootcamp

Need: Support companies in the iterative process of pivoting their innovation solution into the clinical workflow. While doing so, a value-based approach towards the evaluation and assessment of the innovation being adopted (including integration and implementation), scalability and replicability, business model and reimbursement, should all be considered. This is in addition to gathering all stakeholders' perspectives via quantitative and qualitative data, that is fed into the health economic evaluation of the innovation solution provided (product or a service).

Short programme description: Value-based healthcare Bootcamp Goals:

- A description of the clinical workflows and innovation journeys
- Stakeholders mapping and value definition
- Indication of the way of measuring the value (cost and benefit) for each stakeholder.
- Use of validated methodology to gather stakeholders' perspectives.
- Dimensions and indicators to be used (KPI's)
- Identification of the economic model to be used.
- Business model description

Target audience: Innovation provided by companies or start-ups with:

- Product/service CE marked to ensure the safety, health and environmental protection, except for those product/services that the EU has not specifications.

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[6] https://www.ahrq.gov/talkingquality/measures/types.html

- Demonstrated high level of analytical and/or clinical performance.
- Demonstrated clinical evidence (outputs and outcomes)
- Demonstrated direct impact in patients' outcomes

Timeline: The Bootcamp programme should ensure a minimum of 2-months (8-10 weeks) engagement of participants with proposed curriculum and faculty. To be delivered once each year, funded for 2 years.

EIT grant per activity: Max. 120K€ for year 1 and 70K€ for year 2 (please see the §3.3 for explanation on the co-funding principles)

Specific characteristics

Minimum number of countries involved: 2

KPIs Mandatory KPIs

EITHE03.1: Supported Start-ups/Scale-ups

EITHE03.2: EITRIS EIT RIS Start-ups/scale-ups Supported

Tags: Value-Based healthcare, high value care

2.3. Call for activities within the flagship "Facilitating the uptake of Digital Medical Devices"

With the raise of digital health, Europe is still behind[7] in terms of ease of evaluation, reimbursement, and adoption of Digital Medical Devices (DMD).

Through this flagship, EIT Health aims to transform, harmonise and strengthen the use of Digital Medical Devices (DMD) through (i) prescription and fast track reimbursement in EU countries for already certified medical devices and (ii) the harmonisation of clinical criteria and methodologies for evaluating DMD to ensure the transposability of medical outcomes between member states for faster reimbursement.

This will be achieved through the seamless integration of EIT Health's offer consisting of educational programmes, business focused services and programmes, and innovation projects, into a comprehensive innovator's journey: starting from increasing learners' awareness of DMD concepts and identifying healthcare needs that can be solved through digital technology to developing innovative solution, validating them, launching new DMD products on the market and receiving reimbursement. In parallel, public affairs activities will be devised as relevant to encourage the digital health transformation in Europe.

To increase awareness about the flagship, learners will learn about digital health and DMD concepts via **Winter / Summer School**. Master and PhD level learners and healthcare and medical professionals will be able to upskill in digital health topics through the **Labelled fellowship programme.**

Consortia driven by start-ups or medium- large-size industry players that reached Proof of Value stage will be welcomed to apply with **Start-up driven and Partner driven Innovation projects**. These projects will aim to validate and receive regulatory approvals for patient centered DMD solutions. Additionally, institutions engaged in collaborative projects will be able to provide challenges to Winter / Summer School students, as well as join as mentors, speakers or judges. As the last step in the innovator's journey, start-ups and scale-ups with CE-marked patient-centered DMDs can apply to **DiGinnovation Programme**, aimed at supporting consortia on their pathway to reimbursement. EIT Health's **Bridgehead programme** will additionally link DiGinnovation companies to local expertise through EIT Health network, catalysing the market access efforts.

Along the whole innovation journey, several transversal activities will support innovators at various stages. The **Mentoring and Coaching network** will connect entrepreneurs, industry players and/or Winter / Summer School students to the wide network of experts; **U-Labs and Test Beds** will help start-ups with user validation labs to organise and execute a validation study of their patient-centered DMD; and **Finance Booster** offers healthcare start-ups support in financial literacy and prepares them for the next funding rounds. EIT Health network events and media resources will provide opportunities for the dissemination of project outcomes, as relevant.

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

In the sections below, a more detailed explanation of the activities and services within the DMD flagship offer is provided.

Call for Winter / Summer School

Need: To train talents on digital medical devices development concepts under Innovation and Entrepreneurship education approaches during their graduate studies.

Short programme description: It is designed with the ambition of creating a reference programme for short courses in Innovation and Entrepreneurship education – carving a path toward start-up creation for aspiring entrepreneurs. I & E (Innovation and Entrepreneurship) elements are central and are delivered with a hands-on approach. It covers min. 5 ECTs.

Target audience: Graduates (Bachelor, Master, PhD level)

Timeline: 2-3 weeks Winter / Summer School format, to be delivered once each year, funded for 3 years before the programme becomes self-sustainable.

EIT Grant per activity: Max 160K€ for year 1, 115K€ for year 2 and 70K€ for year 3 (please see the 3.3 for explanation on the co-funding principles). EIT Health assumes costs for marketing and prizes on Mentoring & Coaching Network (for the winning teams).

Specific characteristics:

- The Winter / Summer School exposes learners to innovation and entrepreneurship in a dynamic and hands-on short course, preparing them to continue on a path toward further I & E pursuits.
- The delivery of a Winter / Summer School aims at covering 5 ECTS.
- Minimum 2 HEI –one of them leading the consortium and/or one from RIS region. At least one non-academic Partner.
- A Winter / Summer School includes:
  3. Development of the Winter / Summer School Track, including: • arranging consortium meetings; • developing education content (including developing challenges, which shall be based on UN SDG3 related targets 3.1. to 3.9); • sourcing coaches, mentors and speakers; • arranging hosting logistics (agenda, venues, supporting technology, etc.).
  4. Delivery of a two-to-three-week Winter / Summer School Track for a minimum of 70 students, including: • Online, pre-learning, levelling course: Delivery of an online, pre-learning course is encouraged to facilitate Winter / Summer School participants starting off at the same level, allowing them to make the most of the learning experience. • Support for the ideation and development of group projects. • Real-life health challenges. • Presentations and meetings with relevant stakeholders, experts and role models. • Organisation and implementation of learning sessions, case studies. • Final pitch and winner selection, delivered in collaboration within the KIC.
- A dedicated Education Lead will collaborate closely with the Winter / Summer School Tracks Activity Leads to support the coordination of the Winter / Summer School Series. The Education Lead will focus their support on areas such as: marketing, registration, recruitment, learner monitoring, monitoring of implementation, a final closing event and facilitating synergies between tracks.

Mandatory KPIs:

- EITHE08.1: Participants in (non-degree) education and training (minimum 70 /year).
- EITHE08.2EITRIS: Number of EIT RIS Participants with (non-degree) education and training (minimum 12).
- KIC09: Programme Attractiveness and Demand (minimum of three applicants per available spot).

Tag: digital medical devices, patient centred DMD

Call for modules toward a labelled fellowship programme

Need: To enable personalised learning pathways aimed at skilling, upskilling and reskilling Master and PhD-level students and graduates, healthcare and medical professionals in the field of Value-based healthcare transformation.

Short programme description: Modules toward EIT Labelled Fellowship Programme

Target audience: Master students, PhD students, healthcare professionals

Timeline: Up to 12 months (TBC)

EIT Grant per activity: Max 300K€ (please see the §3.3 for explanation on the co-funding principles).

Specific characteristics:

- Call to contributing institutions for existing courses addressing the specific need and target audience
- To be noted, per EIT Label Framework, the EIT Labelled Fellowships programme must be administered and managed by EIT KICs. Hence, EIT Health calls for modules that will feed into the EIT Labelled Fellowship journey.

Mandatory KPIs:

- Labelled Fellows (new KPI)

Tags: digital medical devices, patient centred DMD

Call for start-up-driven and Partner-driven Innovation project

Need: To accelerate development, evaluation and validation, certification, and market access of patient centred DMD in Europe for faster market entry and wider adoption.

Short programme description: Collaborative start-up or industry-driven project Consortia that focus on validating, certification, and market access of patient-centred DMD solutions.

Target audience: Industry, healthcare providers, academic Partners, start-ups

Timeline: 24-month collaborative project; end date no later than 31 December 2025

EIT Grant per activity: Max 1.5M€ (please see the §3.3 for explanation on the co-funding principles)

Specific characteristics:

- Collaborative project with the involvement of industry, healthcare provider and/or start-up stakeholders from a minimum of 2 countries from two different Regional Innovation Hubs.
- Specific clinical condition at core of project already defined and corresponding technology or solution ready to enter clinical validation stage.
- Solution or technology maturity level between IML5 (Proof of Value), and IML6 (Initial Clinical Trials) at proposal submission, to advance through IML7 (Validation of Solution) and IML8 (Approval & Launch) within project timeframe.
- A dossier for the relevant ethics committee approvals to facilitate clinical study submitted and approval foreseen before project start (for multicentric studies, ethics committee approval in place for at least one centre before project start).
- For Start-up Driven Innovation project, the start-up is at the core of the project – without the start-up, there is no Innovation project.
- Additional start-up requirements for a start-up at the core of a Start-up Driven innovation project:
  - Start-up is a for-profit SME according to the EU definition – an enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro.
  - Be legally incorporated and established in one of the EU Member States or Horizon Europe associated countries. Be incorporated on/after 1st January 2013 and before the submission deadline.
  - Have at least 2 paid FTEs working in the start-up at the time of submission.
  - Have a CEO working full-time in a company at the time of submission.
  - Start-up applying for at least 300k€ EIT Health grant.

Mandatory KPIs:

- EITHE01.1: Designed/Tested Innovation (within framework of project)
- EITHE01.2: Marketed Innovations (no later than 1 year following completion of project)
- KPI13: Number of citizens/patients that benefitted from solutions developed or implemented in EIT Health activity
- At least one customised KPI linked to Patient Reported Outcome Measure (PROM)

Tags: Digital Health, patient centred DMD

DiGinnovation – Call for Fast Track Start-up Driven Innovation project

Need: To accelerate reimbursement, market access, and wider adoption of DMDs in Europe.

Short programme description: DiGinnovation selects top digital health start-ups/scale-ups[8] 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 while ease the reimbursement process.

Target audience: start-ups/scale-ups, industry, healthcare providers, payors, academic Partners.

Timeline: 9-month collaborative project.

EIT Grant per activity: Max 350K€ (please see the §3.3 for explanation on the co-funding principles)

Specific characteristics:

- Collaborative project with the involvement of industry, healthcare provider and/or start-up stakeholders from a minimum of two countries from two different Regional Innovation Hubs
- Specific clinical condition at core of project already defined and corresponding technology or solution ready to enter clinical validation stage
- Solution or technology maturity level IML7 (Validation of Solution) and IML8 (Approval & Launch) with the aim to move to reimbursement and IML9 (Clinical Use) by maximum 1 year following the end of the project
- A dossier for the relevant ethics committee approvals to facilitate clinical study submitted and approval foreseen before project start (for multicentric studies, ethics committee approval in place for at least one centre before project start)
- Start-up is a at the core of the project – without the start-up, there is no Innovation project.
- Additional start-up/scale-up requirements for Start-up Driven innovation project:
  - Start-up/scale-up is a for-profit SME – an enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro
  - Be legally incorporated and established in one of the EU Member States or Horizon Europe associated countries. Be incorporated on/after 1st January 2013 and before the submission deadline
  - Have at least two paid FTEs working in the start-up at the time of submission
  - Have a CEO working full-time in a company at the time of submission
  - Start-up applying for at least EUR 150 000 EIT Health grant
  - The start-up's DMD solution must be already CE-marked and classified as I-IIa or IIb in case of France as targeted market (more details to come and be aligned with French DiHA) medical-grade solution under Medical Device Regulation (MDR) 2017/745.
  - The start-up's DMD solution must meet the requirements for reimbursable applications in the targeted country.

Mandatory KPIs:

- EITHE01.1: Designed/Tested Innovation (within framework of project)
- EITHE01.2: Marketed Innovations (no later than 1 year following completion of project)

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[8] In this case, a start-up is defined as a for-profit SME in search for a repeatable and scalable business model, and a scale-up is defined as a for-profit SME that experiences exponential growth and market development through entry into the new Partners and strategic Partnerships.

- KPI13: Number of citizens/patients that benefitted from solutions developed or implemented in EIT Health activity
- At least one customised KPI linked to Patient Reported Outcome Measure (PROM)

Tags: Digital Health, patient centred DMD, reimbursement, DiGA, DiHA, mHealth Belgium

2.4. Calls for activities within the flagship "Harnessing the full potential of health data for Innovation"

Innovators in the EU have so far met a fragmented framework for the sharing, processing and re-use of health data both within and across member state borders.[9] Yet the continued transition to digitalised approaches to healthcare delivery leads to the emergence of vast sets of health data, collected at levels of individual citizens, healthcare providers, industrial stakeholders and policy bodies. The volume and diversity of datasets now gathered unlocks unique opportunities to test and validate healthcare solutions, while contributing to the building of resilient health systems and enabling individuals to make decisions on the management of their personal health data. New proposals for a European Health Data Space (EHDS), as set forward by the European Commission, aim to put in place a legislative framework to address challenges in health data access and sharing.[10]

Through the "Harnessing the full potential of health data for innovation" flagship, EIT Health embraces the power of data to innovate by bolstering the secondary use of data for innovation, treatment, development, and public health.

The **Winter / Summer School** will build students' knowledge and understanding of data-focused approaches to healthcare, catering for their entrepreneurial spirit and helping to navigate today's data-driven health ecosystem. Healthcare and medical professionals undertaking or having undertaken formal education will be able to access a palette of learning opportunities linked to the EHDS from within the EIT Health ecosystem under **Fellowship** programmes, raising the aptitude of the healthcare workforce in working with health data. **Non-degree education** modules will be set-up and delivered through the **EIT Health Academy** platform to train healthcare professionals in technical competencies needed in a digitally-transformed health system, including the exploitation of datasets and health registries for innovation, while supporting citizens and patients to take control of their health data and understand the relevance of data sharing in informing and improving the continuum of their care pathway. This will thereby raise digital health literacy and enable co-creation and co-delivery within healthcare. Industrial collaborators, healthcare providers and small-and medium-sized businesses will be invited to apply for funding in a **consortium to undertake clinical validation of their solution through tapping into existing health registries or biobanks**, thereby supporting EHDS ambitions for the re-use of health data in innovation and regulatory activities within 'FAIR' principles for the '*Findability*, *Accessibility*, *Interoperability*, and *Reuse'* of data assets.

Collaborators participating in EIT Health activities will benefit from the reach of the EIT Health network to explore the full potential of their innovation across data enabled markets. Innovators will be able to connect with prominent experts and players in the health data space through the EIT Health **Mentoring and Coaching Network**, or to validate their solution concept via **User Validation Labs and Test Beds** enroute to analysis across larger datasets. EIT Health network events and media resources will provide opportunities for the dissemination of project outcomes, as relevant. A cross-EIT KIC **Artificial Intelligence Community** (AIC) helps to foster collaboration in, educate and increase the uptake of AI in support of the EHDS.

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[9] https://eithealth.eu/wp-content/uploads/2021/11/EHDS_report.pdf

[10] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

Call for non-degree education module for healthcare professionals

Need: To raise awareness, knowledge and technical skills in digital health for successful deployment of innovation

Short programme description: Call for the design, creation, and delivery of innovative, impactful, and high-quality non-degree education programme (training module) to educate and equip healthcare professionals with the skills needed to successfully deploy innovation and digital transformation in healthcare delivery, including through the re-use of health data.

Target audience: Healthcare professionals

Timeline: 4 weeks training module

EIT Grant per activity: Max 50K€ (please see the §3.3 for explanation on the co-funding principles). EIT Health

Specific characteristics:

- Call to contributing institutions for new innovative education programme addressing the specific need and target audience
- Proposals to commit to multi-annual delivery of the implemented training programme for up to 3 years
- Training module to be hosted and delivered on the EIT Health Academy Platform
- Future participants to receive European certification from EIT Health via EIT Label system
- Training module to follow quality criteria of UEMS EACCME for CPD accreditation[11]

Mandatory KPIs:

- KIC04.1: Healthcare professionals trained by EIT Health (non-degree) education programmes
- EITHE08.1: Participants in (non-degree) education and training (including EIT RIS)

Tag: Digital Health, innovation, health registry, biobank

Call for non-degree education module for patients and citizens

Need: To improve digital health literacy to enable citizens and patients to take control of their health data to help drive co-creation and co-delivery within the healthcare system.

Short programme description: Call for the design, creation, and delivery of innovative, impactful, and high-quality non-degree education programme (training module) to raise awareness among citizens and patients on concepts linked to health data and health data sharing**.**

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[11] UEMS EACCME – Union Européenne des Médecins Spécialistes – European Accreditation Council for Continuing Medical Education – uems.net
CDP: Continuing Professional Development

Target audience: Citizens, patients

Timeline: 4 weeks training module across 3 years

EIT Grant per activity: Max 50K€ (please see the §3.3 for explanation on the co-funding principles)

Specific characteristics:

- Call to contributing institutions for new innovative education programme addressing the specific need and target audience
- Proposals to commit to multi-annual delivery of the implemented training programme for up to 3 years
- Training module to be hosted and delivered on the EIT Health Academy Platform
- Future participants to receive European certification from EIT Health via EIT Label system

Mandatory KPIs:

- EITHE08.1: Participants in (non-degree) education and training (including EIT RIS)

Tag: Digital Health, innovation, health registry, biobank

Call for Winter / Summer School

Need: To train talents on data-driven solutions and concepts under Innovation and Entrepreneurship education approaches, when they are recent graduates.

Short programme description: It is designed with the ambition of creating a reference programme for short courses in Innovation and Entrepreneurship education – carving a path toward start-up creation for aspiring entrepreneurs. I & E (Innovation and Entrepreneurship) elements are central and are delivered with a hands-on approach. It covers min. 5 ECTs.

Target audience: Graduates (Bachelor, Master, PhD level)

Timeline: 2-3 weeks Winter / Summer School format, to be delivered once each year, funded for 3 years before the programme becomes self-sustainable.

EIT Grant per activity: Max 160K€ for year 1, 115K€ for year 2 and 70K€ for year 3 (please see the 3.3 for explanation on the co-funding principles). EIT Health assumes costs for marketing and prizes on Mentoring & Coaching Network (for the winning teams).

Specific characteristics:

- The Winter / Summer School exposes learners to innovation and entrepreneurship in a dynamic and hands-on short course, preparing them to continue on a path toward further I & E pursuits.
- The delivery of a Winter / Summer School aims at covering 5 ECTS.
- Minimum 2 HEI –one of them leading the consortium and/or one from RIS region. At least one non-academic Partner.
- A Winter / Summer School includes:

5. Development of the Winter / Summer School Track, including: • arranging consortium meetings; • developing education content (including developing challenges, which shall be based on UN SDG3 related targets 3.1. to 3.9); • sourcing coaches, mentors and speakers; • arranging hosting logistics (agenda, venues, supporting technology, etc.).
6. Delivery of a two-to-three-week Winter / Summer School Track for a minimum of 70 students, including: • Online, pre-learning, levelling course: Delivery of an online, pre-learning course is encouraged to facilitate Winter / Summer School participants starting off at the same level, allowing them to make the most of the learning experience. • Support for the ideation and development of group projects. • Real-life health challenges. • Presentations and meetings with relevant stakeholders, experts and role models. • Organisation and implementation of learning sessions, case studies. • Final pitch and winner selection, delivered in collaboration within the KIC.

- A dedicated Education Lead will collaborate closely with the Winter / Summer School Tracks Activity Leads to support the coordination of the Winter / Summer School Series. The Education Lead will focus their support on areas such as: marketing, registration, recruitment, learner monitoring, monitoring of implementation, a final closing event and facilitating synergies between tracks.

Mandatory KPIs:

- EITHE08.1: Participants in (non-degree) education and training (minimum 70 /year).
- EITHE08.2EITRIS: Number of EIT RIS Participants with (non-degree) education and training (minimum 12).
- KIC09: Programme Attractiveness and Demand (minimum of three applicants per available spot).

Tag: data-driven entrepreneurship and innovation

Call for modules toward a labelled fellowship programme

Need: To enable personalised learning pathways aimed at skilling, upskilling and reskilling Master and PhD-level students and graduates, healthcare and medical professionals in the field of value-based healthcare transformation

Short programme description: Modules toward EIT Labelled Fellowship Programme

Target audience: Master students, PhD students, healthcare professionals

Timeline: Up to 12 months (TBC)

EIT Grant per activity: Max 300K€ (please see the §3.3 for explanation on the co-funding principles).

Specific characteristics:

- Call to contributing institutions for existing courses addressing the specific need and target audience

- To be noted, per EIT Label Framework, the EIT Labelled Fellowships programme must be administered and managed by EIT KICs. Hence, EIT Health calls for modules that will feed into the EIT Labelled Fellowship journey.

Mandatory KPIs:

- Labelled Fellows (new KPI)

Tag: Digital Health, innovation, health registry, biobank

Call for start-up-driven and Partner-driven Innovation projects

Need: To support the exploitation of existing health data for secondary use (clinical studies).

Short programme description: Collaborative industry, start-up, academic institution or healthcare provider-led project consortia that focus on validating technologies and building sustainable business models through exploiting existing health registries and biobanks, speeding up clinical trial development and bringing solutions to market faster.

Target audience: Industry, healthcare providers, academia, start-ups

Timeline: Up to 24-month collaborative project; end date no later than 31 December 2025

EIT Grant per activity: Max 1.5M€ (please see the §3.3 for explanation on the co-funding principles)

Specific characteristics:

- Collaborative project with the involvement of industry, academia, provider or start-up stakeholders from a minimum of two countries from two different Regional Innovation Hubs
- Specific clinical condition at core of project already defined and corresponding technology or solution ready to enter clinical validation stage
- Solution or technology maturity level between IML5 (Proof of Value), and IML6 (Initial Clinical Trials) at proposal submission, to advance through IML7 (Validation of Solution) and IML8 (Approval & Launch) within project timeframe.
- Project will focus on the i) accelerated delivery of clinical study through use of health registry or biobank data, ii) analysis of results and iii) subsequent deployment of technology or solution on the market
- Relevant privileges to access health registry or biobank in place before project start.
- Dossier for the relevant ethics committee approvals to facilitate health registry- or biobank-based clinical study submitted and approval foreseen before project start (for multicentric studies, ethics committee approval in place for at least one centre before project start).
- For Start-up Driven Innovation project, start-up is a at the core of the project – without the start-up, there is no Innovation project
- Additional start-up requirements for a start-up at the core of a Start-up Driven innovation project:
  o Start-up is a for-profit SME according to the EU definition – an enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro

- Be legally incorporated and established in one of the EU Member States or Horizon Europe associated countries. Be incorporated on/after 1st January 2013 and before the submission deadline
- Have at least 2 paid FTEs working in the start-up at the time of submission
- Have a CEO working full-time in a company at the time of submission Start-up applying for at least EUR 300 000 EIT Health grant

Mandatory KPIs:

- Designed/Tested Innovation (within framework of project)
- Marketed Innovations (no later than 1 year following completion of project)
- Number of citizens/patients that benefitted from solutions developed or implemented in the EIT Health activity
- At least one customised KPI linked to Patient Reported Outcome Measure (PROM)

Tags: Digital Health, Medtech, Biotech, innovation, prevention, health registry, biobank

3. Important rules applied to the Flagships Call for BP2023

3.0. Introduction

EIT Health is committed to supporting the best ideas and activities with the highest potential to generate impact on the healthcare delivery or system. Thus, proposals must meet the highest expectations and performance on the creation of societal impact (please refer to Strategic Agenda 2021-2027 for details).

This call is open to applications from EIT Health Associate or Core members as well as new organisations. The geographical origin of applicant is limited to EU Member States or countries associated to Horizon Europe.

Organisations will not be eligible to receive funding until they have acceded to the new Horizon Europe legal framework and are eligible to receive EIT-funding as grant recipients. Individuals cannot apply for funding under this call.

In case of questions of eligibility, you can reach out to eligibility@eithealth.eu

New organisations that are requesting more than a €50k grant in one calendar year must become a member of the association to be eligible to claim costs in successful selected activities, except for start-ups applying to the start-up-driven projects.

All activities that will be selected must lead to specific deliverables and outputs (defined in the proposals) over a defined time schedule and they will be financed by EIT Health (the KIC) only for a defined duration.

All activities that are selected must aim to reach their own financial sustainability and scalability under a specific timeframe.

All activities that are selected must commit to contributing financially to the EIT Health's sustainability through different models that are explained at a later stage.

Above and beyond the specific EIT Health rules of participation, all activities must comply with Horizon Europe and EIT rules.

3.1. Societal impact

As explained in the introduction of the document and of this chapter, activities seeking support through EIT Health's Business Plan 2023 are expected to contribute to the achievement of high societal impact. To do so, the following actions must be considered in each application:

Involving citizens and patients

Involvement happens when individual citizens and patients and/or civil society organisations share their views and experiences to guide and inform how activities are designed (co-design), carried out (co-creation), shared, and adopted. Activities should be done "with" or "by" people, rather than "to" or "for" them. Examples of such activities include involving patient and citizen as members of project consortia and/or advisory groups and inviting them to respond to surveys or participate in focus groups and discussion forums. Participation of citizens and patients as subjects of research and innovation that is done solely "to", "about' or "for" them (e.g. participation in clinical trials or usability studies) does not qualify as involvement.

Designing solutions that will benefit citizens and patients

Benefit happens when citizens and/or patients report a positive impact on their life because of using (direct impact) or being touched (indirect impact) by the solution developed and implemented in the EIT Health activities.

This impact is extremely valued by EIT Health and must be at the core of any proposals. For this reason, this indicator will be part of the selection process from the short proposal stage on. Thanks to the impact analysis introduced during the last Call for Innovation projects, we were able to study health impact that should be created by each Innovation proposal three years after the project ends.

Thanks to this study, we consider **the expected health impact as 150,000 European citizens and/or patients to have benefitted from the Innovation project three years after it ends** (independently from health conditions and range of applications) to be the minimum for any Innovation projects proposals in any track.

Designing activities that deliver those outcomes that matter most to citizens and patients

Outcomes that matter to patients go beyond the clinical end points, symptom burden, the functional impact and health-related quality of life. They include improvements to patients' life, independence, pain relief, mobility, emotional wellbeing, and recovery time – to give a few examples.

Complying with ethical, legal and social principles

Compliance with ethical rules and standards, relevant European legislation and international conventions is required. The diversity of participants (race, gender, age, unheard voices) and consideration for gender differences in research and innovation content will also be noted. The accessibility of digital and physical spaces for people with disabilities will be considered.

Implementing designed and tested innovations

Each innovation proposal should aim during the activity lifetime to implement innovative products, services, and or approaches that will either be filed for some form of intellectual property protection (i.e., patents, trademarks, registered designs, copyrights); progress towards commercialisation; or develop prototype, proof of concept, beta version, pilot product, service or model or test innovative products through testbeds or other innovative platforms.

Launching product or services on the EU market

Each proposal should aim at introducing and scaling products/services/HVC approaches to the market during the activity duration or within a certain number of years depending on the call track after completion thereof. EU markets should be the favourite first markets where products/services/HVC approaches should be introduced and scaled. Innovations include new or significantly improved products (goods or services) and processes sold.

All the points described above are expected to be demonstrated in the proposals through dedicated KPIs, milestones and/or deliverables and should further be shown through reporting. Successful projects will be invited to be part of the Innovation projects portfolio.

NB: EIT Health is also currently studying how to implement and monitor a similar impact framework for start-ups that are benefitting from support from Business Creation programmes.

3.2. Financial sustainability

As stated in the introduction, all activities selected in EIT Health portfolio must commit to contributing to the long-term financial sustainability targets of the KIC by aiming at generating financial contribution back to the KIC.

Different models will be made available depending on the type of the selected activity.

For Innovation projects, we foresee the following models:

- Grant for option (only applicable to start-up-driven Innovation projects)
- Financial backflow (applicable to all Innovation projects, including start-up-driven projects – in case of start-up driven projects, membership fees will be requested from the start-ups)

NB:

1. Start-up-driven projects will need to choose at the short proposal stage which model to go further with. No change of model will be allowed later.
2. The financial contribution models linked to Education and Business Creation programmes will be presented in the final call document to be issued on 15 September 2022.

Find below details for the financial contribution models linked to Innovation projects.

Grant for option model

In the case of start-up-driven projects, EIT Health will invest in selected start-ups through direct grant and in-kind contribution.

In return, EIT Health shall participate in the economic success of the start-up via an option to assume shares in the start-up in the case of certain "financial events".

Main principles:

- By using the option instrument, EIT Health intends to receive treatment comparable to a shareholder, and to participate in the financial success of the start-up without assuming equity on the moment EIT Health signs the Option Agreement with the start-up
- The instrument of an option is internationally known, is accepted and does not include debt-elements
- The option will be exercised in certain financial events. Thus, EIT Health will only participate in the upside of the start-ups if start-ups are successful
- The option will dilute in financing rounds in the same ratio as equity-shares
- EIT Health will participate in the following financial events:
  (i)   sale of more than 50% of the shares in the company
  (ii) sale of more than 50% of assets as well as licensing of substantial IP rights of company
  (iii) Initial Public Offering (IPO)
  (iv) Liquidation
- In these financial events, EIT Health has the right, but no obligation, to exercise the option agreement, which EIT Health can do in two ways:
  (i)   Assuming equity
  (ii) receiving the compensation payment (if decided so by a start-up).

- In the event of a merger, the option of EIT Health shall be converted into new option on the level of the new entity. The conversion shall occur under the same economic conditions agreed upon for the shareholders
- As long as the option is not yet exercised, EIT Health does not hold equity in the start-up and will not have rights of a shareholder
- EIT Health gets the right to decide whether it wants to take a seat on the Advisory Board of the start-up as long as EIT Health holds at least a participation equivalent to 8% on a fully diluted basis

The number of shares EIT Health is entitled to subscribe in the financial event will be defined through the valuation analysis.

Valuation analysis will be performed by an independent party for the conditionally selected projects after the hearings.

Additionally, instead of performing valuation assessment, EIT Health can accept post-money valuation of the last qualified financing round[12] if the financing round was concluded no later than one year prior to application to this call or pre-money of the co-investment in a qualified financing round concluded right before the start of the programme.

Should no agreement on the valuation be achieved with a start-up, the full Innovation project will not be considered for funding.

Individual valuation must be agreed prior to the project start. The individual valuation of the start-up will be part of the Term Sheet and Option Agreement with the start-up.

This will be agreed in parallel to the signing of the Project Grant Agreement (PGA).

Backflow model

The model of backflow will apply in the case of Partner-driven Innovation projects and Quality Assessment Innovation projects.

The amount of backflow is capped to an amount equalling the EIT funding received by the consortium, plus a project-specific, risk-related mark-up to be defined for each individual case.

The individual backflow shall be primarily contributed by the Commercialisation Partner(s), which are expected to be Industry Partners that commercialise the product or service and only in extraordinary cases other types of Partners.

The backflow shall only apply for the event of the successful commercialisation of the project.

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[12] "Qualified Financing Round" is an equity financing round (including financially comparable measures) in which new shares are issued to existing shareholders and/or new investors against contributions and/or other payments in cash (e.g., nominal amount of newly issued shares, premiums or any other payments into the Company´s capital reserves), yielding gross proceeds to the Company from private investors of no less than € 500,000.00. In this case, please provide a signed Investment and Shareholders´ agreement as a proof of the post-money valuation of the Qualified Financing Round and proof that Private Investors have invested at least € 500,000.00. "Private Investors" include but are not limited to: Business Angels, Super Angels, CVCs, VCs, family offices and other private investment firms.

The definition of success, related to the successful commercialisation of the project, shall be defined at the time of full proposal submission, and will be agreed upon with EIT Health after project approval.

The amount, time and conditions for the backflow will be crucial criteria for the selection of the funded projects and the option selected for backflow must be outlined in the full proposal to a sufficient level of detail that will allow a proper assessment of the project's risks and benefits.

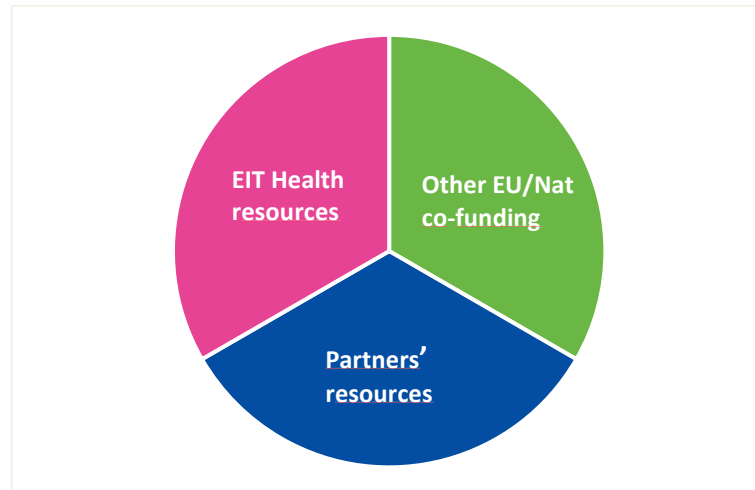A shared revenue plan will need to be defined at full proposal stage submission and this will include:

- Percentage of shared revenue

- Extra risk-related specific project mark-up

- Threshold from whereon the payback period starts (e.g. certain revenue threshold to be defined; positive gross margin threshold; break-even threshold)

- Use of operating profit or free cash flow instead of revenue as baseline is possible if a higher percentage share than in the case of revenue is presented
- Backflow start point from whereon the payback is due (standard clause of not later than 3 years after project end)
- Backflow end point until when payback is due (standard clause of 5 years after backflow start point)

If the project is accepted into the portfolio, details of the backflow will be agreed prior to the signing of the Project Grant Agreement (PGA) and will be outlined in the agreement.

Indeed, backflow mechanism (amount, caps, timeline, responsible party/ies, conditions, etc.) must be fully defined and agreed upon in writing by both parties before the project starts i.e., funds will be released only after both parties have agreed on the backflow mechanism details.

3.3. 1/3 Principle co-funding

The EIT Health activity portfolio aims to be financially structured around the 1/3 co-funding principle. This is summarised in the scheme below:

The 1/3 principle consists of:

- 1/3 EIT grant support to activities
- 1/3 activity Partners co-funding with own resources
- 1/3 co-funding from external resources like regional, national or any other EU fundings

The principle aims to leverage EIT Health fund by creating robust synergies with other public funding programmes and demonstrating the commitment of Partners through high impact achievements.

The way to operate the 1/3 principle is currently under development as each type of activities needs to be considered individually and also as part of a whole portfolio to establish rules to implement the 1/3 principle.

Concrete cases as well as detailed framework of application will be fully presented in the final call document to be published on 15 September 2022.

3.4. New selection process – set-up phase

From this year on, a new selection process will be introduced. It will consist of four phased approach leading to the final activity selection. This can be seen as a funnel concept to enable only the best proposals to be finally selected.

This process aims on one hand to simplify the application requests i.e., Partners are asked to provide the necessary information for assessment at the necessary moment, and on the other hand to strengthen the proposals to ensure more impact and success for activities that are selected in the EIT Health portfolio.

Below is an overview of the main principles of the process that will be fully presented in the call document on 15 September 2022.

Phase 1: Shortlisting (approx. 1 month)

Consortia will be invited to submit a short proposal form as well as general information on their activity. At this stage, it will be accepted that consortia are not complete and that details of activity's plan are not finalised. No commercialisation plan or sustainability plan will be expected at this stage.

The minimum requirement to apply (including eligibility criteria) will be specified in the call document which will be issued in September.

Proposals will be shortlisted after internal and external reviews. Depending on the available budget per call track, a certain number of proposals will be invited to the next phase. EIT Health will apply a ratio of three invited consortia for one selected consortium.

Reviews will be based on the following criteria:

Shortlisting criteria
Project Excellence and Strategic Fit (50%)
Implementation and Feasibility (10%)
Impact and Sustainability (40%)

Phase 2: Support programme (approx. 1.5-2 months)

The support programme will give the opportunity to each consortium invited, to work further on their activity plan and complete their team. Consortium will receive mentoring and coaching advice to support strengthening their proposal. More details on the programme content will be communicated to invited teams in due time.

The support programme is a service offered by EIT Health to all pre-selected applicants to enhance the quality of their proposals, define their strategy in terms of the 1/3 principal implementation and refine synergies with other activities (also part of the support programme or already in the portfolio).

It is mandatory to take part, except for consortia who have already been through the programme.

In parallel, start-ups that choose the grant option as their financial model will go through due diligence. If they don't pass the due diligence, the full consortium will be disregarded from the selection process.

Full proposals are expected to be submitted at the end of the support programme.

Phase 3: Evaluations (approx. 1 month)

Evaluation will happen for all consortia that submit full proposals. After evaluation, full proposals will be ranked. Portfolio analysis will then take place. It will consist of the review of the main activities' characteristics i.e., the current evaluation scores as well as assessment of societal impact, financial contribution model, and the 1/3 principle co-funding model. An ELSI review will also take place to ensure that all elements are well defined in this domain.

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

Evaluation will be based on the following criteria:

Evaluation Criteria
Project Excellence and Strategic Fit (20%)
Implementation and Feasibility (40%)
Impact and Sustainability (40%)

Phase 4: Contracting (approx. 3 months)

Activities that are accepted for financial support will need to go through negotiation steps (valuation analysis for start-ups that haven chosen the grant model option, back flow conditions etc.) and elements of contracting steps (project grant agreement, option agreement for start-ups that have chosen the grant model option, financial contribution to the KIC agreement etc.).

As soon as all contracts will be in place, pre-financing can be released, and projects can start their activities.

4. Flagships call guidelines

4.1. Timeline

The flagships call will consist of a one-year long call with three deadlines, known as cut-off dates: **2 November 2022, 1 March 2023 and 1 June 2023.**

The cut-offs are the deadlines for when a consortium can submit a short proposal for a dedicated call track.

It is important to note that not all activities called within the flagship framework described in chapter 2 will be called at all 3 cut-offs. You can find below the table summarising at which cut-off the activities are called for:

	Cut off 1 – 2 Nov. 2022	Cut-off 2 – 1 March 2023	Cut-off 3 – 1 June 2023
New models to deliver healthcare			
Winter / Summer School	Yes	No	No
Modules toward a labelled Fellowship programme	No	Yes	Yes
Training Modules on Advanced High Value Care Principles	Yes	No	No
Service Quality Assessment Call for projects	Yes	Yes	Yes
Bootcamp in VBHC for mature start-ups	No	No	Yes
Facilitating the uptake of Digital Medical Devices			
Winter / Summer School	Yes	No	No
Module toward a labelled Fellowship Programme	No	Yes	Yes
Start-up and Partner driven projects	Yes	Yes	Yes
DiGinnovation – Fast Track Start-up driven projects	No	Yes	No
Harnessing the full potential of health data for innovation			
Winter / Summer School	Yes	No	No
Module toward a labelled Fellowship Programme	No	Yes	Yes
Training module for professionals	No	Yes	No
Training module for patients and citizens	No	Yes	No
Start-up- and Partner-driven projects (registry based)	Yes	Yes	Yes

Each cut-off is followed by a set-up phase as described in the previous chapter. This phase is intended to last around 6 months (this time is not fixed and will mainly depend on the type of activity).

The detailed timeline of the implementation of the setup phase for each cut-off will be described in the call document published on 15 September 2022.

4.2.   Rules to apply

All rules to apply (registration, submission platform, detailed eligibility criteria at each phase etc.) will be detailed in the call document that is issued on 15 September 2022.

4.3.   Where to get help

EIT Health has pan-EU representation via eight Regional Innovation Hubs, 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 Regional Innovation Hub / InnoStars.

Innovation Hub / InnoStars	Institutions type	Contact person	Email address
Austria	All	Christos Vaitis	christos.vaitsis@ext.eithealth.eu
Belgium-Netherlands	Start-ups	Hayley Every	hayley.every@eithealth.eu
	Other	Akvile Zalatoryte	akvile.zalatoryte@eithealth.eu
France	Start-ups	Manon Pommier	manon.pommier@eithealth.eu
	Other	Robin Eggert-Griscelli	robin.griscelli@eithealth.eu
Germany-Switzerland	Start-ups	Bojana Trajkovska	bojana.trajkovska@eithealth.eu
	Other	Jeff Wilkesmann	jeff.wilkesmann@eithealth.eu

InnoStars	All	Chiara Maiorino	chiara.maiorino@eithealth.eu
		Manal Al-Hammadi	manal.al-hammadi@eithealth.eu
		Marta Passadouro	marta.passadouro@eithealth.eu
		Zsolt Bubori	zsolt.bubori@eithealth.eu
Scandinavia	Start-ups	Per Horn	per.horn@eithealth.eu
	Other	Zara Pons Vila	zara.pons-vila@eithealth.eu
Spain	Start-ups	Joan Grasas Leon	joan.grasas@eithealth.eu
	Other	Claudia Navarro	claudia.navarro@eithealth.eu
Ireland-UK	Start-ups	Lucy Campbell	lucy.campbell@eithealth.eu
	Other	Graham Armitage	graham.armitage@eithealth.eu

In case of applications by non-Partners without Hub affiliation, please contact the above-mentioned persons according to the table below:

Hub	Affiliated countries
Austria	Austria
Belgium-Netherlands	Belgium, Luxembourg, Netherlands, Israel
France	France
Germany	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