

# Proposal template Part B: technical description

Note: As per the instructions online handbook, all tables encoded and automatically exported by the Portal have been deleted in this template to avoid duplication.

# **Executive Summary**

EIT Health is one of eight Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT), an EU body and Institutionalised Partnership under Horizon Europe's Pillar III – Innovative Europe. EIT Health's vibrant community of more than 150 partner organisations from the worlds of business, research and academia, empowers a network of world-leading health innovators. We bridge the gap between industry and academia to take on some of Europe's biggest health challenges – promoting better health of citizens, strengthening healthcare systems and contributing to a sustainable health economy. EIT Health collaborates across disciplines, borders and sectors, reinforcing excellence, creating knowledge and innovation, and encouraging greater investment, to deliver outcomes that matter most to citizens and patients.

In the eighth year since its inception, EIT Health is consolidating its activities under a single unified structure: the Flagship. All activities will now contribute to different Flagships, priority areas that are determined through a participatory process of stakeholder engagement and are updated annually. Concentrating on Flagships allows EIT Health to address our targeted societal challenges by bundling successful but separately developed activities of our operational pillars of Business Creation, Education and Innovation so that they tackle single- issue, highly focused topics based on EU health priorities.

The Flagship concept provides a single call document and consolidated programme, offering participants one standardised annual process with multiple intakes. It lets EIT Health provide the European health ecosystem a predictable route of engagement that can prioritise key performance indicators of our Strategic Agenda and the EIT Impact Framework. EIT Health Flagships create a simpler and more congruent journey for project participants, allowing early-stage to late-stage support for start-ups, academic participants, and the wider innovation community. Ultimately, Flagships allow new means of collaboration, to help novel solutions that are closer to market, catalyse innovation in the knowledge triangle and leverage resources for increased impact.

The Flagship process ensures maximum future impact by addressing our pillar activities holistically and lets us assist project partners from within and outside the EIT Health partnership in consortia building and impact by design at early stages of their ideation. A programme to support consortia with finalising proposals is now a mandatory step integrated into the Flagship activity selection cycle.

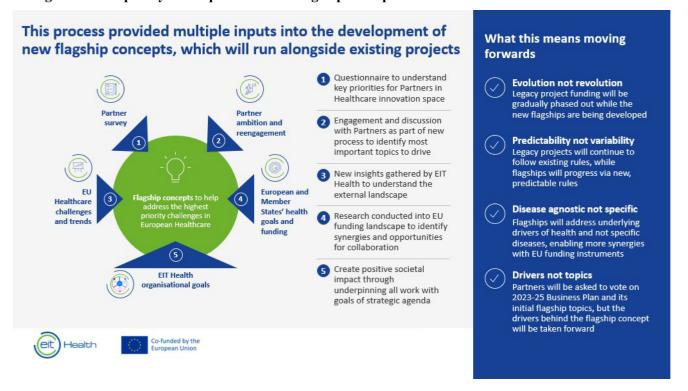
The Flagship structure and its participatory design is driven by experience from previous years. The concept is underpinned by the belief that planned EIT Health impact can only succeed if content focus is highly relevant to the needs of the European healthcare innovation system and the timing is suitable for innovators to act. Considering the multi-annual nature of the Business Plan, involvement, and collaboration between stakeholders from the knowledge triangle at the inception of Flagship development was key to ensuring full engagement. The participatory development of the Flagship concept is illustrated on the following page.

As outlined in our strategy, EIT Health has taken the necessary steps toward financial sustainability by incorporating the required co-funding rate of 30 percent into Business Plan 2023-2025 and the Flagship concept. To prepare the KIC's full program portfolio for further increases in co-funding requirements, EIT Health introduced the 1/3 concept as a guiding financing structure into its 2023-2025 Flagship calls. The 1/3 concept outlines that 1/3 of the funding of any project is provided by EIT Health, another 1/3 needs to be provided by project partners, and the final 1/3 should ideally be secured through approved additional third-party national, regional or European funding. In 2023–2025. EIT Health prioritises the utilisation of its network to connect projects and funding authorities. EIT Health's established team of Public Affairs and Stakeholder Relationship managers will connect co-funding bodies on all levels of government with EIT

Health projects. The introduction of this additional co-funding requirement within the first Flagship call in 2023 can provide participants clarity and give EIT health experience for continuously increasing co-funding requirements post- 2025.

The implementation of the Business Plan will fully comply with the EIT Financial Sustainability principles, KIC fund principles, Innovation Principles, EIT RIS Hub Minimum Standards and Good Governance principles.

Figure: Participatory development of the Flagship concept



To provide an operational set-up that can best drive the Flagship concept, EIT Health will complete its internal governance reform in 2023, ensuring full alignment and effective and good governance across its eight European regional hubs and its Central Office for implementation of this Business Plan.

The KIC will also review its membership fee model, with a view to offering an attractive engagement package and advancing the benefits of the full openness of its calls. An adjusted model will be finalised in 2023. The new fee model has two aims: accelerating growth by facilitating easier entry into the EIT Health partnership, and keeping the level of income for the institutional, legal, tax and European funding requirements.

Following a period of incredible demands and investment in the health sector, the ongoing War against Ukraine and the consequent energy and living cost crisis pose the highest risk to the success of the Business Plan in the upcoming period. There is a possibility of economic recession and the shifting focus of public attention from health to other sectors. To mitigate EIT Health will proactively engage current, and new organisations to keep the interest levels high.

EIT Health will continue supporting the development of deep-tech innovation projects to solve the pressing challenges in healthcare while also addressing unmet market and patient needs. A strong position for generation of robust business models and self-sustainable products and services after the grant period is over is a landmark for the KIC. Starting with BP 2023-2025, it will be possible to reinvest some of the returns generated by project successes into supporting the next generation of new innovations.

**KIC's target societal challenges:** EIT Health's Business Plan 2023-2025 has been developed around defined societal needs. Based on learnings from previous years, we will focus on closer-to-market ideas. Through an annual joint assessment, EIT Health aims to incorporate stakeholder feedback consistently to

ensure that the Flagship topics remain relevant, accessible to our partners and impact-focused in their design and delivery. In 2023-2025 via the indicators below, EIT Health will:

- Accelerate needs-based health innovations to achieve wide market uptake in Europe by fostering
  collaborative projects that connect innovators with various stakeholders from the healthcare
  systems.
- Increase the value and impact of EU-based SMEs in the health and healthcare sector to enhance their ability to compete on the global level.
- Attract and develop the skills of those with the potential to design, develop or utilise healthcare innovations, through novel education and training offers.
- Support healthcare providers, professionals and payors to transform care towards outcomes that have the highest impact and are of the most importance to patients.
- Impact and drive healthcare innovation policy in Europe, based on evidence, learnings and experience from EIT Health activities.

Key Performance Indicator (KPI)	Achieved in 2019	Achieved in 2020	Achieved in 2021	Target 2022	Targets 2023	Targets 2024 and 2025 *
Innovations launched on the market	7	23	8	17	20	22
Innovations launched on the market with a sales revenue of at least 10k **	7	23	1	17	20	22
KIC Supported Start-ups/Scale-ups	386	489	327	276	154	265
Start-Ups Created of/for Innovation	4	0	4	3	3	6
Start-ups created having a financial transaction of at least 10k**	4	0	4	3	3	6
Investment attracted by KIC- supported start-ups and scale-ups	143.5	301.2	480.4	199	199	402
Start-ups created by students enrolled and graduates from EIT- labelled programmes	0	0	0	4	8	22
Graduates from EIT Labelled Programmes	53	54	150	90	75	635
Participants in (Non-Degree) Education and Training	6,261	8,253	5,838	11,841	3,640	9,080
EIT Labelled Students and Graduates who Joined Start-ups	1	0	3	8	12	32
TOTAL # citizens and patients benefitting	39,9 12	26,7 09	279,27 7	0,625**	0,625***	1m***

 $<sup>*</sup>Targets\ reflect\ the\ SA\ targets,\ in\ full$ 

Note: RIS contribution is 15% of the targets as per the SA

<sup>\*\*</sup>Sub KPI's which feed into Parent KPI target above

<sup>\*\*\*</sup> cumulative targets

#### 1. Excellence in regard to the KIC's Multiannual Strategic Agenda 2021-2027

#### 1.1 Objectives and ambition

The proposed Business Plan 2023-2025 has been designed to target pivotal societal challenges and to strive toward the following EIT Health Strategic Agenda 2021-2027 goals: promoting better health of citizens, strengthening healthcare systems in Europe, and contributing to a sustainable health economy. To measure its progress, EIT Health has defined strategic objectives that will allow us to track our performance between now and 2027. The proposed Business Plan 2023-2025 has been designed along the same objectives and will be monitored against them.

Flagship design, a major development at EIT Health, will ensure strategic alignment of Business Plan 2023-2025 to our Strategic Agenda 2021-2027. The Flagship concept stemmed from our enhanced stakeholder engagement – which allowed us to gain a deeper understanding of the health ecosystem needs enhancing our awareness of today's most pressing healthcare challenges. The Flagship approach gives EIT Health a more problem-oriented and guided approach than we have had in the past. By implementing the Flagships, we are realigning our strategy so we can successfully deliver on the Strategic Agenda goals. This means calls will be developed around clearly defined societal needs and will focus on closer-to-market ideas.

A cornerstone of the Flagship design is the strengthened KTI integration, in particular the education dimension and how it will be integrated into the knowledge triangle to contribute to innovation ecosystems. At both at the call stage and at the implementation phase, enhanced KTI integration requirements are required and also supported during the support program. Please see a table of enhanced KTI synergies in section 1.2, Methodology.

Through the process of an annual joint assessment, EIT Health aims to incorporate stakeholder feedback to ensure that the Flagship topics remain relevant, patient-centric and, most importantly, focused on impact in their design and delivery. Stakeholder engagement is a priority in Business Plan 2023-2025. With the new Flagship concept in place, EIT Health will provide clear opportunities and benefits for participants.

Our ambition is to tackle pressing healthcare challenges and provide demonstrable socio-economic improvements to society in four key areas that have been identified as a priority at EU level:

- 1. **Defining new models to deliver healthcare:** 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 Flagship will be the concept of value-based healthcare, where success measures are based on patient outcomes and the shift from treatment to prevention.
- 2. Facilitating the uptake of Digital Medical Devices and Diagnostics: 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; and (ii) the harmonisation of clinical trial protocol design to ensure the replicability and consistency of medical outcomes between member states for faster reimbursement.
- 3. Supporting the deployment of Important Projects of Common European Interest (IPCEI) to address market failures: Sixteen 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.
- 4. 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. It will enable 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.

Looking at the "New Models to Deliver Healthcare" as an example, the added value for participants includes:

- Business entities have increased opportunities to collaborate with healthcare providers and payors to generate evidence and validate value-based models for reimbursement.
- Research entities have greater opportunity for collaborative evidence generation with existing health data repository, healthcare stakeholders and industry, to drive innovation in value-based
- Academic entities will foster paths for learners towards entrepreneurship, bridging the gap between academia and industry by translating research into innovative solutions.

Call. Together with a well-managed portfolio, strategic development of the 2023 Call enables EIT health to position the different activities in innovation, business creation and education towards common targets. Our approach emphasises the need for the entire organisation to "live" its objectives by incorporating our strategy across our activities. This emphasis, and a cross-pillar approach in activity selection, will break down silos amongst pillars and reduce fragmentation of activities – an element previously identified as a weakness.

Synergies with other European initiatives, like Horizon Europe Pillar II and Pillar III (e.g. EIC and IHI), and national and regional initiatives, will also be further strengthened by identifying needs and engaging with patients, health care providers, health authorities and regulators. Dedicated activities with these institutions, such as those offered within the framework of the EIC-EIT Health Collaboration Pilot, are expected to continue under new modalities. Overall, the present strategic direction creates a trusted organisation with a business model that is able to deliver both economic and social value and is fully open to new partners while leveraging the benefits of its Network ++ organisation allowing for a clear point of entry with the Flagship concept.

EIT Health aims to deliver societal impact, understood as the implementation of widespread, demonstrable socio-economic improvements to society. EIT Health believes that societal impact is:

- constructed from the connection between innovation and society (Citizen & Patient Engagement);
- measured against what really matters to people (High-Value Care);
- assessed on principles of integrity and fairness (Ethics & Legal principles). To measure impact, we can look at different metrics:
- Quality of life: Benefit for patients and citizens has been included as a measure when building the business plan portfolio (e.g. innovation projects). As an example, the number of people who experience an improvement in Quality of Life and/or Life Years Gained, has been part of the evaluation and selection process, and will be included in monitoring and reporting (e.g. societal impact study) thus ensuring a direct link with EIT Health's target societal challenge.
- Systemic change: For our second objective, strengthening healthcare systems in Europe, we have selected projects demonstrating efficiency gains. We will measure how well inputs (resources, such as number of hours worked by healthcare staff) are used to produce outputs (e.g. health outcomes, survival). Gains may be the result of new collaborations, new players, new payment models, digital tools etc. Knowledge Triangle Integration (KTI) is crucial for the envisioned transformation in health care, e.g. we need to educate change-agents that scale sustainable and systemic solutions.

#### **Lessons learned**

**Innovation:** EIT Health will aim to continue supporting development of deep-tech innovation projects to solve the pressing challenges in the healthcare sector without forgetting the need to solve both unmet market and patient needs. EIT Health is progressing from the generation of robust business models and selfsustainable products and services (post-funding) to reinvesting some of the returns generated by project successes into supporting a generation of new innovations through the sustainability of the KIC. This will start to be possible in BP 2023-2025. Implementation of the Flagship concept will also lead to closer integration of Innovation, Education, and Business Creation programmes and services, achieving significant synergies, and reinforcing the innovator's journey. The dedicated Support Programme will support proposals prior to final selection, to de-risk and strengthen the project plan.

Education: Education will aim at contributing to reduce the shortage of entrepreneurial skills and competence around deep-tech as well as upskilling and reskilling the workforce to ease the adoption of innovations and solutions. Starting from the targets included in EIT Health's strategic agenda and embracing the principles of the EIT Label for different segments, Education aims at supporting EIT labelled programmes as well as further developing the Academy online learning platform under the proposed Flagships, which all face extensive talent and capacity gaps. The knowledge triangle will be strengthened through closer collaboration with Innovation projects and start-ups, WorkInHealth and a greater focus on challenge-based learning using real-world challenges. Stabilisation of the portfolio should contribute to settling the existing revenue sharing model, now adapted to the 1/3 funding principle. In addition, the WorkInHealth (WIH) / TalentForce initiative will yield complementary funding for needs-driven training and education programmes that address talent gaps evidenced through the WIH Skills Observatory.

**Business Creation:** The Business Creation area will continue to support European start-ups, adjusting and aligning the goal of promoting European Start-up ecosystem to EIT Health's new strategic Flagships. The Accelerator programmes have had diverse revenue-generating ideas for reaching financial sustainability, and lessons learnt will be incorporated into the Business Plan and the operations of Invest Health. Mentioned in the Strategic Agenda 2021-2027 as the "EIT Health Impact Facility", Invest Health is an independent, forprofit entity with commercial structure and mindset, owned 100% by EIT Health e.V. It has the goal of implementing and driving financial sustainability objectives of EIT Health e.V. Both InvestHealth and Business Creation will continue to work together to forger new modalities of collaboration with European institutions, such as the EIF, EIB and EIC to reinforce linkages that will help to guarantee quality deal flow and investment.

Corporate Affairs: Visibility raising vehicles such as Events will be carefully considered and aligned with public affairs and stakeholder relations. Media engagement is critical, and key media relationships such as with Politico must be cultivated. Digital strategy will focus on SEO, and social media will be more dynamic and discussion led. Improved horizon scanning will determine the most strategically relevant EU/regional/national instruments to pursue and establish joint actions and cooperation possibilities. Internal processes are to be improved for adequate information exchange and timeliness with respect to portfolio and alliance development/funding successes to drive more effective dissemination. Clear metrics will be devised to assess engagement across internal and external audiences. Increased engagement will facilitate collaboration and networking. Cross organisational planning tools will help leverage opportunities for dissemination purposes.

RIS: EIT Health RIS will focus on accelerating and strengthening innovation across the RIS innovation ecosystems and addressing the innovation divide between regions; fostering, attracting, and retaining entrepreneurial talents in RIS regions to ensure the flow of talents and establish a pool for entrepreneurs and skilled healthcare workforce of the future; improving access to finance for RIS start-ups and scale-ups and giving them skills to become integral players of European markets; improving conditions of KTI collaborations to allow innovators to experiment with new ideas and help them to finalize their proof of concepts.

#### Financial Sustainability Approach 2023-2025

In recognition of the strategic recommendation on expanding the effectiveness of its financial sustainability mechanisms the KIC has initiated an overall review of its Financial Sustainability Assumptions. The KIC needed to recognize, that the previously defined matrix, based upon the jointly agreed Strategic Agenda, is not fully fit for purpose in its third year in application.

This means the KIC will, as soon as a sound new matrix could be drafted on these findings, reach out to EIT to jointly take stock on how the Financial Sustainability definitions outlined in the Strategic Agenda should be adjusted to be a functional strategic guidance for the KIC.

Recognizing this, the KIC has taken two actions imminently. Firstly, on a budgetary level the KIC has taken a review of all program lines initiated under previous Business Plans and has taken the decision of phasing out those that are not contributing strongly enough to the financial sustainability goals.

Secondly, on a budgetary level the KIC has secured that expected financial sustainability returns may only be utilized the year after their realization, in order to have sound budgetary planning and foresee in practice any risks associated with underperformance on a financial sustainability dimension.

In line with the request of the EIT GB and together with the respective external partners the KIC has initiated an update on the Business model of both the Venture Centre of Excellence as well as for its participation in the Important Project of Common European Interest (IPCEI) in the area of health. All tasks are ongoing in

line with the recommendations received by the EIT GB in December 2022 and are executed as soon as possible.

The principal design of the Financial Sustainability (FS) approach for the period 2023-2025 will conform to the FS Strategy presented in the EIT Health Strategic Agenda 2021-2027 of 20 April 2021. In that regard, the approach will comprise four elements, i.e., Membership Fees, External Grants, Success/Service fees, and returns of investments.

**Membership fees:** The EIT Health Association (EIT Health e.V.) comprises more than 300 public and private European legal entities that contribute financially to complement the EIT funds granted to innovation activities. The size of the contribution depends on the type of organisation and its calculation is applied systematically within the association. The existing membership fee model is foreseen to evolve into a model composed of a fixed base fee and a variable fee, dependent on engagement levels. See Section 1.2, Methodology, for more details.

External grants or contributions: It is assumed that the decreasing EIT grant will not be covered by business income alone. Access to local and national funds, as well as other European funds, will be pursued as well. EIT Health will also bid for projects by responding to calls for European agencies that are aligned with the greater mission of EIT Health. Involvement in such projects highlight our expertise in healthcare ecosystem building and providing business creation services while providing an opportunity to connect to other European networks and actors. This and additional funding income is expected to reach at least €5.5 million in 2027 and include:

- Contributions from national and international bodies or institutions.
- Capital endowments.
- Bequests, donations and contributions from individuals, institutions, foundations or any other bodies established under national law, e.g., Bavarian Grant.
- Financial instruments, including those funded from the general budget of the Commission:
  - o European Innovation Council, EIC;
  - o European Education and Culture Executive Agency, Erasmus + BeWell Project;

#### **European Innovation Ecosystem, EIE.**

**Success fees:** These correspond to fees obtained from start-ups in exchange for high-value services that result in the company achieving certain predefined financial milestones (fundraising, exit events, IP license agreement etc). Main areas of operation will include mentoring, start-up support, and innovation and networking platform services. Services may be provided in collaboration with EIT Health partners. Development and implementation of these services will also be supported through alternative funding mechanisms pursued by EIT Health to develop the necessary capacity to provide the services. Currently running programs to be strengthened include: GoldTrack, Venture Centre of Excellence, and Bridgehead.

**Return on investments:** The expected cumulative amount of income by 2027 is €31.1 million. EIT Health will develop its asset positions in the form of *options for equity* and will continue to expand on its asset portfolio through the continued implementation of the Grant for Option model across various programmes. In addition, the new approach of EIT Health is to aim for faster return on investment ensuring a faster contribution to the Financial Sustainability. This will be obtained by having higher FS requirements (e.g., having Innovations launched after one year as a core KPI). Overall return will be observed at the three EIT Health pillars:

• Education: Education programmes developed with EIT Health support to partners since 2020 will contribute to the KIC's financial sustainability. Education activities are currently required to produce online education modules (e.g., Academy) on which EIT Health can capitalize to gain exposure and income following a business-to-customer approach that will issue EIT Certificates. EIT Health and EIT Health Partners will develop education modules to allow shared revenue models of mutual benefit. EIT Health will also use its capacity and know-how developed over the years to cater to the education and training needs of the corporate healthcare sector. The expected revenue from the executive and professional education programmes in 2023-2025 is €1,500,000.00, including contribution from WorkInHealth / TalentForce. Degree programmes remain an investment by EIT Health and will continue to operate to strengthen EIT Health's network and innovation ecosystem to support greater interaction and integration of

entrepreneurship and innovation in the context of high-value care.

- Innovation Projects: Technology development projects will deliver economic and societal impact, and financial return to EIT Health, through equity models and repayable grants incorporated in various programmes. As such, successful projects and start-ups will strengthen Europe's health ecosystem (e.g., Start-Up Amplifier) and will contribute to the sustainability of EIT Health by allowing the KIC to own valuable equity and/or generate strong financial returns.
- Business Creation: EIT Health took its first FS steps in 2018 with four mechanisms still in use:
  - 1. Equity instruments in the form of a Grant for Option model. Such models are incorporated in Wild Card and in selected Gold Track companies. Within this model, innovation projects of competitive start-ups are funded through grants in return for the right to assume options in the start-up. EIT Health participates in the future successes of the supported start-ups vis a vis other shareholders
  - 2. Success fees implemented in various models where start-ups commit to paying EIT Health a fee upon reaching certain financial events. The nominal value of the success fee and the financial triggers depends on the programme, eg. 0.95% for reaching significant financial events for up to three years post Gold Track participation and a 6% success fee on revenue capped at 3x the grant generated in a new market for a period of three years for Bridgehead companies. The Venture Centre of Excellence also employs a success fee model on funds raised from new investors.
  - 3. The membership fee model in the Venture Centre of Excellence in partnership with the European Investment Fund, created and operated by EIT Health.
  - 4. Service fee for programmes designed and developed with and for the client through Open Innovation as a service. EIT Health will capitalise on its existing resources and expertise to scout and accelerate innovations and offer these services to private and public actors for a service fee.

**Table 1. Income 2021-2025** 

Income (EUR million)	2021 Expected	2021 Observed	2022 Expected	2022 Observed* **	2023 Expected**	2024 Expected*	2025 Expect ed**
Membership fees	7.1	7.12	7.1	6.3	6.1	5.5	5.5
External grants	3.4	1.25	3.5	2.0	3.5	4.0	4.5
Success fees – education*	0.2	0.00	0.4		0.6	0.9	1.1
Success fees, services and consulting	1.2	2.08	2.1	0.3	3.7	5.2	5.8
RoI	0.0	0.00	0.0		1.4	1.4	4.1
Total	11.9	10.45	13.1	8.32	16.3	18.6	22.6

From Sponsorships and participation fees in Business Creation Pillar. \*\* From EIT Health Strategic Agenda. \*\*\* Based on YTD Q2 2022 numbers

#### **1.2** *Methodology*

#### **KIC** ecosystem/Partnership

EIT Health will continue to develop and maintain a well-respected community of best-in-class partners and other stakeholders who together can influence, shape and drive healthcare innovation between and across healthcare systems in Europe. The key evolution in the ecosystem is that EIT Health is pro-actively positioning itself as an open partnership that is both EU-backed and open to all who share its goals and values and who have the capabilities to contribute. The partnership model is currently under a transition phase: the KIC is defining criteria for partner admittance and a scalable model that can accommodate a growing network of organisations, to create critical mass for activity and impact at the European, as well as regional, level. Clear value propositions are being formulated for members in this open partnership, including the vast collaboration possibilities at national/EU level, the diversity of the network and the

engagement with policy makers and regulators. Applications for membership are processed quickly and transparently. Transitionary actions towards openness in calls can be found in the section below on "Activity Selection".

New membership fee models are also under development and will be finalised in 2023. The primary goals of the new fee model are twofold: accelerating growth by facilitating easier entry into the EIT Health partnership, and keeping the level of income for the institutional, legal, tax and European funding requirements. As of today, we are working along the lines of having a base fee according to organisation type (SME, public, private) that may be complemented with a variable fee component, which may be coupled to funding disbursed (from EIT or other sources) or other added-value services provided.

The External Project Partners (EPPs, or new organisations) participating in EIT Health Business Plans and proposals continue to grow from year to year with 171 new EPP's participating in the call for projects starting in 2021, and 241 EPP's participating in the call for projects starting in 2022. The main call for 2023-2025 has been launched in September (see annex Financial Support to Third Parties FSTP); however, we expect that with increased openness and planned synergies with other European Funding instruments such as Important Projects of Common European Interest (IPCEI) the number of new entities engaging will continue to rise.

Since 2022 EIT Health is undergoing major governance reform in close interaction with EIT. The new organisational set-up will make operations more efficient and ensure effective supervision/control by the KIC LE over the Co-location Centres (CLC's) and InnoStars. After general agreement by the Partner Assembly on this matter in June, the PA has approved the required updated Articles of Association at its PA meeting in November 2022. Final decisions on the adoption of the new governance models are also being taken on local level in Q4 2022 and January 2023. Implementation of the new structure, including creation of new legal entities, updating of Articles of Association at central and CLC level, and the transfer of assets, has been well- advanced by the end of 2022 and will become effective, in some cases, by early 2023. The KIC LE and 9 affiliated entities (including CLC's) are participants in the project. The new German CLC has been formed and is currently waiting for its PIC number, therefore the relevant budget is currently parked with the KIC LE until it is technically possible to include them and an amendment can be made. As agreed EIT Health will update EIT – besides the continuous exchange - comprehensively in later January.

The new governance structure will also enhance the KIC LE's influence on the organisational and Managing Directors' objectives and performance reviews at CLCs/InnoStars level. The future governance structure and contractual agreements will include the fulfilment of the Good Governance Principles across all entities.

To best serve its network and further strengthen its regional representation, the KIC already agreed in 2021 to setting-up a seventh CLC. The Austrian CLC, with its Office in Vienna, is going to be fully operational during BP 2023-2025 and will be an integral part of the KIC's network. The new CLC acts as the natural point of contact for all new Austrian Partners from this point onward and is an additional, regionally rooted point of contact, including partners previously supported by the German-Austrian-Swiss CLC.

EIT Health and its ecosystem are working to obtain other sources of funding from public budgets and are confident in achieving the Strategic Agenda targets.

#### **Activity Selection:**

As regards activity selection, Call 2021, Call 2022, and Call 2023 have fed into the current legacy portfolio. The main call for 2023-2025 has at the time of writing just been launched, therefore most 2023-2025 activities are yet to be selected and will be selected via a "Flagship concept". Irrespective of the strategic direction of a call, the following methodology is applied.

The KIC adheres to best practices in its set up, ensuring sound financial management through regular reviews and audits of its own resources and those of its activities, employing the four-eyes principle for all transactions above a certain threshold. A lean structure is controlled by the Supervisory Board. Risk management is ongoing, involving periodical reviews of the portfolio, or monitoring (including expenditure) and reflections on lessons learned coupled with risk forecasts based on those insights. There is a clear separation of functional staff – the FMT as the functional management team are the decision makers in stopping activities, independently from local interest. Management is accountable to adhere to antifraud guidelines. A whistle- blower policy is in place. From 2023, training on audit requirements will become mandatory for all staff and subgrantees, for the latter it will be executed during the contracting phase.

## In terms of call planning, preparation, submission, and evaluation of applications:

As of 2022, the KIC provided the call document to the EIT 30 days before publishing; all calls clearly outline the mandatory KPIs per activity type, ensuring applications feed into the KIC's KPI requirements. All calls remain open for a minimum of two months and are published on both the KIC's website and, as of 2022, on the EC Funding and Tenders Portal. Please see Annex Financial Support to Third Parties (FSTP) for details.

In terms of openness, since 2022, all calls have been open to all participants irrespective of their entity status. In addition, the previous €50,000 cap for External Project Partners (EPP's) was removed from the Articles of Association. As a transitionary measure, all entities (except start-ups) are requested to become an associate or core partner if funding over €50,000 will be granted. In the unlikely event that a new entity applies to become a partner and is refused, there will be no implication on the grant allocated. The project consortia requirements also have evolved: All granted projects only need to have one EIT Health partner, but – in this transition period – 50% of Innovation Project consortia must be already existing partners.

In addition, participation in KIC Calls is open to any entity established in any third country ("eligibility for participation") if considered essential for the action and only with EIT approval. The KIC outlines the rules of participation in the call document. The KIC plans and implements matchmaking events throughout the year, to support proposal ideation and to facilitate collaboration between current and new partners. In April 2022, a Matchmaking event was held in Barcelona, attracting over 154 participants, including start-ups and new organisations. Several matchmaking events took place in Q4 2022, soon after the Flagship call opened. CLCs play a key and continuous role in supporting the composition of a winning, pan European consortia.

Evaluation of proposals follow the guidelines of Annex 5 in the MGA. Criteria are based on a) project excellence and strategic fit; b) implementation; and c) impact and sustainability. EIT Health has increased the requirements on creation of societal impact that contributes to achievement of widespread and demonstrable socio-economic improvements and financial sustainability. Only projects that will contribute considerably to impact and financial sustainability are invited to the final evaluation stage.

Evaluation is performed by at least three external experts. In addition an independent expert, i.e., an EIT officer, may be present as an observer. Evaluators sign a common no-conflict-of-interest declaration and share a common fee structure. As of the beginning of 2023, a systematic review of external evaluators will take place ensuring a minimum percentage of new evaluators per call/year. Proposals follow a 2-3 step evaluation process which includes 1. remote evaluation; 2. a support programme (previously an optional step); and 3. formal hearings. The final score is calculated based on 25% of the remote evaluation score + 75% of the hearing score.

## Novelties of the new Flagship Call and Evaluation Process:

The first Flagships Call will be a year-long call with three cut-off dates: 2 November 2022, 1 March 2023 and 1 June 2023. These are the deadlines for when consortia can submit a short proposal for a dedicated call track.

#### Phase 1: Remote Evaluations/Pitch Day and Shortlisting (approx. 1 month)

Consortia will be invited to submit a short proposal form (Expression of Interest) and general information on their activity. At this stage, consortia and full activity details may not be complete. The minimum requirements to apply for Phase 1 (including eligibility criteria) are specified in the call document (please see Annex FSTP).

Proposals will be shortlisted after internal eligibility check and review. Proposals which pass both steps will go through a pre-selection step. This pre-selection step will consist of an online pitch for Innovation and Education activities and remote evaluation for Business Creation activities.

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

The support programme is mandatory step and 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 co-funding principle and refine synergies with other activities (whether part of the support programme or already in the portfolio). The support programme applies to all types of proposals and activities across the three Flagships.

In parallel, start-ups that choose the grant in return for option model 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: Hearings and Final selection (approx. 1.5 months)

Hearings will take place within two weeks of the submission of final proposals. After hearings 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 hearings scores as well as assessment of societal impact, financial contribution model, and the 1/3 co-funding principle.

Hearings evaluation will be based on the following criteria: Project Excellence and Strategic Fit (20%), Implementation and Feasibility (40%), Impact and Sustainability (40%). For details on thresholds and criteria for each phase, please consult the FSTP annex.

Before a funding decision is communicated to selected projects, ELSI experts (specifically recruited for this task) review proposals and flag issues to EIT Health's Ethical, Legal and Social Issues (ELSI) Board. All proposals are required to complete an ELSI self-assessment form. The form addresses a number of critical issues, including vulnerability and diversity of participants, etc. As of Call 2023, launched in 2022, the ELSI form reflects Horizon Europe's Ethics self-assessment form. Additional information is collected on activities incorporating clinical trials. Please see the annex on Clinical Trials. Conditional ELSI clearance is granted by the ELSI Board if the assessment reveals that one or more "ELSI requirements" should be implemented in the project deliverables before the agreement can be signed. Conditions may include, for example, appointing an independent ethics advisor or ethics board or making an ethics check involving further information/documents; adjusting methodology, etc. EIT Health's ongoing project monitoring will include ELSI compliance checks to ensure that the conditions have been addressed. The ELSI Board may also express its veto of any projects presenting insurmountable ELSI compliance issues. ELSI Board recommendations are provided to the EIT Health Strategic Management Team, to inform their decision about project selection.

As a final part of the process of building the business plan, a portfolio analysis is performed to assess how the newly selected projects will fit into the already existing portfolio (e.g. related to aspects like focus area, risk-return ratio, commercial maturity and health impact). Debriefing with the hearings' evaluators, as well as with area/pillar managers, is used to identify the main lessons learned and improvements for the next year.

Applicants receive notification of the selection result at a pre-determined and pre-published time. The selection notification includes the summary evaluation report along with pre-conditions to be fulfilled before contracting. This includes a financial review with checks such as no double funding, and no sub-granting between related entities (these checks are also performed during monitoring checkpoints in the implementation phase). A standard redress procedure remains in place and is publicly available on the KICs website. The results of the call are published on the relevant KIC website, only after contracting is complete. Call reports to EIT are provided including information such as number of proposals, ranking lists, and evaluation details.

#### **Strengthened KTI Integration through the Flagship Concept:**

Flagship activities offer a new palette of opportunities to interact with each other, strengthening the integration of the Knowledge Triangle through bringing about exchange among Education, Business Creation and Innovation type activities.

Activity	Winter/Summer School	Modules towards a labelled fellowship programme	Module on advanced high value care principles	Start-up-driven and Partner-driven Innovation projects, and Fast Track Start-up driven Innovation (DiGinnovation)	Start-up-driven and Partner-driven Innovation projects: Service Quality Assessment	Bootcamp on VBHC models	Training module for healthcare professionals (non- degree)	Start-up-driven and Partner-driven Innovation projects: health registry or biobank-based
Winter/Summer School		1		2				
Modules towards a labelled fellowship programme	1		3				6	
Module on advanced high value care principles		3			4			
Start-up-driven and Partner-driven Innovation projects, and Fast Track Start-up driven Innovation (DiGinnovation)	2					5		
Activity	Winter/Summer School	Modules towards a labelled fellowship programme	Module on advanced high value care principles	Start-up-driven and Partner-driven Innovation projects, and Fast Track Start-up driven Innovation (DiGinnovation)	Start-up-driven and Partner-driven Innovation projects: Service Quality Assessment	Bootcamp on VBHC models	Training module for healthcare professionals (non- degree)	Start-up-driven and Partner-driven Innovation projects: health registry or biobank-based
Start-up-driven and Partner-driven Innovation projects: Service Quality Assessment			4			5		
Bootcamp on VBHC models					5			
Training module for healthcare professionals (non- degree)		6						7
Start-up-driven and Partner-driven Innovation projects: health registry or biobank- based							7	

#### (1) Winter/Summer School ≠ Modules towards a labelled fellowship programme

Fellows from the labelled fellowship programme will have the opportunity to attend a Winter/Summer School as a requirement under the Label.EIT Health will link as an administrator for the activities delivered under Winter/Summer School and the Labelled Fellowship programmes. This interaction is applicable for activities under three flagships: New models to deliver healthcare, Facilitating the uptake of Digital Medical Devices and Diagnostics, and Harnessing the full potential of health data for innovation.

# (2) Start-up driven and Partner driven Innovation projects (in any flagship) and Fast Track Start-up Driven Innovation (DiGinnovation)<sup>11</sup> projects ≠ Winter/Summer School

Innovation project consortia are encouraged to identify and commit to participation in a minimum of one option among the following as appropriate to help facilitate Knowledge Triangle Integration under the flagship:

- Sit on the panel evaluating final pitches from learner participants at the end of the Winter / Summer School Track, and/or;
- Contribute to the development of challenges learner participants will address as part of the Winter / Summer School content, based on UN SDG3 related targets 3.1. to 3.9, and/or;
- Deliver a talk or lecture on the innovative technology or solution at the core of the innovation project, as well as the aims of the innovation project to Winter / Summer School learner participants as part of the learner curriculum, and/or;
- Offer a visit to Partner facilities to Winter / Summer schools learning participants to facilitate understanding of how innovation is delivered on the ground.

## (3) Modules towards a labelled fellowship programme → Module on advanced high value care principles

Non-degree education modules are expected to follow the quality criteria of UEMS EACCME for CPD accreditation, catering for healthcare professionals' national revalidation requirements. Furthermore, nondegree education modules accredited under the European Credit Transfer and Accumulation System (ECTS) will feed into the EIT Labelled Fellowship journey, permitting continued professional development for module participants.

This interaction is applicable for activities under the flagship: New models to deliver healthcare.

## **Innovation projects: Service Quality Assessment**

Healthcare professionals from innovation consortia (Service quality assessment Innovation project) will be invited to undertake the advanced module during the support programme of the innovation project. Completion of the advanced education module is mandatory for the clinical trial lead and data analysis lead in the consortium accordingly (as applicable based on consortium composition) and strongly recommended for the other consortium members. More information on the support programme will be shared with selected proposals as they progress through the process.

This interaction is applicable for activities under the flagship: New models to deliver healthcare.

## (5) Value-based Healthcare Bootcamp ≠ Start-up-driven and Partner-driven Innovation projects: **Service Quality Assessment**

Start-ups completing the bootcamp programme will be encouraged to further develop their business model and, with the support of the Regional Innovation Hubs, will be able to explore collaborative opportunities to bring their solutions and services to new markets in the form of Innovation projects.

Likewise, the start-ups participating in Innovation Projects on service quality assessment will be encouraged to apply for the bootcamp on VBHC models to speed up their business model validation.

This interaction is applicable for activities under the flagship: New models to deliver healthcare.

## professionals (non-degree)

A non-degree education module is expected to follow the quality criteria of UEMS EACCME for CPD accreditation. Furthermore, Non-degree education modules accredited under the European Credit Transfer and Accumulation System (ECTS) will feed into the EIT Labelled Fellowship journey, permitting continued professional development for module participants.

This interaction is applicable for activities under the flagship: Harnessing the full potential of health data for innovation.

## (7) Training module for healthcare professionals (non-degree) ≠ Start-up-driven and Partnerdriven Innovation projects: health registry or biobank-based

Healthcare professionals from innovation consortia (registry-based innovation project) will be invited to undertake the non-degree education module during the lifetime of the Innovation project. Completion of the non-degree education module is mandatory for the clinical trial lead and data analysis lead in the Consortium accordingly (as applicable based on Consortium composition). Participation should therefore be a planned

milestone in the project work programme.

This interaction is applicable for activities under the flagship: Harnessing the full potential of health data for innovation.

## In terms of contracting, monitoring and post-impact assessment:

As per the regular KIC procedure, contracts are signed via an electronic signature process, contain relevant financial and legal representatives, and are expected to be signed within a pre-determined time frame. This is checked by the PMO/Grant management teams before the project Kick-Off. All partners, irrespective of receiving a grant or not, receive anti-fraud and code-of-conduct materials.

A monitoring framework is in place with go/no go points checked at least once a year in the lifecycle of a project. (See Section 2 for details.) These conditions are made clear in project contracts and detailed in the Kick-off package and Project Implementation Handbook. Financial checks and audits take place periodically, alongside performance monitoring. Post-impact assessment is already underway for KIC projects. It is currently under revision and will launch officially in 2023, with an aim to capture impact, results and input in a structured, shareable manner.

## Minimum requirements for activity selection to be included in a KIC portfolio:

All of These requirements are based on EIT principles and will be supervised by the EIT in the context of Monitoring Plan 2023-2025.

Minimum requirement	Description
Setup & General Aspects  1. Sound financial management: principles of economy, efficiency and effectiveness, including a lean and cost-efficient structure that keeps	1. The KIC adheres to best practices in its set up, ensuring sound financial management through regular reviews and audits of its own resources and those of its activities, employing the four-eyes principle for all
administrative and management costs to a minimum [as per MGA Art. 7].	transactions above a certain threshold. A lean structure is controlled by the Supervisory Board.
<ol> <li>Pan-European character.</li> <li>Clear separation between KIC staff</li> </ol>	2. A Pan-European character is a strict eligibility criterion for all funded projects
delivering management and operational functions (so that staff advising the activities are not the ones ultimately making the decision to stop them).	3. There is a clear separation of functional staff – the FMT as the functional management team are the decision makers in stopping activities, independently from local interest
4. Risk management.	interest
<ol><li>Management adhering to anti-fraud guidelines. KIC has a whistle-blower policy.</li></ol>	4. Risk management is ongoing, involving periodical reviews of the portfolio, or monitoring (including expenditure) and reflections on lessons learned coupled
<ol><li>KIC employs the four-eyes-principle for all transactions and decisions above an agreed threshold.</li></ol>	with risk forecasts based on those insights.  5. Management is accountable to adhere to antifraud
<ul><li>7. Training on understanding audit requirements and interacting with auditors.</li></ul>	guidelines. A whistle- blower policy is in place. From 2023, training on audit requirements will become mandatory for all staff and subgrantees, for the latter it will be executed during the contracting phase.
	6. See no. 1
	7. From 2023, training on audit requirements will become mandatory for all staff and subgrantees, for the latter it will be executed during the contracting phase
Call planning and preparation:	

- 1. KIC adopts EIT templates for call documents.
- 2. KIC applies to get call approval from EIT (and time limits apply).
- 3. Self-assessment form for meeting the KPI requirements to be completed at application stage.
- 4. KIC confirms the case for financial sustainability and co-funding.
- 1. There are currently no EIT templates for call documents that we are aware of that are available for adoption. The KIC would welcome call templates.
- 2. The KIC provides call documents to the EIT 30 days before publishing.
- 3. All calls clearly outline the mandatory KPIs per activity type, ensuring applications feed into the KIC's KPI requirements. The application forms require mandatory KPIs for different project types
- 4. All calls clearly outline the Financial sustainability and co-funding requirements. The call is confirmed by EIT before launch.

#### Outreach to beneficiaries:

- 1. KIC publishes the call on the KIC's website and on the EC Funding & Tenders portal.
- 2. KIC puts procedures in place for guiding applicants and potential beneficiaries.
- 3. KIC has a process for supporting proposal ideation.
- 4. KIC has a process for facilitating brokerage and matchmaking among existing and new partners.
- 1. All calls remain open for a minimum of two months and are published on both the KIC's website and, as of 2022, on the EC Funding and Tenders Portal. Please see Annex Financial Support to Third Parties (FSTP) for details.
- 2/3. The KIC has set procedures in place for guiding applicants and potential beneficiaries. Collaboration leads in all CLCs have the primary role of guiding beneficiaries and supporting proposal ideation.
- 4.The KIC plans and implements matchmaking events throughout the year, to support proposal ideation and to facilitate collaboration between current and new partners. Communication and marketing resources are allocated to ensure reach and engagement.

#### Process for submitting applications:

- 1. A common minimum period when a call remains open.
- 2. Submitting a report to EIT confirming the proposals submitted, ranking list and evaluation method followed.
- 3. Formal applicant notification about the selection result, attaching the summary evaluation report and the conditions to be fulfilled before contracting (if any).
- Publishing the selection results on the relevant KIC website, after their contracting is complete.
- 1. All calls remain open for a minimum of two months and are published on both the KIC's website and, as of 2022, on the EC Funding and Tenders Portal.
- 2. This report is submitted via the obligatory DELs in the BP, the call reports and corda submissions.
- Applicants receive formal notification at a predetermined time outlined in the call document, containing the summary report and conditions to be fulfilled before contracting and administrative next steps.
- 4. Selection results are published on the EITH KIC website when both the GA is signed with the EIT and contracting is complete. This is led by the comms and dissemination in house team.

#### Process for evaluating applications:

- 1. Criteria that combine Horizon Europe (i.e. a) Excellence, b) Impact, c) Ouality and efficiency of the implementation) with KIC portfolio strategic fit and compliance with the financial sustainability principles and knowledge triangle integration and, for multi-beneficiary projects.
- Evaluation performed by a minimum
- 1. Evaluation of proposals follow the guidelines of Annex 5 in the MGA. Criteria are based on a) project excellence and strategic fit; b) implementation; and c) impact and sustainability. EIT Health has increased the requirements on creation of societal impact that contributes to achievement of widespread and demonstrable socio-economic improvements and financial sustainability. Only projects that will contribute considerably to impact and financial sustainability are

- number of external experts to ensure fairness and transparency.
- 3. Report by independent expert observer.
- 4. Pool of external evaluators renewed on a periodic basis (e.g., min percentage of new evaluators).
- 5. Evaluator contract with conflictof interest declarations (common template).
- 6. Remuneration of external evaluators (common base fee structure).
- 7. Mechanism to evaluate external evaluators with the option to swiftly remove those who do not meet the expected standards.

invited to the final evaluation stage.

- 2. Evaluation is performed by at least three external experts.
- 3. In addition an independent expert, i.e., an EIT officer, may be present as an observer.
- 4. As of the beginning of 2023, a systematic review of external evaluators will take place ensuring a minimum percentage of new evaluators per call/year
- 5-6. Evaluators sign a common no-conflict-of-interest declaration and share a common fee structure.
- 7. An evaluation mechanism is in place for evaluators. Feedback on evaluators is gathered from review organizers (chair and rapporteur) on the panel. Reviews are recorded in case of specific audit or appeal. Evaluators can be swiftly removed in case of any demonstrated "misbehaviour" noted by the chair/rapporteur and the partners or appeal/complaint from the team. We are mindful also about written feedback and coherent scoring. If written feedback and scoring are not coherent or are of poor quality, an evaluator is removed.

## Process for informing applicants:

- 1. A standardised redress/appeal procedure in place.
- 2. Dissemination of evaluation results.
- 1. A standardised redress/appeal procedure is in place and publicly available on the KIC website and in the call document.
- 2. Evaluation results are shared in full with the selection notification at a predetermined and pre-communicated time.

## Process for contracting

- 1. Fixed number of days for completing contract negotiation.
- 2. Each partner identifies individuals with legal and financial responsibility, who are named in the contract.
- 3. Each partner receives code of conduct and anti-fraud materials.
- 4. Adopt a common electronic signature process to minimise contractual delays between the KICs and partners.
- 1. The KIC outlines a set time period for completing contract negotiation. As of mid 2023, the contracting period will take place before the kick-off in order to avoid implementation delays
- 2. The legal and financial responsible persons per partner are identified. Keeping this information upto date is a responsibility outlined in the contract itself
- 3. All partners irrespective of receiving grant receive code of conduct materials which include some anti-fraud element. A comprehensive anti-fraud policy is an obligatory deliverable for the KIC in 2023. These materials will be shared with all stakeholders when ready.
- 4. As per the regular KIC procedure, contracts are signed via an electronic signature process. In past years this was limited to project grant agreements, but in 2023 has been extended to all agreements. Improvements have already been noticed.

#### Process for monitoring

1. Confirmation of no subgranting between related entities.

1-2. Financial checks and audits take place periodically, alongside performance monitoring. These confirm no sub-granting between related entities and no double

2. Confirmation of no double funding for the same work.

funding for the same work. In addition these declarations must be made by all applicants before funding is received.

Process for post-impact assessment

- 1. Facilitate dissemination/communication/exploitat ion of results.
- 2. Follow the impact of KAVA output after a certain period.
- 3. Engage in Cross-KIC activities.
- 4. Providing input to innovation policy discussions.
- 1. Post-impact assessment is already underway for KIC projects. It is currently under revision and will launch officially in 2023, with an aim to capture impact, results and input in a structured, shareable manner. Success stories are shared with the communications team who then disseminates according to the appropriate channels.
- 2. As per the new contractual obligations, the impact of KAVA output is followed up until 5 years after funding.
- 3. The impact of Cross-KIC activities will be followed, partners are continuously encouraged to engage in Cross-KIC activities.
- 4. The PASR (Public Affairs and Stakeholder Relations) team is responsible to feed lessons learned and results from to the relevant policy discussions. When the KIC begins to publish results on the Funding and Tenders Portal, this will provide a more structured opportunity.

## Data from Completed Calls which feed into BP 2023-2025

The following graph shows data from the calls feeding into 2023-2025 thus far. As mentioned above, the Flagship call, which was launched in September, will be **the first major new intake** into BP 2023-2025.

In line with the citizen science dimension of Open Science, EIT Health recognises involvement of citizens and patients in the health innovation pathway as essential to achieving our mission and delivering societal impact. For this reason, in addition to a highly integrated and inclusive partnership model (~ 150 partner organisations and institutions from academia, business, research and healthcare delivery) that is designed to leverage the innovation potential of society as a whole, EIT Health promotes contributions of citizens and patients as co-designers and co-creators and pursues relationships with European civil society organisations (e.g. European Patients Forum and BioMed Alliance). In BP 2023-2025, some 2.25 million patients and citizens will benefit/be involved, though the complete amount will only be measured at the reporting stage.

When it comes to open access to research results, the following actions are taken to ensure open sharing:

- Projects can report on number of publications accepted for publication as a KPI.
- Issues of dissemination and sharing of scientific results are touched upon in the monitoring process.
- In High Value Care projects, a special focus is put on systematic data capture, transparent outcome comparison across providers, and creation of learning communities, to further disseminate and replicate results. Additionally, generation of national and federated network registries is welcome in the projects.
- A strategic initiative of the High Value Care Forum features the use cases of successful implementation of HVC initiatives, that can be used as blueprints for other institutions.

An example of an Innovation Project focusing on open science is HARMONICS (2022-2024). HARMONICS targets implementation of a high value care model for effective value creation throughout the stroke care pathway. The project will benchmark best practices and clinical results to ensure optimal stroke outcomes, propose innovative value-based payment models, enhance efficiency of healthcare systems at regional level and improve patient value perception and quality of life.

#### Social science

The involvement of experts in social sciences, particularly health economics and behavioural sciences, is of

high relevance to the success of EIT Health. Engagement of experts from the social sciences, arts and humanities are important to foster the understanding of culture, ethics and values that are needed to contribute to the successful execution and implementation of many health innovation projects.

#### **Gender dimension**

EIT Health is committed to gender mainstreaming of its activities with a gender responsive portfolio (encompassing education, entrepreneurship and innovation activities) and balanced gender representation in staff and decision-making positions to create a fully inclusive innovation ecosystem.

An EIT Health Gender Mainstreaming Policy is to be defined by December 2022 and adopted in 2023, outlining general goals, objectives and approach, as well as the organisational arrangements for implementation of the policy. The Gender Mainstreaming Action Plan will define a short time horizon for implementation of the policy, committing to a set of concrete steps undertaken based on sufficient gender data and analysis. This Action Plan will include: 1) an impact assessment and audits of procedures and practices to identify gender bias; 2) innovative strategies to correct any bias; 3) targets and progress monitoring based on indicators.

The call proposal forms for all pillars now systematically include an ELSI self-assessment form that questions projects on gender balance. In 2021, EIT Health began collecting structured data, including gender data, on participants in funded projects. This data collection at the reporting stage will continue. It will be a basis for future insights, and can provide knowledge, for example, on the gender balance of our learners or the CEOs of supported start-ups. BP 2023-2025 also includes activities directly targeting or benefitting women, e.g. the Be RIGHT Innovation Project, with breast cancer risk management; the Business Creation pillar's Women Entrepreneurship Bootcamp; and in Education, Future Female Founders Summer School.

In addition, EIT Health is implementing since 2022 and will continue in 2023 a programme on its culture and values, where diversity aspects are also being addressed. This has been started with the EIT Health own workforce, and will be expanded to partners and other stakeholders at a later point.

#### 2. **Impact**

#### 2.1 KIC's pathways towards impact

EIT Health has initiated different actions to secure that, in the next Business Plan period, the KIC improves the ability of its pathways to achieve the expected outcomes and economic and societal impacts specified in the KIC Strategic Agenda and in the EIT Impact Framework. On an operational level, the KIC is improving means to demonstrate impact by improving the collection and accessibility of its data, to continuously assess the fulfilment of impact targets, thereby allowing maximisation of expected outcomes and impacts.

To strengthen its pathways, the KIC has regrouped its activities portfolio under the Flagship concept. Flagships aim at including closer-to-market innovations to secure higher KPI fulfilment and measurability. In practical terms, Innovation projects will be required to have a higher maturity level at entry point than in previous years and the Innovations launched on the Market Core KPI will be expected no later than one year following project closure instead of three years.

Flagship topics are defined yearly, with the first Flagship wave being implemented in 2023. Overall, the first Flagships – have a focus on EIT Health's objective of addressing the societal challenges of the ageing population, as well as our strategic agenda. The Flagship on new models to deliver healthcare focuses on value- based healthcare, a concept particularly of importance for the ageing population. The Flagship on facilitating the uptake of digital medical devices in Europe groups action around a segment of health care development with relevance to the older population. The Flagship on harnessing the full potential of health data for innovation aims at understanding the importance and relevance of data sharing in informing and improving the continuum of care pathways. These overarching Flagship topics aggregate several individual pillar actions. To ensure that each selected action indeed provides a closer-to-market action and incorporates a Flagship, the support programme to finalise each activity before selection has been integrated into the Flagship concept. The following are more detailed descriptions of how our various pathways contribute to impact.

#### **Business Creation**

The Business Creation pathways will contribute to a number of core EIT KPIs, especially to:

- EITHE0.3.1 Supported start-ups/scale-ups
- EITHE0.6.1 Investment attracted by KIC supported start-ups/scale-ups

Business Creation activities will support an estimated 419 start-ups and scale-ups through our Accelerator programmes and contribute to attracting more than €601 million in investment. Invest Health will begin its operations as service provider and assume portfolio management responsibilities of EIT Health assets. The ability to support portfolio companies will maximise the potential of generating perennial revenue streams to sustain its innovation support activities.

## Education

The Education pathways will contribute to a number of core EIT KPIs, especially to:

- EITHE05.1 Start-ups created by students enrolled and graduates from EIT labelled programmes
- EITHE05.2 EITRIS EIT RIS start-ups created of EIT labelled programmes
- EITHE07.1 Graduates from EIT labelled programmes
- EITHE07.2 EIT RIS Graduates from EIT labelled programmes
- EITHE08.1 Participants in (non-degree) education and training
- EITHE08.2 EIT RIS Participants with (non-degree) education and training

Education will pursue the objective of allocating at least 75% of the EIT grant to labelled programmes in the portfolio from 2024. This will be achieved through the addition of two new master programmes, the implementation of the Recognition Scheme for degree programmes in their post-funding phase, as well as the launch of EIT labelled fellowships. During 2023, the KIC will submit a scheme for non-degree labelled certification: the aim is to offer labelled certification learning journeys (non-degree) involving the EIT Health Academy platform. This will bring to 700+ the number of graduates from EIT labelled programmes.

The KIC will contribute to the Deep Tech Talent Initiative by training 2,300 learners in fields such as

biomedical engineering, digital health and health data. A contribution can also be expected from the activities of the WorkInHealth - European Institute for Talent Skilling Intelligence that will will run a gap analysis on skills in the health sector in 2023, and will match talents with industry.

All programmes in the education portfolio will aim at attracting RIS participants to education and training activities. Degree programmes will additionally support the increase in the number of Graduates from EIT labelled MSc/PhD programmes and the creation of start-ups of EIT labelled MSc/PhD programmes in RIS countries. The implementation and deployment of the other two segments of the EIT Label Framework, namely Labelled Fellowship and Labelled Competence Certification for non-degree participants, will also target RIS participants.

### Innovation

The Innovation pathway will contribute to a number of core EIT KPIs, especially to:

- EITHE01.1 Intellectual Property Rights
- EITHE0.2.4 Innovations launched on the market
- EITHE0.6.1 Investment attracted by KIC supported start-ups/scale-ups

The marketed innovations deriving from Innovation Projects will address the European market, with the potential to scale to other markets like the US and Asia. The European digital health market was valued at USD

47.6 billion in 2022 and is expected to expand at a compound annual growth rate (CAGR) of 27.1% from 2022 to 2030. The European medical technology market was estimated to be roughly €140 billion in 2020.¹ The innovative solutions launched by Innovation projects supported by EIT Health in 2017-2023 will aim to impact

1.5 million citizens and patients by 2024.

#### **Regional Innovation Scheme**

All actions within the Regional Innovation Scheme pathways will contribute to a number of core EIT KPIs, especially to:

- EITHE03.2-EITRIS EIT RIS Start-ups/scale-ups supported
- EITHE06.2-EITRIS Investment attracted by KIC supported EIT RIS start-ups/scale-ups
- EITHE08.2-EITRIS EIT RIS Participants with (non-degree) education and training

The InnoStars Innovation Awards aim at funding proof-of-concept phase projects of business-academic consortia to progress towards commercialisation and push them to the next maturity level measured on the CIMIT Healthcare Innovation Cycle (projects are selected with completed CIMIT 2, Idea phase, and by the end of the call the projects complete CIMIT 3, PoC phase). The call is expected to support 30 projects in progressing at least one maturity level between 2023-2025, as anticipated by the KPI (EITHE01.3-EITRIS). The InnoStars Business Planning Awards and InnoStars Investment Awards aim to support at least 90 startups in the following business plan cycle (EITHE03.2-EITRIS), and a total of €17,250,000 in investment is expected to be attracted by RIS start-ups supported by the RIS (EITHE06.2-EITRIS). We plan to engage and train at least 2,550 individuals from RIS countries in our programmes between 2023-2025 (EITHE08.2).

## **Corporate Affairs**

Considering the KIC's increased co-funding rate, and the nature of closer-to-market innovations, the Flagship concept incorporates a wider network of stakeholders earlier on in the KIC's pathways. This helps the KIC ensure long-term functioning of its pathways from the perspective of their financial model and ensure that synergies between alternative European, national and regional instruments are identified and integrated into actions from the beginning. The activities of Corporate Affairs are thus integrated even further than before. Corporate affairs activities are cohesive and consistent, with coordinated execution on the national and regional level by the CLC teams and on the pan-EU level by the Central Office team. Opportunities are collectively assessed and leveraged, ensuring communications, dissemination and stakeholder engagement efforts reach diverse audiences. EIT Health has a unique role to play in connecting stakeholders from across the EU health landscape. Communications, dissemination and exploitation raise

<sup>&</sup>lt;sup>1</sup> Medtech Europe: https://www.medtecheurope.org/datahub/market/

awareness and understanding of healthcare challenges (Flagship domains) that our community is committed to address, reinforcing a clear "value-add" to the healthcare sector. Public affairs and stakeholder relations activity build synergies with EU policies and funding mechanisms, devising new models of cooperation and cross-border collaboration and contributing to acquisition of additional funding. Examples include the EIT Health/EIF VCoE, the 2021-2022 Pilot Agreement with the EIC, and efforts alongside policymakers for deployment of the IPCEI in Health across Europe. The Think Tank connects key opinion leaders to identify important areas where our partnership can align resources and capabilities to build collaborations around the EU. Programme marketing aims to maximise recruitment and participation in (income generating) programmes and the growing Alumni community will serve as the lynchpin to connect partners, start-ups and learners, enriching the innovation ecosystem for all.

While improving its pathways, the KIC has also taken action toward improving the collection and accessibility of its data, enabling continuous assessment of fulfilment of impact targets and maximisation of expected outcomes and impacts. EIT Health has joined an effort with the EIT and other KICs to develop and implement a technology strategy that addresses gaps in technology capabilities related to Horizon Europe, EIT's trajectory, and individual KIC trajectories. This joint effort can improve the capabilities and quality of the IT services while lowering procurement costs for EIT and the KICs and allowing for development of tailor-made solutions. The software implementation is to start from the second half of 2023. It is set for completion in 2024 and is to be fully operational from 2025 onwards. To secure imminent and quick improvements, the KIC set-up a visualisation and monitoring KPI tool based on the end-user friendly BI software solution in September 2022. This KPI monitor allows instant, day-to-day review of all project KPIs and provides a transparent, sharable, and KIC-wide review of all available data points on all programs. This lets the KIC ensure that available data points are accessible, easily usable and can be integrated into day-to-day assessment of KPI fulfilment.

Table 2.1. List of EIT Core and EIT KPIs: Year 2023, 2024 and 2025

EIT area	KPI Code	EIT KPI	Target 2023-25	Indicate WP(s)
	[EITHE02.1]	Innovations launched on the market: Number of innovations introduced on the market during the KAVA duration or within 3 years after completion. Innovations include new or significantly improved goods or services or processes sold.	42	WP3
Innovation [EITHE02.2] Innovations launched on the market by organisations from the market by organ		6 or 15%	WP3	
	[EITHE02.4]	Innovations launched on the market with a sales revenue of at least €10 000 documented.	42	WP3
Business	[EITHE03.1]	KIC Supported Start-ups/Scale-ups: Number of start-ups and scale-ups supported by KICs for at least 2 months in year N, provided the KIC's services contribute to the company's growth (including potential growth).	419	WP 2,4
Creation	[EITHE03.2]	KIC Supported Start-ups/Scale-ups registered in EIT RIS countries: Number of start-ups and scale-ups registered in EIT RIS country supported by KICs for at least 2 months in year N.	62 or 15%	WP 2,4
	[EITHE04.1]	<b>Start-ups created:</b> Number of start-ups established in year N	9	

EIT area	KPI Code	EIT KPI	Target 2023-25	Indicate WP(s)
		as a result / based on the output(s) of KAVA(s), or start-ups created for the purpose of an innovation project to organise and support the development of an asset (but not later than three years after the completion of KAVA).		WP2,3
	[EITHE04.2]	Start-ups created in EIT RIS countries: Number of start-ups registered in EIT RIS country in year N and established as a result/ based on the output(s) of KAVA(s), or start-ups created for the purpose of an innovation project to organise and support the development of an asset (but not later than three years after the completion of KAVA).	1 or 20%	WP 2, 3,
	[EITHE04.4]	Start-ups created having a financial transaction of at least €10,000 EUR for a service/product (result of the KIC KAVA) sold to customers.	9	WP 2, 3
	[EITHE06.1]	Investment attracted by KIC-supported start-ups and scale-ups.	601M€	WP 2,3
	[EITHE06.2]	Investment attracted by KIC-supported start-ups and scale-ups established in EIT RIS countries: Total EUR amount of private and public capital attracted within year N by supported start-ups/scale-ups established in the EIT RIS countries, that have received KIC business creation services support or HEI CBI project support of total duration of at least two months, within a maximum of three years following the last received KIC KAVA incl. project support activity.	90** or 15%	WP 2,3
	[EITHE05.1]	Start-ups created by students enrolled and graduates from EIT-labelled programmes.	30	WP1
	[EITHE05.2]	Start-ups established in EIT RIS countries by students enrolled and graduates from EIT-labelled programmes:  Number of start-ups established in EIT RIS countries in year N by students enrolled and graduates from EIT labelled MSc and PhD programmes or by learners / participants in other EIT labelled activities. To be eligible, a start-up should be created during EIT labelled programme (by students, participants) or within 3 years from the graduation (by graduates) or within 1 year in case of other EIT Label activities.	5 or 19%	WP1
	[EITHE07.1]	Graduates from EIT-labelled programmes.	710	WP1
Education	[EITHE07.2]	Graduates from EIT-labelled programmes with citizenship in EIT RIS Countries: Number of graduates from EIT labelled master's, PhD programmes and other education activities awarded EIT Label (in year N) with citizenship in EIT RIS countries.	60 or 15%	WP1
	[EITHE08.1]	Participants in non-labelled education and training: Number of successful participants in EIT professional development courses, online training courses and other education/training activities delivered or in a process of delivery (by country and type of programme), including data on country of citizenship and gender. Only participants who successfully finished the programme will be counted. For this KPI, only those education and training activities which have clearly defined learning outcomes, and which carry out competency assessment method are applicable.	12,720	WP 1-5

	[EITHE08.2]	Participants in non-labelled education and training with citizenship in EIT RIS countries: Number of successful participants in EIT professional development courses, online training courses and other education/training activity delivered or in a process of delivery with citizenship in EIT RIS countries. Only participants, who successfully finished the programme, will be counted. For this KPI, only those education and training activities which have clearly defined learning outcomes, and which carries out competency assessment method are applicable.	2,544 * *or 20%	WP 4
Knowledge Triangle Integration/	[EITHE10.1]	Active partners collaborating in the KIC: Number of active partners collaborating in the KIC per profile (research; business; HEIs; cities, regions, NGOs; other). Active partner means organisations signed contracts with KICs and with implementing activity role in the reported year (expressed in terms of costs in the budget).	585	WP6
KIC ecosystems	[EITHE10.2]	Active partners registered in the EIT RIS countries collaborating in the KIC: Number of active KIC partners registered in the EIT RIS countries. Active partner means organisations that signed contracts with KICs and with implementing activity role in the reported year (expressed in terms of costs in the budget).	87 or 15%	WP 4,6
	[EITHE11.2]	Financial sustainability coefficient	21.8%	WP7
Leveraging	[EITHE11.1]	FS Revenues	47.7 M€	WP7
investments in R&I	[EITHE12.1]	KICs SIA funding rate: EIT funding divided by the total value of the entire portfolio of activities implemented by the KIC during a given implementation period, including both EIT Funded Activities (EFAs) and Non-EIT Funded Activities (NEFAs).	70%	WP7
	[EITHE13.1]	<b>Financial asset valuation:</b> Value of Financial Assets held by KIC at end of the reporting year in EUR.	25 M€	WP7
Horizontal Outputs	[EITHE18.1]	% of less represented gender in top governance and management positions combined.	50%	WP6
Strengtheni ng I&E capacity of higher education institutions	[EITHE20.1]	Number of new partnerships established as a result of the HEI Capacity Building Initiative: New partnerships established by participating HEIs and businesses, research organisations, other actors.	36	WP1
RIS-specific indicators	[EITHE22.1]	Number of new and established KIC Partners from RIS countries: This indicator will measure:  New KIC Partners from RIS countries. Established KIC Partners from RIS countries.  Mof KIC Partners from RIS countries among all KIC partners.  Mof KIC Partners from the EU-13 Member States among all KIC partners (for each KIC and overall).  Reference to a specific KAVA.	81	WP4

## 2.2 *Measures to maximise impact – Dissemination, exploitation and communication*

Corporate Affairs (CA) activities are a vital component in achieving EIT Health's ambitions, particularly as we redefine our strategy around the Flagship concept and a greater partner-centric approach. CA, and specifically public affairs and stakeholder relations (PASR), will contribute to our financial sustainability strategy through proactive identification and pursuit of synergistic alliances with instruments and initiatives

offering funding possibilities at the EU, regional and national levels. The activities of External Communications and Marketing (complemented by PASR and Think Tank engagement with political, policy and opinion leaders) build visibility among diverse stakeholders, raising awareness and understanding of EIT Health and its value to society, and connecting to stakeholders to shape an environment favourable to innovation and entrepreneurship. Internally, the focus is on reaching staff and partners with high quality, integrated communication that is consistent with the corporate narrative and aligned to EIT Health's core objectives.

KIC's overall planned contribution to the development of the EIT Community brand: EIT Health branding will continue to be closely aligned with the EIT Community brand. The visibility of the EIT Health brand and EU/EIT logo is crucial in the dissemination of our mission and activities and an inherent element of all awareness raising and visibility activities. Since 2019, we have been, alongside EIT, building excellent brand recognition and equity. The digital colour palette was revised in 2022 to ensure full compliance to the EIT brand. Branding guidelines, including a comprehensive brand book, is provided to all activity leads and start-ups with clear instructions and guidance for use. They are available on both Partner and staff digital platforms. Training is provided as needed. Business Plan activities receive a branding briefing and monitoring/reporting in collaboration with the PMO. EIT Health aligns with and supports relevant activity within the wider "EIT family" (such as the EIT Awards) to enhance the groundswell of visibility for EIT, the community and EIT Health. Engagement with EIT is frequent, input is sought (ie, press release review and coordination), and shared planning across the EIT Community (e.g, InnovEIT, or R&D Days) is routine. EIT Health contributes to establishing EIT Community Hubs and visibility of EIT in the RIS countries.

Along with building its own Alumni Community, EIT Health has been leading the cross-KIC EIT Alumni as part of the Strategic Education Cluster since January 2022. This joint endeavour creates a sense of community that strengthens the brand of EIT. Regarding marketing of programmes, the marketing team will continue to work closely with activity managers and with partners to effectively promote funded Education and Business Creation activities to target audiences. Multi-channel campaigns will be executed to leverage brand-compliant marketing materials and platforms, e.g., all activities are promoted via the EIT Health website and social media channels, which are all brand compliant. Branding guidelines are shared with partners to ensure they give visibility to the EU and EIT support and financing when promoting the activities via their institutional channels. Specifically in relation to the promotion of EIT labelled degrees and diplomas, relevant standardised information to increase awareness and drive interest and subsequent participation will be made available on the website. A pilot campaign with a specialised education marketing agency was conducted in 2022, to gain traction and nurture leads. Assessment of its success will help inform methodology deployed in 2023-2025. The KIC will lead the marketing and recruitment of the new degree programmes and will kick start with comprehensive preparation in 2023. As EIT Health will administer the new label segments (Fellowship and Non-degree education), the KIC plans to take ownership of the "go-to" markets for these programmes.

An overview of the KIC's planned external communication activities and achievements across Europe: External communication continues to focus on reinforcing understanding of the EIT Health mission, activities and achievements, as well how we operate as a matured organisation. For 2023-2025, we have greater impetus to clearly express the contribution EIT Health is making to overall EU policy goals through the four Flagship domains, and to communicate the shape of our future portfolio. We will execute compelling dissemination of the successes generated from our evolving and more consolidated portfolio of projects and programmes. Our mix of content and channels targets key audiences, including patients and citizens. All content that is disseminated publicly – whether on the EIT Health website, social media, or (more rarely) in print – is developed with the patient and citizen in mind. There is continuity of key annual deliverables, such as external versions (targeted for the "layman") of our Business Plan and Annual Reports. These deliverables help to promote the KIC, driving increased and improved understanding of who we are and what we do. Corporate materials, such as a company brochure, core slide deck and message house, will be revisited on an ongoing basis to reflect organisational shifts strategically and operationally. These materials are available to all staff to ensure better cohesion and unification across the corporate brand, internally and externally.

**Digital Communications:** The KIC will maximise the potential of digital content across numerous channels in terms of content format, timelines and interaction with audiences. The most externally visible channels, the EIT Health website and "corporate" social channels, show increasing interactions and touchpoints with

audiences, quarter on quarter, year on year. "Internal" platforms, including "Connections", used to engage with Partners and other members of the network, and the "Compass" intranet, remain a focus. Plans are in place to further increase awareness, drive value, enact changes in behaviour (e.g., recruitment into programmes), demonstrate thought leadership and expertise and provide a sense of belonging to EIT Health's mission. Exchange and co-creation with the wider EIT Health Community, including start-ups, students and senior healthcare professionals, takes place on the EIT Health Alumni Network platform. In regional and topic-related groups, health innovators can access Alumni benefits, plan projects together, post job offers, share needs or find mentoring in a specific field. The platform also facilitates EIT Health programme coordination. As of July 2022, the platform had 3,750 members, with an average of 138 sign ups per month since its launch in 2020.

The workplan for 2023-2025 specifically covers:

- Technical management of channels, including SEO strategies and data analytics.
- Improvement of user interface and user experience.
- Development of diverse and targeted content, (e.g., a mix of corporate, marketing, thought leadership content) to be shared via all channels.
- Acquisition methods to drive traffic to the website and followers across social media.
- Methods to drive engagement with content on social media.
- Support for pillars and CLCs relating to content to be shared via central channels.
- Evaluation and reporting including monthly analytics and a quarterly dashboard.

Metrics include, for the website: number of site visitors and page views, and average visit time; for social: new followers, engagement rates, social media impressions and share of voice (compared to other KICs and EIC).

Media Relations/Press Office: The work plan builds on achievements of previous years, where relationships now exist between EIT Health and key media outlets across the EU (e.g., Politico) and also at the national level, though, in some regions, media engagement efforts are still in their infancy. The priority for media engagement is still profile raising and share of voice. Targeted outlets predominantly cover health, but also consumer, business, fintech, and trade. The media workplan for 2023-2025 will include:

- Media monitoring, landscape analysis, media list maintenance.
- Identification of opportunities that promote the KIC and its activities and showcase our portfolio, coupled with the maintenance of a media calendar of specific milestones with media/news value – i.e., signing of MoUs, project results, investment round successes for our supported startups/SMEs, disease awareness days, and winners of competitive programmes like Catapult and Wild Card.
- Pan-EU, proactive and reactive press office work, diverse target outlet outreach, including top tier targets (Politico and Financial Times). This involves pitching ideas and stories, offering interviews with staff and partners and cultivating relationships.
- Media content development: press releases, feature articles, opinion editorials often involving partner organisations – and backgrounders.
- Briefing and support for defined EIT Health spokespeople, including management of interviews, development of briefing materials and liaison with the media.
- Support for CLCs in local activation of the media strategy, including sharing the central plan and providing editable or template materials that can be rolled out locally.

Relevant metrics are: number of media articles, reach, articles with EIT Health in focus or passing mention.

Stakeholder engagement and thought leadership: The Flagships domains offer greater opportunities for involving partners and exploiting the subject matter expertise that sits within the network. Two main strands of activity are: (1) engagement with policymakers at EU and national level; (2) relationship building with third- party stakeholders to form strategic alliances. The Think Tank continues as a thought leadership platform for engagement for pan-EU and national-level subject matter experts and opinion leaders. Thought leadership also includes organisation of, or participation in, high-level policy events; communications materials intended for diverse external audiences, such as adaptations of Think Tank reports, videos and infographics; and specific content for the website and other channels, including opinion editorials, social media takeovers etc.

**Events:** The focus will remain on implementing events that achieve partner involvement, engagement and collaboration, such as Matchmakings, but also a newly devised touchpoint, "The Partner Forum," providing partners with the platform to input and shape the organisational strategy. In 2024 we will hold the first EIT Health Summit in this funding period. It will reflect a revised Summit strategy leading to planning a more portfolio/partner focused event that aims to celebrate portfolio and organisational successes and achievements, as well as an increasingly significant standing in the healthcare innovation space. This smaller event is to take place every 18 months. External event participation opportunities, such as hosting a session at The European Health Forum Gastein every year, is also an event mainstay.

**Dissemination (Value and impact):** Strong emphasis is placed on highlighting, showcasing and promoting specific achievement and outcomes that demonstrate not only the beneficial products and services we support in their journey to the market (for example by noting project successes, such as CE marking), but also the broader contribution EIT Health is making to healthcare ecosystem development, cross border collaboration, healthcare policy development, patient and citizens, and, more broadly, society. The most compelling examples are curated across organisational channels with varied content and formats to target broad and diverse audiences – including patient and citizens via public-facing channels or policy makers via more targeted dissemination (i.e., a policy newsletter to a defined distribution list). Examples include:

- The continuation of the Spotlight Series / Disease Awareness Days digital and media campaigns to highlight relevant portfolio case studies.
- Information provided on the website relating to innovation projects, programme opportunities, a "news and views" section.
- Dissemination of policy statements and Think Tank research outputs (shared with Brussels-level actors directly) and the media.

Focus will also be placed on the "partner perspective" — i.e., partner testimonials on the network, collaboration and outputs of the projects and programmes they lead. There will be increased focus on sharing achievements and best practices within the network, deploying internal communications channels.

Table 2.2. Preliminary list of expected results for dissemination for BP 2023/25 Portfolio

Area	Results	Good Practices
Public Affairs and Stakeholder Relations/EIT Health Think Tank	<ul> <li>Outcomes of meetings with relevant EU policymakers/forging alliances/signing MoUs</li> <li>Policy events organised/attended</li> <li>Policy documents/Think Tank reports published</li> </ul>	Public Affairs Quarterly Newsletter addressed to EU Policymakers
Innovation	<ul> <li>Investment attracted by start-ups in Innovation projects</li> <li>CE Markings obtained</li> <li>Data published</li> <li>Scientific Reports published</li> <li>Implementation of high-value approaches and marketed innovations in healthcare systems</li> <li>New partnerships and collaborations</li> </ul>	<ul> <li>HVC: library of cases, summarising the best practices of implementing new innovation pathways focused on measuring and maximising patient outcomes in various healthcare systems.</li> <li>Spotlight series featuring the top innovations.</li> </ul>

Business
Creation

- Investment attracted by EIT Health supported start-ups and SMEs
- Outcomes of Programmes such as winner of Wild Card, Catapult, and Gold Track
- Awards and other high-profile accolades such as Bits and Pretzels Healthtech
- Investment attracted (to VCoE)
- New investors joining (VCoE)
- High potential companies receiving investment (VCoE)
- Donors attracted (WiH)
- Revenue reinvested (Invest Health)

- Dealroom platform to celebrate the start-ups that have raised impressive funds in the previous month.
- European Health Catapult is selecting start-ups across Europe and promoted regionally in each Regional Innovation Hub. Finalists are invited to EIT Health Summit to pitch in front of investors.
- Social media posts to celebrate start-up selection to Business Creation programmes

Area	Results	Good Practices
Education	Learners who have attended an EIT Health supported training/course and have subsequently achieved a note-worthy innovation or entrepreneurial outcome (e.g. starting a company)  EIT Health Academy – Pathways     Professionals adopting HVC practice     How to bridge the gap among the graduate stage and the action to become innovator/entrepreneur     Awards and other high-profile accolades	<ul> <li>Navigable learning pathways on EIT Health Academy.</li> <li>HVC: professionals declaring change in practice (assessment).</li> <li>Mindset creation for the entrepreneurial intentions to shift and increase (assessment).</li> <li>Showcasing best practices and success stories from EIT Health labelled degree programmes</li> </ul>

## 2.3. Expected impact of the activities for 2023-2025 under the Regional Innovation Scheme

The ambition of EIT Health RIS programme is to create an enabling environment for healthcare innovation in European countries with moderate and emerging innovation capacity (EIS 2022). Through RIS activities, we contribute to the EU efforts to turn the diversity of the EU's territories into a strength, by leveraging the specific assets of each region and facilitating collaboration to build new EU value chains. We will enable regions with aligned areas of specialisation, complementary capabilities, and different levels of innovation performance to collaborate and take forward joint innovation projects targeting EU priorities. We will help to grow an entrepreneurial community in the EIT RIS regions consisting of knowledgeable and skilled professionals – fostering entrepreneurial and innovation skills to enable young innovators to turn an idea into a successful service, product or venture and allowing change-makers to build a thriving innovation ecosystem.

To achieve these goals and ensure the highest impact, we built the RIS as a comprehensive ecosystem development programme with constant learning and self-improving processes. The performance of the regions is constantly measured, the lessons learnt, and experiences gained during the implementation of our activities are channeled back to their health innovation ecosystems, and their action plans are repeatedly updated to improve their performance in fostering social capital, collaboration, quality and capacities.

#### **Economic impact**

By accelerating 50+ start-ups per year in the RIS Investment Track, RIS Validation Track and RIS Proof-of-Concept (PoC) Track, and helping accelerators in the RIS regions to launch local healthcare start-up support programmes, we strengthen the start-up scene, resulting in more jobs created and increased employability.

With the activities under the Investment Track – running the Investment Awards and matching investors with start-ups at the Investor Forums – we boost the Investment attracted by RIS start-ups and scale-ups. This leads to more vital start-ups, more competitive economies, and more products/services launched on the market.

The education programmes within the RIS Academy enable RIS stakeholders to access training targeting the most pressing healthcare workforce needs (like AI and big data). We provide high-quality training, resulting in more qualified professionals and better employability in 22 RIS-eligible countries.

With the DRIVE programme (see RIS WP in section 2), we ensure knowledge transfer towards the RIS regions. We provide the methodology and tailored training, support local capacity-building projects, and contribute to the development of the innovation capacity of 14 RIS countries. This will result in more intense ecosystems consisting of partners from the knowledge triangle (academia, business and research) and boost innovation capacity, while a high number of innovations will improve the RIS countries' competitiveness.

By helping start-ups in market entry, we contribute to more developed healthcare systems, increased efficiency, reduced wasteful spending, improved access to high-quality care, and pathways shifted from treatment to prevention.

#### Societal impact

By selecting and supporting the most promising start-ups with impactful innovations in the Investment, Validation and PoC Track, we contribute to market entry of more and better solutions that lead to improved

quality of care, increased well-being of patients and citizens, healthier lives, and enhanced quality of life.

By delivering a quality education programme within the RIS Academy, through the expertise and capacities of EIT Health partners, we will slow the brain drain in RIS regions, keeping talents in their home countries and enabling improved innovation ecosystems and performance.

By engaging citizens in our activities (e.g. challenge-based hackathons, Innovation Days), we will increase their openness to innovative solutions and healthy living.

We will run women entrepreneurship courses to promote entrepreneurship among women researchers. This will increase women's chances of becoming more successful in the start-up field and contribute to a fair job market by decreasing the barriers for women in the workforce.

With the DRIVE ecosystem development programme, we contribute to knowledge triangle integration (KTI) by mobilising local stakeholders from academia, business and research. We will achieve this by inviting stakeholders to the Morning Health Talks (MHT) event series, integrating them into the development of regional innovation ecosystem development strategies (DRIVE 1st phase), engaging them in implementation of the local plan (through capacity building projects), and letting them collaborate in the Innovation Projects supported (in the Proof-of-Concept Track).

We collaborate closely with other KICs and the X-KIC RIS team in coordinating and consolidating the RIS Hubs at the EIT Community level. We developed together the country-specific roadmaps to strengthen our presence, visibility, and collaboration, and we adjusted our operation, expectations towards the RIS Hubs and reporting processes to comply with the EIT RIS Hub minimum standards and guiding principles. In the last calls for new Hubs, we applied an evaluation criterion to enable the Hub consolidation and follow a coordinated approach.

EIT Health RIS aims to utilise synergies with the Smart Specialisation Strategies. We sought to make more effective use of public, EIT and other EU funds, and to concentrate on specific domains, which are of great importance to create a thriving healthcare innovation ecosystem. In the last couple of years, the DRIVE programme helped the RIS regions to identify and select a limited number of priority areas, focusing on their strengths and comparative advantages, and their existing assets, capabilities and competencies. We built upon the smart specialisation strategies defined for the NUTS 2 region where our Hubs are operating and where we found health related S3 strategies to be applied (e.g. Slovenia, North-West Romania). We will establish alignment with S3 strategies in the two new RIS regions, where we selected new Hubs (Poland and Slovakia).

#### **Financial sustainability**

The RIS joins forces with other institutions and takes advantage of external funds and initiatives, like the HE EIE (European Innovation Ecosystems) and Erasmus+ Alliances for Innovation, Interreg Central Europe, Danube Region Programme, Digital Europe, Inter and European Digital Innovation Hubs. We have been participating in 25 consortia, with two winning proposals and ten in the evaluation phase. Consortium members of five EDIHs expressed their interest to pay the network partnership fee and described their willingness to pay for our services - including the international best practices and ecosystem development tools – and for access to our network and experts and our RIS programmes.

In EIE calls, the RIS is well-positioned, and our RIS Hubs and partners are well-prepared to apply successfully. The work we have completed and the extensive network we have built in the RIS regions in the last couple of years enable us to apply successfully for other local, national and EU funds as consortium members. Currently, we are working on an EIE proposal to improve access to finance in the RIS regions. Some concrete examples:

- We successfully raised Hungarian National Funding for the Catalyst Europe programme. Back in 2020 EIT Health, GE Healthcare and MIT joined forces to launch a health research framework programme, called Catalyst Europe. To make Catalyst Europe a permanent programme, the Hungarian government allocated HUF 150 million/year for the coming 7 years (€375,000/year).
- **NKFIH** HUF 75 million (€187,500) was approved by the Hungarian Innovation Agency to support EIT Health projects run by EIT Health partners in Hungary and InnoStars.

In the coming years we aim at mobilising EIC funds directly to ensure a fast track for RIS-supported start-

ups and scale-ups in the three tracks of the RIS acceleration activities. Here, we rely on EIT and EIT Health CO support.

InnoStars/RIS applied for four Erasmus+ programmes and one Interreg with the Israeli Hub getting high scores well above the threshold, so we can build on the experience we gained.

We continue exploring synergies with other local, national and EU programmes in the RIS regions, like IHI funds together with our InnoStars partners.

There is a growing interest in our capacity building activities, like the DRIVE Accelerator Programme.

The mature RIS programmes, and our existing expertise and capacities, allow us to sell our services in the future in grant management, evaluating and selecting start-ups, presenting deal flow, reaching RIS stakeholders, and delivering education, acceleration, or hackathon type services.

We extend co-funding requirements within the RIS. In the case of the local Capacity Building Project Implementation, we expect a gradual increase in co-funding. In the case of the DRIVE Accelerator Network Programme, we expect 50% co-funding from the accelerators for establishing the healthcare start-up programme.

Each RIS Hub will be encouraged to further investigate its financial sustainability (FS), which will lead to the creation of 14 action plans for sustainability by the end of 2023, to be implemented in 2024-2025 and beyond. FS denotes that the capacity of RIS Hubs is intended to be viable over time. To pursue this, RIS Hubs will set up a clear roadmap and targets to ensure that their capacity building activities are financially viable, and that the local ecosystem development is gradually sustained without EIT funding. Each RIS Hub is expected to continue seeking possibilities for co-funding from private and public funding sources and ensure the diversification of their revenue sources, if applicable. Discovering and attracting local and national funds (ERDF or RRF), as well as other European funds (Horizon Europe or Interreg) for RIS Hub capacity building activities are already pursued (co-funding requirement of EUR 5,000). RIS Hubs will keep leading initiatives to establish synergies between EIT Community activities and the local innovation ecosystem, aligned with the relevant RIS3s and RRPs. By incorporating sustainability principles, RIS Hubs should reach at least EUR 50,000 in co-funding by 2027. There will be a progressive increase in co-funding requirements for RIS Hub capacity-building project implementation (EUR 15,000 in 2024 and EUR 25,000 in 2025 out of EUR 50,000).

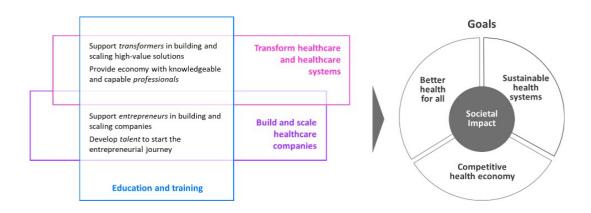
As there is no one-size-fits-all approach, **3 successive actions** will be taken in 2023 to facilitate the design of a tailormade and hands-on strategy for each RIS Hub. First, a deeper understanding of the regional and national public and private financial ecosystems will be expected among RIS Hubs (RIS region-specific maps). The sharing of replicable models and examples on how to leverage external funds or monetise services for innovation capacity building will then be introduced (knowledge-sharing workshops, inspirational talks, and study visits). By doing so, by the end of 2023 RIS Hubs will be able to select the most pertinent and suitable funding instruments and sources and define their activities accordingly (action plans for sustainability), in line with regional and national innovation strategies. RIS Hubs will speed up innovation and create their own sustainability over time by connecting actors, policies/strategies and funding in the best possible manner.

In addition, we run co-created and co-financed challenge-based start-up support programmes, like the highly successful open innovation programmes with Roche, Novartis. The industrial partners are willing to work with start-ups to address industry/market needs, validate the solutions, and support start-ups during the implementation phase.

## 3. Quality and efficiency of the implementation

#### 3.1 Work plan and resources

The strategic objectives of the KIC will be implemented primarily through the delivery mechanisms of each area in the Business Plan: Innovation, Business Creation and Education. The diagram below illustrates portfolio design, the interrelation of the main areas within the knowledge triangle, and their contribution to our goals. Innovation plays a key role in the direct transformation of healthcare systems. Business Creation builds and scales healthcare companies. Education is a transdisciplinary interaction agent that strategically spans the other areas – in Innovation by supporting transformers and professionals, and in Business Creation by training entrepreneurs. The knowledge triangle is also built in at the micro level of KIC Added Value Activity (KAVA). The consortia required for a winning proposal is expected to have a mixture of business and research partners.



The design of the 2023-2025 portfolio begins at the call creation stage, by building the multi-annual strategy into the calls for proposals and evaluation processes and refining specific pathways. These pathways and their planned impacts, which also take the form of mandatory KPIs, are reflected in the EIT Health call documents. The structure of the portfolio is based on general areas, comprised of several segments (or pathways) and further divided into specific KAVAs. The details of the KAVAs (size, budget, number per segment) are determined by the individual call and pathway evaluation criteria. These criteria consider the desired outcome of the pathway, giving weight to activities' pan-European dimension, monetary value vs. impact, partnership, expertise and integration of the knowledge triangle. For example, an Innovation Project with an outcome of a Marketed Innovation requires a different budget and expertise than a one-year Business Creation Bootcamp or Summer School. The call and evaluation criteria are created during the strategic design of the call through a collaborative process guided by the KIC's Strategic Agenda. Granularity is further refined throughout the call phase: short proposals containing similar ideas are often joined to form one project. Joint technical liability shapes the pathway selection criteria, which are designed to secure a selection of projects that can deliver. Technical liability for project implementation lies with the project consortia of each project (KAVA). It is defined in the Project Grant Agreement/sub-granting Agreements with partners. As of 2023, the design of the portfolio will begin to reflect the Flagship structure.

All **newly selected** KAVAs, irrespective of area, will be connected to one of the Flagships. Aligning projects under common challenges (Flagships) ensures stronger synergies within the Knowledge Triangle. Flagship activities will be translated into connected projects under the distinct areas of the Business Plan. As the Flagships call is currently underway, the allocated budget is parked under each area (see table Portfolio Structure).

The impact section outlines the strengthened KTI integration as designed by the Flagship concept.

## 3.1b: Indicative Portfolio Structure

Area (pillar)	Activity type (continuation / Flagship)	Expected number of KAVAs 2023- 2025	EIT Grant 2023-2025
Education	Continuation	15	7,900,851.85
Education	Flagship/New Selection	12	14,067,170.70
Business creation	Continuation	11	32,574,875.96
Business creation	Flagship/Wildcards/New Selection	9	801,193.08
Innovation	Continuation	13	45,150,087.18
Innovation	Flagship/New Selection	30	4,685,339.88
EIT RIS	Continuation	1	15,000,000.00
Communication, Dissemination and exploitation of Results	Continuation	5	14,643,554.17
Management, Organization, Comms	Continuation	5	8,027,515.02

## As requested, the budget breakdown per WP is as follows:

WP	EIT Grant	<b>Total Costs</b>
WP1 - Education	21,968,022.55	31,733,300.34
WP2 – Business Creation	33,376,069.04	39,801,407.87
WP3 - Innovation	49,835,427.06	86,005,931.25
WP4 - RIS	15,000,000.00	16,189,384.01
WP5 - Communication	14,643,554.17	15,314,729.86
WP6 - Mgmt Organisation	8,027,515.02	15,027,515.02
WP7 - FS	0	0

The budget breakdown on EIT funding to EIT labelled activities in 2024 and 2025 has been provided to substantiate 75% ratio in amounts.

Education 75% Ratio Assurance	2023 total budget	2024	2025
EIT Funding to Labelled Activities	8,762,332.97	4,959,633.59	4,959,633.59
EIT Funding to non- Labelled Activities		1,643,211.20	1,643,211.20

#### **Risks and Mitigation Measures**

The main risks to successful implementation of the 2023-2025 Business Plan are related to: 1. the continuous impact of the pandemic; 2. the current economic uncertainty and unstable political climate; 3. the impacts of the transition to "Horizon Europe," including the new legal position of the KIC and its partners, and the governance reform.

**COVID-19** is an ongoing risk impacting the timely implementation of most EIT Core KPIs. It impacts the availability of laboratory and research facilities, the possibility to conduct clinical trials (specifically delaying the Innovations Launched on the Market KPI), usability studies, citizen engagement and student engagement, particularly in mobilities. The creation of start-ups by students may be discouraged, and delays/lack of interest in investment in start-ups is a possibility.

The main mitigations include planning for COVID-related delays at the start of project plans, providing better practices exchange of COVID mitigation strategies and close project monitoring to support or re-orient projects affected, including with project extensions. In terms of investment attracted, proactive investor relations are key to mitigating delays. Post funding monitoring will be put in place to harvest KPIs from previously funded projects.

In order to continue to support staff through the uncertainties of the pandemic, EIT Health maintains its flexible work policy (i.e. working from home or a hybrid model).

The economic and political uncertainty brought on by the war in Ukraine may result in less investment and interest in engagement in social impact activities. Inflation and the rising cost of production and travel affects projects, which will need to deliver with fewer resources. Lack of workforce may delay the staffing of new start-ups or projects.

EIT Health will proactively engage current, and new organisations to keep the interest levels high. As mentioned above, investor relations will be key. Project budgets will be monitored closely, and a mechanism for additional funding/decommitment will be put in place to manage rising costs.

Risks related to the transition to Europe's new programme "Horizon Europe", the new legal position of the KIC and its partners, and the governance reform, remain.

While enhanced openness provides an opportunity to engage with new stakeholders, it poses a risk to the attractiveness of being a current EIT Health partner and engaging in the BP. To this end, the partnership model is under revision and transition (see Section 1).

Although the new legal position of the KIC and its partners has become clear, at the time of writing, the legal agreements were not yet finalised. This may result in tight implementation timelines, delays in contracting before the 2023-2025 Kick-off, and potentially, delayed project starts. As a mitigation measure, a dedicated operations "sprint" in Q4 of 2022 is planned for the operational implementation of legal matters and overall training in operational changes, to avoid project start delays. While UK entities may partake in the BP under the transitional agreement, it remains cumbersome and less attractive, which discourages their participation. The new 60k subgranting threshold for entities that are not automatically eligible (Annex 5, MGA) along with ongoing CLC support are mitigation mechanisms.

The governance reform currently underway continues to absorb time and resources of the KIC LE and the CLCs. Reputation and relationships may be affected by the governance changes, creating an unstable atmosphere for both staff and partners and impacting overall implementation. EIT Health will continue pursuing open communication with all stakeholders, and legal disclaimers will stay in place where appropriate. Governance reform is managed in tight alignment with EIT, CLCs and Partners to balance legitimate interest of all stakeholders and time constraints. .

Table 3.1g: 'Subcontracting costs' items

1. EIT Health e.V.			
	Cost (€)	Description of tasks and justification	
Subcontracting	8,571,163.88	Among others:  - Event agencies, DrIeam, Panopto, FluxLearning (WP1)  - Organization of Pitching Days and Hearings, IPCEI in Health Call evaluation, Due Dilligence, ELSI review, Start-Up valuation, external expertise on FS contracts (WP3)  - Marketing costs such as Campaign development, paid advertising, materials development (WP5)  - 4 Think Thank reports (WP5)  - Local outreach events, publication preparation and launch, PA agency support (WP5)  - Organization of Matchmaking and Summit (WP5)  - Media / Press Office activity (WP5)  - Development of corporate material, various surveys (WP5)  - External expertise on compliance, procurement organization set-up (WP6)	

1.5 Invest Health				
	Cost (€)	Description of tasks and justification		
Subcontracting	1,077,628.18	Among others:  - External expertise for Asset Management (WP2)  - VCoE costs (agreement with corporate / VcoE licencing out between KICs / AI Platform) (WP2)  - SACHS sponsorship event		

1.7 EITSI				
	Cost (€)	Description of tasks and justification		
Subcontracting	337,930.16	Among others:  - Brand protection consulting (WP1)  - Fundraising strategy consulting (WP1)		

Table 3.1h: 'Purchase costs' items (travel and subsistence, equipment and other goods, works and services)

1 EIT Health e.V.				
	Cost (€)	Justification		
Travel and subsistence	702,800.98	Estimated budget for travel and accommodation costs related to necessary F2F meetings for successful implementation of WP1, WP2, WP3, WP5 and WP6		
Equipment	0.00	N.A.		
Other goods, works and services	3,995,833.4	<ul> <li>Among others:         <ul> <li>Costs for support programme &amp; evaluation, external expertise on iDays, event production costs (WP1)</li> <li>External expertise on proposal writing, MedTec LIVE, sponsoring, Catapult costs, Marketing costs (WP2)</li> <li>Organization of Pitching Days and Hearings (WP3)</li> <li>Marketing materials, logistic costs, EU PA monitoring services, Venue costs events, catering, photography, merchandize production (WP5)</li> <li>Online Operations Handbook / Knowledge Base, Ontology / Keywords maintenance and development (WP6)</li> </ul> </li> </ul>		

1.5 Invest Health						
	Cost (€)	Justification				
Travel and subsistence	0.00	N.A.				
Equipment	0.00	N.A.				
Other goods, works and services	468,534.00	Among others: costs associated to events and sponsorship, Alumni programme event, VCoE material and branding, VCoE events with EIF (WP2)				

1.7 EITSI						
	Cost (€)	Justification				
Travel and subsistence	0.00	N.A.				
Equipment	0.00	N.A.				
Other goods, works and services	13,470.34	Among others costs associated to commercial activities (domain name, database maintenance, etc.) (WP1)				

**Table 3.1i:** 'Other costs categories' items (e.g. internally invoiced goods and services)

1.EIT Health e.V.								
	Cost (€)	Justification						
Financial Support to Third Parties	74,667,261.46	<ul> <li>Sub-granting budget for EIT Health partners in (ongoing) legacy projects (previous calls and BP) in WP1,2,3</li> <li>Sub-granting budget for new EIT Health partners project selected under the new Flagship model in WP1,2,3</li> <li>WildCard legacy projects</li> <li>Prizes for competitions in WP2</li> <li>Start-ups sub-grants awarded through the Direct Investment Tool in WP2</li> </ul>						

1.1 CLC Innostars							
	Cost (€)	Justification					
Financial Support to Third Parties	11,119,200.00	RIS budget dedicated to implementation of WP4 by EIT Health partners					

#### Table 3.1j: 'In-kind contributions' provided by third parties

Not Applicable.

#### 3.2 Capacity of participants and consortium as a whole

As a unique network, with the complementarity of public, private, academic and innovation partners, EIT Health combines a broad range of strengths and specific assets to address the health challenges of an ageing population. The BP 2023-2025 will be delivered by our network of more than 280 partners (including EPPs), from specialised areas such as biotech, diagnostics, digital health, pharmaceuticals, ICT, insurance, medtech, retail and telecommunications. They include businesses, healthcare providers, public authorities, payors, clusters, universities, and patient and research organisations – providing a wide range of expertise. New organisations continue to join us, and there is a trend of increasing EPP cooperation.

The innovators involved in the health innovation projects that we support work in cutting-edge research and hold expertise in multiple disciplines, ranging from the natural sciences (predominantly biology, chemistry and physics) to the formal and applied sciences (e.g. computer sciences, business, engineering and technology) – and of course medicine and healthcare. The involvement of experts in the social sciences, particularly health economics and behavioural sciences, helps ensure that EIT Health's work involves an understanding of the culture, ethics and social values needed for successful execution and implementation of many types of healthcare innovation projects.

EIT Health has a wide geographical reach thanks to its KIC Co-location Centres (CLCs) and RIS Hubs offices, which are often shared with other EIT KICs and are used to host events and meetings. These offices are accessible to our partners, start-ups, alumni and other collaborators, with access managed by local office staff in an appropriate manner. In addition to these physical spaces, EIT Health maintains its digital platforms which remain indispensable for fruitful collaboration.

#### Other countries and international organisations:

At the time of writing, the KIC LE and 9 affiliated entities (including CLC's) are participants in the project. As concerns the subgrantees, or organisations carrying out the bulk of the actions, there are currently no recipients receiving a grant from countries that are not automatically eligible. Sub-granting follows the stipulations for KICs in Annex 5 of the MGA.

Third-country entities may in the future participate in KIC activities, in accordance with the Horizon Europe (HE) rules, only if participation is deemed essential for the action and with ex ante EIT approval. At the moment of writing, there are no cases nor costs to justify in the Annex FSTP. Collaboration is foreseen with organisations in the US, to support programme execution (e.g. ACI, Boston, in Gold Track or the Value Institute of Dell Medical School in Austin, Texas in education). In addition, several EIT Health programmes, such as Bridgehead Global, enable the entry into new markets outside Europe and will therefore also foster collaboration with organisations beyond Europe.

#### Particularities regarding the KIC legal structure

In 2022, the former role of the Director of Finance became a C-level position. This new Chief Financial Officer now reports to the CEO (instead of the COO).

At Supervisory Board level, on 4 March 2022 a new Supervisory Board (SB) member, representing the newly created Regional Innovation Hub Austria, and a new representative for the Regional Innovation Hub Germany- Switzerland were appointed by the Partner Assembly. Three new independent Supervisory Board members have been chosen by the SB and have been approved by the Partner Assembly on 13. September 2022. This ensures fulfilment of the GGP requirement that at least half of all SB Members have an independent status. Please see explanations about EIT Health's Governance Reform in Section 1.2.

#### **Anti-fraud Policy**

Fraud, corruption, bribery, or other means of obtaining undue or improper advantage are not to be promised, offered, authorised, given, or accepted. This prohibition covers promising, offering, authorising, giving, or accepting anything of value to or from any third party, including national or European government officials,

either directly or indirectly through a third party, to obtain or retain certain subsidies, approvals or authorisations, or an exemption from certain legal or contractual obligations. EIT Health Staff shall not commit or participate in any fraudulent acts. EIT Health Staff shall immediately report any fraudulent acts by others concerning EIT Health that comes to their knowledge, it being understood that Supervisory Board members shall report such act to the Chairperson of the Supervisory Board and all other persons shall report to the CEO. In case the Supervisory Board Chairperson and/or CEO would be involved or cited in the improper advantage claim, the Supervisory Board Deputy Chairperson, or the COO instead of the CEO are the alternative reporting routes. Non-compliance will result in disciplinary measures established in the relevant HR policies including guidance on how to prevent such occurrences and when incidences occur. Moreover, EIT Health's Whistleblowing Policy provides additional guidance on how fraud, corruption and bribery can be reported.

#### Audit control system, grant assurance and monitoring

EIT Health will implement in the period 2023 – 2025 a two-tiered grant assurance and monitoring system that will comprise a Mid-year Cost Check and a Yearly Cost Reporting.

The Mid-vear Cost Check (MCC):

- 1. Will be conducted on legal entities (EIT Health Partners, sub-grantees) considered by EIT Health high-risk partners. The high-risk partner status will be assigned to sub-grantees that meet at least one of the following criteria:
  - a. A cumulative EIT sub-grant between January 01, 2023, and December 31, 2025, equal to or greater than €60,000.00.
  - b. Have had any amount of EIT funds rejected in previous Business Plans.
  - c. Have or have had an unsatisfactory result in the latest PMO Monitoring Review prior to the MCC.
- 2. Will be implemented within 60 days of the end of the first semester of each year.
- 3. Will follow a stratified random sampling, e.g., by partner type, by high-risk partner status, etc.
- 4. Will yield a list of partners that will be added to the existing high-risk partner group for the next MCC.
- 5. Will yield a list of observed cost items per partner that will be deducted from the next disbursement of EIT grant at partner level.

The Yearly Cost Reporting (YCR):

- 1. Will affect all legal entities participating each year, applying an increased sampling weight to high-risk partners.
- 2. Will include a CFS audit for partners with a cumulative EIT sub-grant between 1 January 2023, and 31 December 2025, equal to or greater than €430,000.00. The cost of the CFS will be covered by dedicated EIT funds.
- 3. Will be implemented within 60 days of the end of the last month of each year.
- 4. Will follow a stratified random sampling, e.g., by partner type, by high-risk partner status, etc.
- 5. Will yield a list of partners that will be added to the existing high-risk partner group for the next
- 6. Will yield a list of observed cost items per partner that will be deducted from the next disbursement of EIT grant at partner level.

The MCC and YCR will inform the calculation of the subsequent disbursements of EIT funds. Depending on the project start date<sup>2</sup>, a partner's participation in the MCC or YCR may be waived by EIT Health.

The disbursement of EIT funds<sup>3</sup> in the period 2023 – 2025 will be carried out in line with the following principles:

- There is a project-start disbursement within 60 days of signature of the PGA.
- All subsequent disbursements will be done yearly in the month of May following the results
- Each May disbursement will be calculated using the amounts of A) the immediate previous disbursement, B) the reported EIT grant of the prior YCR, C) the retained grant-insurance, and D) an extra amount to be determined and announced yearly by EIT Health by the end of each YCR.

<sup>2</sup> Currently at EIT Health: three intakes in 2023, start of projects

#### <sup>3</sup> Currently on EIT's Call:

- First prefinancing = up to 70% of 2023 Grant = within 30 days after signed GA = 5% retained as insurance
- Report for second prefinancing = within 60 days after month 12 = covers month 1 12 = mustcontain a report on the use of the first prefinancing = warning if less than 70% of prefinanced funds have been used.
- Second prefinancing = within 60 days of receiving report = up to 100% of 2024 Grant = 5% retained as insurance
- Interim Report = within 90 days after month 18 = covers month 1 18 = report on the use ofprefinancing + CFS
- Interim Payment = within 90 days of getting Interim Report = amount up to 90% of total grant (prefinancing 1 + prefinancing 2 + Interim payment)
- Final report = within 90 days of month 36 = covers month 1 36 = report on the use of prefinancing + CFS
- Final payment = within 90 days of getting final report = balance payment of total grant

#### FINANCIAL SUPPORT TO THIRD PARTIES

For calls that allow 'Financial support to third parties', project participants must add this document to the application and upload it as annex to proposal part B in the submission system.



A Fill in only the applicable section to your call (Financial support in the form of grants or prizes).



4 For more information on terms and conditions: see Work Programme General Annexes section B and Horizon Europe Model Grant Agreement Articles 6.2.D.1 and 9.4.

#### Financial support in the form of a grant awarded after a call for proposals

Where this possibility is indicated under the relevant topic in the Work Programme and in the relevant calls for proposals, provide a description of the use of financial support to third parties. This description must address at least the following:

- 1. clearly detail the objectives and the results to be obtained and
- 2. contain the following specifications (as a minimum):
  - a) the maximum amount of financial support for each third party; this amount may not exceed 60 000 EUR, unless explicitly mentioned in the Work Programme topic. If your project requires a higher amount per third party than the threshold amount set in the call conditions, justify and explain why this is necessary in order to fulfil your project's objectives.
  - b) the criteria for calculating the exact amount of the financial support
  - the different types of activity that qualify for financial support, on the basis of a closed list
  - the persons or categories of persons that may receive financial support, and
  - e) the criteria for giving financial support

Please check in the Work Programme and call for proposals if there are other conditions that apply and, if so, include them in the specifications or in any other element of the proposal as appropriate.

#### Financial support in the form of a prize

Where this possibility is indicated under the relevant topic in the Work Programme, provide a description of the use of financial support to third parties. This description must address at least the following:

- 1. clearly detail the objectives and the results to be obtained and
- 2. contain the following specifications (as a minimum):
  - a) the eligibility and award criteria
  - b) the amount of the prize and
  - c) the payment arrangements.

Please check in the Work Programme and the call for proposals if there are other conditions that apply and, if so, include them in the specifications or in any other element of the proposal as appropriate.

	HISTORY OF CHANGES					
VERSION	PUBLICATION DATE	CHANGE				
1.0	10.03.2021	Initial version (included in the standard HE proposal template)				
1.1	20.11.2021	Standalone template document. Clarification that it must be submitted as an annex to proposal part B.				

## EIT Health BP2023-2025

# Financial support in the form of a grant awarded after a call for proposals

Note 1: FSTP above 60k explicitly allowed in Call for Proposal the KIC is responding to

Note 2: All Innovation Projects must follow the Innovation Principles to be eligible

Project Area and Segment	Objectives and Results to be Obtained	Criteria for calculating the exact amount of financial support	Type of Activities that qualify	The persons or categories of persons that may receive financial support	Criteria for giving financial support
Education – Winter/Summer Schools	Objectives: To train talented individuals on value-based healthcare concepts under Innovation and Entrepreneurship (I&E) education approaches during their graduate studies.  Results:  EITHE08.1: Participants in (non-degree) education and training	Pre-defined in Call document  Up to €160,000 will be awarded for Year One of a W/S School, considering the following costs as the maximum eligible for each category:  • Up to €70,000 for mobility travel	1. 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.  2. 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.	1st level:  Multi-beneficiary pan European consortium from HE eligible countries  2 <sup>nd</sup> level:  Master students PhD students Post-doctoral students Multidisciplinary students Consortia meeting	Common scorecard for all projects – overall criteria identic for all archetype:  • Project Excellence and Strategic Fit (20%)  • Implementation and Feasibility (40%)  • Impact and Sustainability (40%)  The weight of each criterion will be different on each phase of the

	<ul> <li>(minimum 70 /year).</li> <li>EITHE08.2EITRIS:         Number of EIT RIS         Participants with (nondegree) education and training (minimum 12).</li> <li>KIC09: Programme         Attractiveness and Demand (minimum of three applicants per available spot).</li> </ul>	expenses.  • Up to €4,500 for event catering.  • Up to €60,000 for trainers and mentors.  • Up to €25,500 for trainers and mentors (travel).  The decreasing funding model will function as follows over a 3-year period:  • Year One: Up to €160,000  • Year Two: Up to €115,000  • Year Three: Up to €70,000 (final year of funding)	3. 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  4. Consortium rules apply. Visit Partnership specificities to learn more.  Must include a minimum of two Higher Education Institutions (HEI), from two different eligible countries, whereby:  • One HEI must be an EIT Health Core or Associate Partner  • One HEI must belong to a RIS region.  There must also be at least one non-academic or industry partner	the requirements listed on the left	Selection process
Education — Labelled Fellowship Programmes	Objective: To enable personalised learning pathways aimed at skilling, upskilling and reskilling Master and PhD-level students and graduates, healthcare and medical	Pre-defined in Call document  900K available for the 3 Labelled Fellowships; up to 300K€ per flagship	1.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.	1 <sup>st</sup> level:  Multi-beneficiary pan European consortium from HE eligible countries	Common scorecard for all projects – overall criteria identic for all archetype:  • Project Excellence and Strategic Fit (20%)

professionals in the field of value-based healthcare transformation.

#### Results:

- EITHE07.5 Students enrolled in EIT-labelled programmes
- EIT07.1 Graduates from EIT-Labelled programmes
- EIT07.2 EIT RIS
   Graduates from EIT
   labelled MSc/PhD
   programmes
   EITHE07.2-EITRIS
- EITHE05.1 Start-ups created by students enrolled and graduates from EIT-labelled programme
- EITHE05.2 EIT RIS Startups created by students enrolled and graduates from EIT-labelled programme.
- EITHE09.1 Students and graduates from EIT labelled programmes who joined start-ups
- EITHE09.2 EIT RIS Students and graduates

pathway.

Consortia aiming at responding for common elements can submit proposals with budgets covering the 3 flagships over 2023-25.

Consortia aiming at responding for flagship-related contents can submit proposals with budgets covering the 3 flagships over 2023-25, attaining the contents shall be ready for the 2023-24 academic year.

Indicative amounts:

Common elements for the 3 flagships: up to 150K for I & E and Leadership modules and up to 150K for Recognition of

- 2. 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.
- 3. 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-updriven projects
- 4. Consortium rules apply. Visit Partnership specificities to learn more

Must include a minimum of two Higher Education Institutions (HEI), from two different eligible countries, whereby:

- One HEI must be an EIT Health Core or Associate Partner
- 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 / modules repurposing as well as assessment supervisors.

2<sup>nd</sup> Level:

- -Master and Doctoral level learners having completed or not their studies.
- -Professionals willing to upskill / reskill themselves in the related fields.

First learners will be recruited to start their pathways in 2023 Fall.

- Implementation and Feasibility (40%)
- Impact and Sustainability (40%)

The weight of each criterion will be different on each phase of the Selection process

	from EIT labelled programmes who joined start-ups.	Prior Learning.  Flagship-related contents and assessment: max. 200K.  Grant cannot be used for LMS platform, challenges definition and recruitment / marketing related costs.  Proposals shall present full budgets for the whole granting period.			
Education – Training	Objectives: To raise	Pre-defined in Call	1.This call is open to applications from	Multi-beneficiary pan	Common scorecard for all
Module for Professionals	awareness, knowledge and	document	EIT Health Associate or Core members	European consortium from	projects – overall criteria
	technical skills in digital		as well as new organisations.	HE eligible countries	identic for all archetype:
	health for successful deployment of innovation		2. Projects must involve members from		Project Excellence and
	acployment of innovation	Max 50k€ for three	a minimum of two countries and from		Strategic Fit (20%)
		years	two different Regional Innovation Hubs.	The module must precisely	-
	Results:		3.The geographical origin of applicant is	define the groups of patients and citizens which	• Implementation and Feasibility (40%)
	nesure.		limited to EU Member States or	will benefit from this	Teasibility (40/0)
	KIC04.1: Healthcare		countries associated to Horizon Europe.	training.	Impact and Sustainability
	professionals trained by		4. Organisations will not be eligible to		(40%)
	EIT Health (non-degree) education programmes		receive funding until they have acceded		The weight of each
	education programmes		, , , , , , , , , , , , , , , , , , , ,		

EITHE08.1: Participants in (non-degree) education and training (including EIT RIS)	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.	criterion will be different on each phase of the Selection process
	5. Training module must be need- and data-driven, evidence-based and relevant to target audiences.  Demonstration of robust educational design is expected through instructional design best practices and evaluation /	
	outcome measurement framework defined from the outset.  6. Consortia should ensure the relevant GDPR requirements are covered to allow for such.	
	7. Target audiences must be precisely defined  8. Proposals must commit to multiannual delivery of the implemented	
	9.Training module will be hosted and delivered on the EIT Health Academy Platform	
	10.Training module to follow quality criteria of UEMS EACCME for CPD accreditation  11. Consortium will apply for UEMS	

			EACCME credits		
Education – Training Module for Patients and Citizens	Objective: 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.  Results:  • EITHE08.1: Participants in (non-degree) education and training (including EIT RIS)	Pre-defined in Call document  Max 50k€ for three years	1.This call is open to applications from EIT Health Associate or Core members as well as new organisations.  2. Projects must involve members from a minimum of two countries and from two different Regional Innovation Hubs.  3.The geographical origin of applicant is limited to EU Member States or countries associated to Horizon Europe.  4. 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.  5. Training module must be need- and data-driven, evidence-based and relevant to target audiences. Demonstration of robust educational design is expected through instructional design best practices and evaluation / outcome measurement framework defined from the outset.	Multi-beneficiary pan European consortium from HE eligible countries	Common scorecard for all projects – overall criteria identic for all archetype:  • Project Excellence and Strategic Fit (20%)  • Implementation and Feasibility (40%)  • Impact and Sustainability (40%)  The weight of each criterion will be different on each phase of the Selection process
			6. Consortia should ensure the relevant GDPR requirements are covered to allow		

			for such.  7. Target audiences must be precisely defined  8. Proposals must commit to multiannual delivery of the implemented training programme for up to 3 years  9. Training module will be hosted and delivered on the EIT Health Academy Platform		
Education — Training Modules on Advanced High Value Care Principles	Objective: 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.  Results:  • EITHEO8.1: Participants in (non-degree) education and training	Pre-defined in Call document  Max 50k€ for three years	1.This call is open to applications from EIT Health Associate or Core members as well as new organisations.  2. Projects must involve members from a minimum of two countries and from two different Regional Innovation Hubs.  3.The geographical origin of applicant is limited to EU Member States or countries associated to Horizon Europe.  4. 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.  5. Training module must be need- and data-driven, evidence-based and relevant to target audiences.	1st Level:  Multi-beneficiary pan European consortium from HE eligible countries  2 <sup>nd</sup> Level:  Individuals and professionals working in healthcare transformation projects.  Master and PhD-level students and graduates, healthcare and medical professionals	Common scorecard for all projects – overall criteria identic for all archetype:  • Project Excellence and Strategic Fit (20%)  • Implementation and Feasibility (40%)  • Impact and Sustainability (40%)  The weight of each criterion will be different on each phase of the Selection process

			Demonstration of robust educational design is expected through instructional design best practices and evaluation / outcome measurement framework defined from the outset.  6. Consortia should ensure the relevant GDPR requirements are covered to allow for such.  7. Proposals must commit to multiannual delivery of the implemented training programme for up to 3 years  8. The training module will be hosted and delivered on the EIT Health Academy Platform  9. Training module to follow quality criteria of UEMS EACCME for CPD accreditation  10. Consortium will apply for UEMS EACCME credits		
Innovation Projects – Partner Led	Objectives: To accelerate development, evaluation and validation, certification, and market access of patient-centred DMD in Europe for faster market entry and wider adoption.  Mandatory Results:	Max financial support amount calculated based on cost of mandatory segment objectives – Pre-defined in Call Document	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.	Multi-beneficiary pan European consortium from HE eligible countries Involvement of industry, healthcare provider and/or start-up stakeholders from a minimum of 2 countries from two different Regional Innovation Hubs	Common scorecard for all projects – overall criteria identic for all archetype:  • Project Excellence and Strategic Fit (20%)  • Implementation and Feasibility (40%)  • Impact and Sustainability

	EITHE02.1: Number of all innovations introduced on the market during the KAVA duration or within 1 year after completion. Innovations include new or significantly improved products (goods or services) sold.  KIC13: 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)		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).		The weight of each criterion will be different on each phase of the Selection process  Complies with Innovation Principles
Innovation Projects – Start up Driven	Objectives: To accelerate development, evaluation and validation, certification, and market access of patient-centred DMD in Europe for faster market entry and wider adoption.  Results:  • EITHE02.4: Innovations launched on the market	Max financial support amount calculated based on cost of mandatory segment objectives – Pre-defined in Call Document	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	Multi-beneficiary pan European consortium from HE eligible countries Involvement of industry, healthcare provider and/or start-up stakeholders from a minimum of 2 countries from two different Regional Innovation Hubs	Common scorecard for all projects – overall criteria identic for all archetype:  • Project Excellence and Strategic Fit (20%)  • Implementation and Feasibility (40%)  • Impact and Sustainability (40%)  The weight of each

with a sales revenue of	turnover not exceeding 50 million	criterion will be different
at least 10 000 EUR	euro, and/or an annual balance sheet	on each phase of the
documented; to be	total not exceeding 43 million euro.	Selection process
reported during the	Be legally incorporated and	
KAVA duration or within	established in one of the EU Member	Complies with Innovation
1 year after completion.	States or Horizon Europe associated	Principles
Innovations include	countries. Be incorporated on/after	
new or significantly	1st January 2013 and before the	
improved products	submission deadline.	
(goods or services) and	Have at least 2 paid FTEs working in	
processes sold.	the start-up at the time of submission.	
At least one customised	Have a CEO working full-time in a	
KPI linked to Process	company at the time of submission.	
Outcomes Measure	Start-up applying for at least 300k€ EIT	
At least one customised	Health grant.	
KPI linked to Clinical		
Outcomes Measure		
• If applicable: EITHE02.1:		
Innovations launched		
on the market, or		
EITHE02.4: Innovations		
launched on the market		
with a sales revenue of		
at least 10 000 EUR		
documented; to be		
reported during the		
KAVA duration or within		
1 year after completion.		
Innovations include		
new or significantly		
improved products		

	(goods or services) sold				
Innovation – DIGI Innovation	(goods or services) sold  Objectives: To accelerate reimbursement, market access, and wider adoption of DMDs in Europe.  Results:  • EITHE02.4: Innovations launched on the market with a sales revenue of at least 10 000 EUR documented; to be reported during the KAVA duration or within 1 year after completion. Innovations include new or significantly improved products (goods or services) and processes sold.  • KIC13: Number of citizens/patients that benefitted from solutions developed or implemented in KAVAs  • At least one customised KPI linked to Patient Reported Outcome Measure (PROM)	Pre-defined in Call document  Max 350k€ Grant for the EIT Funded Activity (EFA)  The grant allocated for start-up must be included in the range [150k€ - 350k€]. Start-up may receive the full Grant of 350k€ provided additional partners part of the project bring co-funding in line with co-funding requirements.	At Short Proposal stage  One participant ONLY – the start-up.  At full proposal stage  At least two project partners must be involved (minimum one must be an EIT Health member).  At least 50% of the project entities must be EIT Heath registered members at the full proposal submission stage.  The participants must come from at least two different countries from two different Regional Innovation Hubs.  A dossier for the relevant ethics committee approvals to facilitate clinical study submitted and approval to commence study foreseen before project start (for multicentric studies, ethics committee approval in place for at least one centre before project start).  The start-up is at the core of the project – without the start-up, there is no Innovation project.  Start-up is a for-profit SME according to the EU definition – an enterprise which employs fewer than 250 persons	Multi-beneficiary pan European consortium from HE eligible countries Involvement of industry, healthcare provider and/or start-up stakeholders from a minimum of 2 countries from two different Regional Innovation Hubs	Common scorecard for all projects – overall criteria identic for all archetype:  • Project Excellence and Strategic Fit (20%)  • Implementation and Feasibility (40%)  • Impact and Sustainability (40%)  The weight of each criterion will be different on each phase of the Selection process  Complies with Innovation Principles

	process of pivoting their innovation solution into the clinical workflow. While doing so, a value-based approach towards the	The decreasing funding model will	well as new organisations. The geographical origin of applicant is limited to EU Member States or countries associated to Horizon Europe.	HE eligible countries  Innovation provided by	<ul><li>identic for all archetype:</li><li>Project Excellence and Strategic Fit (20%)</li></ul>
Business Creation – Bootcamp in VBHC	<b>Objective</b> : Support companies in the iterative	Pre-defined in Call document	This call is open to applications from EIT Health Associate or Core members as	Multi-beneficiary pan European consortium from	Common scorecard for all projects – overall criteria
			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 a start-up at the time of submission.  • Have a CEO working full-time in a start-up at the time of submission.  • Start-up applying for at least 150k€ 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.  • The start-up's DMD solution must meet the requirements for reimbursable applications in the targeted country.		
			exceeding 50 million euro, and/or an		

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).

#### Results:

function as follows over a 2-year period:

Year One: Up to €120,000

Year Two: Up to €70,000 (final year of funding)

EIT Health assumes costs for programme marketing and infrastructure necessary to facilitate recruitment and selection process.

After the grant period, it is expected that the Bootcamp will continue its activity and, if agreed, can extend its collaboration with EIT Health by applying to the Recognition Programme.

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.

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-updriven projects

Involvement of industry, healthcare provider and/or start-up stakeholders from a minimum of 2 countries from two different Regional Innovation Hubs.

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).

Programme consortia must include a minimum of two institutions, from two different eligible countries.

We anticipate that lead partners are incubators, innovation clusters, universities and/or industry partners

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

- Implementation and Feasibility (40%)
- Impact and Sustainability (40%)

The weight of each criterion will be different on each phase of the Selection process

	with experience in designing programmes to support start-ups.	
	All Bootcamp consortia partners must have a good track-record in supporting health start-ups. We expect that healthcare institutes, business partners — such as insurance companies, innovation networks, and government organisations — are likely to be part of the proposal, to provide access to their network.	

### EIT Health BP2023-2025

## Financial support in the form of a prize

Project Area and Segment	Objectives and Results to be Obtained	Eligibility and award Criteria	Amount of the prize	Payment Arrangements
Business Creation – Bridgehead	Bridgehead: The awarded participants are the start-ups that have won the entry ticket to the Bridgehead programme in 2023/2024/2025. There are 30 selected start-ups for Bridgehead Europe and Global. The participants will be evaluated by a panel of external subject-matter experts, 3 evaluators per application, according to standardized criteria, specified in the award criteria column. The experts are highly recognised individuals that belong to healthcare community of the EIT Health network. Evaluators are selected based on their expertise in innovation, business creation and market development in life sciences with a balanced contribution of science, industry and market access component. Guidelines on impartiality and conflict of interest waiver are provided to evaluators before the evaluation process took	To qualify for the Bridgehead Programme, a company must:  - Be registered in Europe  - Sell a product or services in at least one market in Europe and be ready to open up a new market  - Deliver innovative, transformative products or services in biotech, medtech or digital health  - Have fewer than 250 full time	1,000 Euros per Start-Up	The payment arrangements are following the EIT HEALTH policies and guidelines and are executed by EIT Health HQ Finance Department. Start-ups are centrally registered in EIT Health Optimy system.

	place.	employees		
	The selected startups will be awarded to participate in a networking event to foster community building among the Bridgehead startups. The purpose of their participation is to boost the start-ups capacities in internationalisation and to exchange Bridgehead experiences among other Bridgehead participants.	The awarded companies are those that are scored highest in the ranking, according to the following evaluation criteria:  - Business model		
		& development strategy  - Promising and credible scale-up, overall impression  - Market opportunity & traction		
		- Need to internationalise and expand - Impact of the programme and clarity of direction		
Business Creation –	Catapult: The pitch event and the	- Management capability  Startups applying	Catapult: 78 000 €/year (2k for 30	The payment

Catapult	award session will be planned and the concept drafted in one document. The 21-30 jury members (i.e. European and international investors, corporates, research and innovation major players) will be identified and invited to join the jury. The pitch event and the awarding ceremony will be prepared in close cooperation with EIT Health HQ at a major European healthcare event. The execution of this part lies in the responsibility of the project team. The nominees will be supported in the preparation for the pitches. After the successful implementation of the award	for the prizes must be: selected based on performance and by the jury members; registered in Europe and has a registration number; be in the space of healthcare and providing innovative solutions to benefit patient lives, agree to EIT	semifinalist; 2k for 9 finalist) and 210 000€/year (150k as awards given to selected startups in the final selection, 60k for travel and subsistence)	arrangements are following the EIT HEALTH policies and guidelines and are executed by EIT Health HQ Finance Department. Start-ups are centrally registered in EIT Health Optimy system.
	implementation of the award ceremony the prizes will be transferred to the winners.	lives, agree to EIT Health subgranting agreement and data terms and conditions.		
Business Creation – Community Building	Community Building: events sponsorship for EIT Health to tap into local and regional community for entrepreneurship and business creation, building a strong relationship with startups and connecting the journey to EIT Health Business Creation.	artups applying for the prizes must be: selected based on performance and by the jury members; registered in Europe and has a registration number; be in the space of	Community building: 15 000 €/year (for startups selected to participate in events)	The payment arrangements are following the EIT HEALTH policies and guidelines and are executed by EIT Health HQ Finance Department. Start-ups are centrally registered in EIT Health Optimy system.

		healthcare and providing innovative solutions to benefit patient lives, agree to EIT Health subgranting agreement and data terms and conditions.		
RIS – Engage local players in KIC activities - InnoStars Investment Awards	The aim is to support start-ups (EITHE03.2 EITRIS) to improve their skills in fundraising: they get handson experience in creating an investment strategy, defining USP, optimizing pitch content, establishing and managing investor relations, optimising term sheet and investment conditions, benefit from participating in board meeting simulation. Once completed the programme the top10 performers get the chance to compete for prizes at InnoStars Grand Final and with the prize, the 3 best of the best teams are further encouraged to continue the development of their solution, expand to further markets and establish investor relations utilizing the knowledge they gain during the award programme. By completing the project the teams have better prospects in attracting	Incorporated start-ups seeking investment are selected via an open call to receive training and compete. Based on their performance during the project period, the top 10 participants (selected by independent experts) qualify for Grand Final, where they pitch and an international jury selects the best three performers who will be provided with	45.000 €/year  The top 10 participants (selected by experts by pre-defined criteria) take part in the Grand Final, pitch in front of a jury where the top three performers are provided with prizes of 20.000-15.000-10.000 €	20.000-15.000-10.000 EUR are paid for the first, second, and third-ranked start-up respectively, payment in a lump sum after the Grand Final.

Awards validation. The programme also and selected by offers bootcamps and individual mentoring which improve the skills experts based on with prizes of independent experts based on	ear ee performers are provided	20.000-15.000-10.000 EUR are paid for the first,
in KIC activities - InnoStars Validation Awards  (EITHE03.2 EITRIS) for business development and product validation. The programme also offers bootcamps and individual mentoring which improve the skills  MVP are invited via an open call and selected by independent experts based on		
of the founders in business planning, pitching skill development, market validation, market entry strategy development and individual mentoring to reach an investment- ready level.  With the help of the programme, the founders are equipped with skills to successfully follow the start- up journey, be aware of the necessary steps to reach the market, and have tools in their hands to have a better chance of reaching the market and shortening time-to-market.  As a direct outcome of the programme the start-ups have improved business plans, and those 10 ranked as having the best/most promising business plans compete for prizes. The top three performers are awarded prizes to boost their solution development and receive	of 20.000-15.000-10.000 €	second, and third-ranked start-up respectively, payment in a lump sum after the Grand Final.

	commercialization.			
RIS – Engage local players	Granting local innovation consortia	Local innovation	45.000 €/year	20.000-15.000-10.000
in KIC activities -	of at least 2 local stakeholders (one	consortia with at		EUR are paid for the first,
InnoStars Proof-of-	academic and one non-academic	least 2 local	The top three are provided with prizes	second, and third-ranked
Concept Awards	Partner) with the aim of developing	stakeholders (one	of 20.000-15.000-10.000 €	start-up respectively,
	their project to reach proof-of-	academic and one		payment in a lump sum
	concept and capacitating the	non-academic		after the Grand Final.
	participating research teams in	Partner) are		
	business topics, so that they acquire	selected by		
	new skills to validate and develop	independent		
	their solutions while developing a	experts via an		
	deeper understanding of:	open call to		
	<ul> <li>Market roadmap;</li> </ul>	progress towards		
	•New tools to implement strategies;	commercialization		
	•Enlarge network and get first-hand	by at least one		
	contact with experienced	CIMIT level (IML2		
	entrepreneurs and work in an	to 3). Besides the		
	international environment.	fund, training,		
		mentoring, and		
	By completing the programme the	networking		
	project is expected to progress	opportunity, are		
	towards commercialization by at	provided with the		
	least one CIMIT IML level	chance to		
	(EITHE01.3EITRIS - complete IML3	participate in the		
	proof-of-concept level).	Grand Final and		
	The ten 2 colutions selected at the	pitch in front of an international		
	The top 3 solutions selected at the Grand Final by an international jury	jury, and the top		
	get prizes with the aim to further	three performers		
	improve the market prospects of	selected by the		
	the most promising projects and	jury are entitled		
	further contribute to market entry.	to prizes.		
	raither contribute to market entry.	το ριίζες.		

RIS – Engage local players	The programme helps the	Talents are	28.000 €/year	14*2.000 EUR for the
in KIC activities -	participants to gain knowledge in	invited to		winning teams of the
Innovation days	the field of innovation, design	innovation days	14 teams of the 14 local innovation	local innovation day
	thinking, and entrepreneurship,	where experts	days hosted by the hubs receive prizes	events. One instalment
	receive practical tools on ideation,	guide them	(2.000 EUR/team)	after the events.
	how to test ideas and how to pitch	through health		
	an innovative idea. Moreover, the	innovations. The		
	talents have the opportunity to test	teams will work		
	their skills and work on real-life	on real-life		
	challenges where the best ideas are	challenges and		
	awarded prizes.	they will have the		
		chance to pitch		
	The aim is to promote health	their solutions.		
	innovation among university	The best solutions		
	students and enable young talents	will be selected by		
	to start their journey in healthcare	experts and		
	innovation.	provided with		
	As an autoema of the programme	prizes to the		
	As an outcome of the programme	teams and will be		
	the students are more open to	invited to a final		
	innovations, and the pipeline of	event		
	potential innovators is also widened.			

## Annex 1 to FSTP Annex: EIT Health Flagship Call Document and Annexes

Note: The Call document and it's annexes below provides details on the selection procedure and condition for all planned Financial Support to Third Parties. Each project type described above has its own extensive summary with detailed requirements.





15 September 2022

# EIT Health Flagships Call Document



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# 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). For this Call we want to highlight that the KIC has a new Hub operational since January 2022. The new Austrian Hub with its office in Vienna is the first point of contact for all interested future Partners from Austria. For this Call the Hub supports all Austrian partners that were previously supported under the umbrella of the German-Austrian-Swiss Hub.

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 <u>Strategic Agenda 2021-2027</u> 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 at the front and centre of their care.

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

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

Please refer to the <u>Impact Section</u> 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
- EIT Health and its Partners will be working together on four clearly defined challenges to create a higher impact
- There will be clear alignment with EU policy priorities across the healthcare landscape
- 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 an assessment process with our EIT Health community, four flagship areas 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 & Diagnostics<sup>1</sup>

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.

<sup>1</sup> **Definition of Digital Medical Device:** <u>The European Commission's definition</u> 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).





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 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.

For this flagship, 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. Cross-pillar activities within flagships

# 2.1. Call for activities

EIT Health is launching a call for cross-pillar activities for each of the flagships described above, with the exception of the flagship "Supporting the deployment of IPCEI to address market failures" which will have its own specific call and timeline due to its status as an already existing programme and its reliance on additional collaborators.

The table below provides an overview of the activities that will be called for, for each flagship, at different cut-off points (for details of the cut-offs, see 4. Selection process for Flagship Call BP2023):

New models to deliver healthcare	Facilitating the uptake of Digital Medical Devices & Diagnostics	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
Start-up and Partner-driven projects (Service Quality Assessment)	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		Start-up and Partner-driven projects (health registry / biobank 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.





# 2.2. Services for selected activities

Consortia progressing through the EIT Health journey will, at specific points in the selection process, as well as during the project lifespan in case of successful selection, be able to benefit from services available through the Business Creation pillar and other EIT Health functions to improve skills, assess financial readiness, develop products, or execute validation or marketentry studies. These services include:

- Mentoring and Coaching Network support (MCN): Mentoring and coaching network support is an optional service which can be provided to all selected consortia when applicable. A mentor can be assigned during the whole project lifetime to ensure continuity of support. For instance, Innovation projects (Partner and start-up driven ones) could benefit from one hour a month across 1 to 1.5 years (but this would not be expected in the initial six months). EIT Health could support the costs of the service.
- Ulabs support (Ulabs): Ulabs support is an optional service that can be provided to all selected consortia. This programme brings together a network of living labs, accelerators, hospitals, and innovation centers that can support a connection between start-ups and the future end users, including patients, clinicians, and medical staff. This programme can help the selected consortia to connect with User Validation Labs to organise and execute a validation study.
- Bridgehead programme: Bridgehead is an optional service for start-ups participating in start-up driven projects but will be a mandatory service in fast-track start-up driven projects (DiGinnovation).

In the frame of DIGinnovation, start-ups that are invited to the consortium building/support programme step (see

*Important dates for a* special case of Fast Track start-up driven Innovation project type (DiGinnovation) in cut-off 2 are outlined below:

	DiGinnovation
Submission date of short proposal	1 Mar 2023
Eligibility check notification	9 Mar 2023
Filtering (internal review) notification and invitation to pitch day	23 Mar 2023
Due diligence	24 Mar – 5 Apr 2023
Pitch day	5 Apr 2023
Pre-selection notification (external review)	6 Apr 2023





Phase 2: Support programme (approx. 1-2 months), will be introduced to Bridgehead's catalysers via individualised matchmaking.

The catalysers are pre-selected accelerators, incubators and clusters from EIT Health network with a proven track record in building, accelerating and scaling-up healthcare companies and will support start-ups with a soft-landing service to facilitate new market access and reimbursement activities.

The start-up will have an opportunity to select a suitable catalyser and include its work plan and budget in the full proposal before it is submitted. In case the project gets selected, catalysers will receive up to EUR 40k, based on the specific tasks and budget included in the full proposal. This grant will be added on top of the maximum project grant and will be counted as in-kind contributions towards the options in a start-up.

Here are some examples of services catalysers can provide to a start-up (specific services should be discussed with each catalyser individually depending on the start-up needs):

- Initial market validation
- Scaling user base
- Develop action plan for reimbursement
- Connection to Key Opinion Leaders (KOLs) on the market in question

Start-ups in other start-up driven projects will have preferential access to Bridgehead in 2025, after the project is over and at a suitable maturity stage. More details on the conditions of the service implementation will be discussed with selected consortia during each project's lifetime.

• **Finance Booster programme:** Finance Booster is an optional service for start-ups participating in start-up driven projects. Early-stage start-ups (pre-seed, seed stage) from start-up driven projects that are looking to fundraise can join Finance Booster programmes taking place annually in November.

The Finance Booster is a four-week programme that provides support in understanding the start-up's finances and prepares them to talk to investors. It includes three online group training sessions on highly requested start-up topics related to finance (funding strategy, term sheets, and stacking up figures in business plans). The training will be concluded with a mock pitch in front of real investors. Start-ups from start-up driven projects will have preferential access to Finance Booster and the participation fee of EUR 1200 will be waived. Instead, these services will be counted as in-kind contributions and towards options in a start-up.

#### • EIT Health Innovators Community

The EIT Health Innovators Community is a multidisciplinary community of 3000+ innovators closely connected to EIT Health. Created in 2017, this cross-cutting initiative aims at connecting participants of EIT Health's Education, Innovation and Business Creation programmes.





The Innovators Community platform is a dedicated meeting space, allowing members to learn from one-another, expand their network and enhance their skills. It provides access to member benefits and deals, jobs, events and mentoring services. EIT Health programme leaders use this space to coordinate their activities and interact directly with their participants in designated groups. Regional groups allow members to plan events together and network locally.

Leveraging the Innovators Community and the features of the community platform is an optional service for selected consortia or start-ups. More information on the community platform can be found here.

For consortia members, the platform provides opportunities for community building, programme promotion, and activity coordination currently free of charge. It also offers direct access to the talent pool of EIT Health's alumni through the job board and member database. This service offer is free for consortia in 2023. From 2024 we plan to introduce paid features to enhance our offer with differing levels of access for certain user groups. We are exploring the use of a freemium model to access these features.

For start-ups, the space provides access to a global community of like-minded innovators. Members can participate in curated networking events, trainings and workshops, have direct access to exclusive jobs and mentoring opportunities, and can access the wider EIT Alumni Community – allowing them to connect with professionals outside the Health domain.

To propose those services in the most robust manner, the Business Creation team will launch various calls for interest to select new catalysers for the Bridgehead programme, new experts, mentors, coaches, evaluators for MCN and new LLs²/TB³s for Ulabs support with a thematic focus on each flagship. If you are interested in joining the relevant programmes as a mentor, coach, or catalyser, please consult the dedicated information on the corresponding application processes here:

- For Bridgehead you can find more information about the programme by visiting our website <a href="here">here</a>. If you are interested in applying, please reach out to Programme Manager, Sabine Runge (sabine.runge@eithealth.eu), who will provide you with the application link as soon as the call is open
- For MCN you can find more information about the programme by visiting our website <u>here</u>. If you are interested in applying as a mentor please follow the link <u>here</u>
- For Ulabs you can find more information about the programme by visiting our website <a href="here">here</a> and to apply and offer validation services to start-ups please follow the link <a href="here">here</a>.

<sup>&</sup>lt;sup>2</sup> Living Labs

<sup>&</sup>lt;sup>3</sup> Test beds





These three calls are independent from the current Flagship Call for activities presented in this document.

# 2.3. Activities within the flagship "New models to deliver healthcare"

#### Introduction

Europe's healthcare systems are unsustainable<sup>4</sup>. 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,<sup>5</sup> 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 Knowledge Triangle. 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 processes and service innovations 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

 $<sup>^4\</sup> https://www.europarl.europa.eu/cmsdata/150781/Full\%20version\%20all\%20presentations.pdf$ 

 $<sup>^{5}\</sup> https://apps.who.int/iris/bitstream/handle/10665/329382/Policy-brief-1997-8073-2019-3-eng.pdf$ 





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 and start-ups, that have reached commercialisation stage will be welcomed to apply to start-up or Partner driven **Service Quality Assessment Innovation projects**. These projects will aim to generate the needed evidence to convince payors that the value brought to the patient is worth changing the reimbursement model, therefore promoting the incorporation of innovative solutions and services into new markets. 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, in line with detailed interaction sections below: 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 which 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 that take place at regional, national and EU level which 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.

Short description of the activities called in this flagship

# Call for Winter / Summer School

**Need:** To train talented individuals on value-based healthcare concepts under Innovation and Entrepreneurship (I&E) education approaches during their graduate studies.

**Short description:** The Winter/Summer school's ambition is to create a reference programme of short courses in Innovation and Entrepreneurship education — carving a path for aspiring





entrepreneurs to create their own start-ups. I&E 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.

**Who should apply**: Higher Education Institutions in collaboration with non-academic organisation

Programme 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.

Please see Annex 1 – Call for Summer/Winter School summary" for the details of the programme content and eligibility criteria.

#### 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 description:** Modules toward EIT Labelled Fellowship Programme

Who should apply: contributing institutions of existing courses

Programme target audience: Master students, PhD students, healthcare professionals

Timeline: Up to 12 months and continued implementation

Please see Annex 2 – Call for modules toward a labelled fellowship programme summary" for the details of the programme content and eligibility criteria.

#### 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 description:** Those modules should be online and will be available through the EIT Health Academy Platform. Onboarding and administrative access will be granted to selected consortia for modules to be implemented in the Academy platform.

Who should apply: contributing institutions

Programme target audience: Individuals and professionals working in healthcare

Timeline: Max. 8 weeks programme. Workload for participants 20 to 40 hours





Please see Annex 5 – Call for training Modules on Advanced High Value Care Principles summary" for the details of the programme content and eligibility criteria.

# Call for start-up-driven and Partner-driven innovation project: Service Quality Assessment

**Need:** Contribute to restructuring healthcare delivery towards measurable outcomes which create 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 description:** Collaborative projects that aim to promote the market uptake of innovative products and services of added value for patients, by assessing the quality of the healthcare service improvement using patient reported and real-world data, 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). The desired outcome of these projects is an innovation process that can be replicated in different clinical settings which will lead to more products brought into different European markets, resulting in broader impact.

# Who should apply:

- 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) who want to generate convincing data to back their products or services aimed at value-based business models.

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

Please see Annex 6 – Call for Partner-driven Innovation projects summary" and Annex 7 – Call for Start-up driven Innovation projects summary" for details on the programme content and eligibility criteria at each stage.

### Call for Bootcamp in Value-based Healthcare

**Need:** To 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, which would then be fed into the health economic evaluation of the innovation solution provided (product or a service).

**Short 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.

Who should apply: Programme providers

**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
- 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 two months' (eight to ten weeks') engagement of participants with proposed curriculum and faculty. To be delivered once every year and funded for two years.

Please see Annex 9 – Call for Bootcamp in VBHC summary" for the details on the call content and eligibility criteria at each stage.

# 2.4. Activities within the flagship "Facilitating the uptake of Digital Medical Devices & Diagnostics"

#### Introduction

With the rise of digital health, Europe is still behind<sup>6</sup> 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 which can be solved through digital technology, to developing innovative solutions, validating them, launching new DMD products on the market

<sup>&</sup>lt;sup>6</sup>https://www.europarl.europa.eu/RegData/etudes/STUD/2021/695465/IPOL\_STU(2021)695465\_EN.pdf





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 study digital health and DMD concepts via the **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 who have reached the 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 the 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
- **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.

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

Short description of the activities called in this flagship

# Call for Winter / Summer School

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

**Short description:** The Winter/Summer school's ambition is to create a reference programme of short courses in Innovation and Entrepreneurship education — carving a path for aspiring entrepreneurs to create their own start-ups. I & E (Innovation and Entrepreneurship) elements are central and are delivered with a hands-on approach. It covers min. 5 ECTs

**Who should apply**: Higher Education Institutions collaborating with non-academic organisation/s

Programme 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

Please see Annex 1 – Call for Summer/Winter School summary" for details on the call content and eligibility criteria at each stage.

# 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 description:** Modules toward EIT Labelled Fellowship Programme

Who should apply: contributing institutions of existing courses

Programme target audience: Master students, PhD students, healthcare professionals

Timeline: Up to 12 months (TBC)

Please see Annex 2 – Call for modules toward a labelled fellowship programme summary" for details on the call content and eligibility criteria at each stage.

# 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 Partner-driven project that focuses on validating, certification, and introduction to the market of patient-centred DMD solutions and innovations

Who should apply: organisations keen to build a collaborative consortium to address need

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

Please see Annexes Annex 6 – Call for Partner-driven Innovation projects summary" and Annex 7 – Call for Start-up driven Innovation projects summary" for details on the call content and eligibility criteria at each stage.

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

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





**Short description**: DiGinnovation selects top digital health start-ups/scale-ups<sup>7</sup> 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 speeding up the launch of the innovation on the market, while easing the reimbursement process

Who should apply: Start-ups keen to build a collaborative consortium to address need

**Timeline**: a nine month collaborative project

Please see Annex 8 – Call for Fast Track Start-Up driven Innovation projects (DiGinnovation)" for more details on the call content and eligibility criteria at each stage.

# 2.5. Activities within the flagship "Harnessing the full potential of health data for Innovation"

#### Introduction

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 the Member State borders. Yet the continued transition to digitalised approaches towards 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. 9

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 EIT Health's ecosystem under Fellowship programmes, raising the aptitude of the healthcare workforce in working with health data. Non-degree education

<sup>&</sup>lt;sup>7</sup> 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.

<sup>8</sup> https://eithealth.eu/wp-content/uploads/2021/11/EHDS\_report.pdf

<sup>&</sup>lt;sup>9</sup> https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space en





modules will be set-up and delivered through the **EIT Health Academy** platform to train healthcare professionals in technical competencies they need to thrive in a digitally transformed health system. This includes the exploitation of datasets and health registries for innovation, supporting citizens and patients to take control of their health data, and understanding 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<sup>10</sup>, 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 EIT Health's network, with the ability 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.

Short description of the activities called in this flagship

# 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 description:** Call for the design, creation, and delivery, of an 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: a four-week training module

Please see Annex 3 – Call for training module for professionals summary" for details on the call content and eligibility criteria at each stage.

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<sup>&</sup>lt;sup>10</sup> Non-exhaustive lists of health registries and biobanks are available through the EIT Health Scandinavia Regional Innovation Hub <u>website</u>, and BBMRI-ERIC <u>website</u>.





## 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 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

Target audience: Citizens, patients

Timeline: a four-week training module across 3 years

Please see Annex 4 – Call for training module for patients and citizens summary" for more details on the call content and eligibility criteria at each stage.

# 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 description:** The Winter/Summer school's ambition is to create a reference programme of short courses in Innovation and Entrepreneurship education — carving a path for aspiring entrepreneurs to create their own start-ups. I & E (Innovation and Entrepreneurship) elements are central and are delivered with a hands-on approach. It covers min. 5 ECTs

**Who should apply:** Higher Education Institutions collaborating with non-academic organisation/s

Programme 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

Please see Annex 1- Call for Summer/Winter School summary" for the details on the call content and the eligibility criteria at each stage.

# 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

Who should apply: contributing institutions of existing courses

Programme target audience: Master students, PhD students, healthcare professionals

Timeline: Up to 12 months (TBC)





Please see Annex 2 – Call for modules toward a labelled fellowship programme summary for the details on the call content and the eligibility criteria at each stage.

# Call for start-up-driven and Partner-driven Innovation projects: health registry or biobank-based

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

**Short description**: Creating a collaborative industry, start-up, academic institution or healthcare provider-led project consortia that focuses on validating technologies and building sustainable business models through exploiting existing health registries and biobanks, speeding up clinical trial development and bringing the new innovation developed in the project to market

Who should apply: organisations keen to build a collaborative consortium to address need

Timeline: Up to 24-months; end date no later than 31 December 2025

Please see Annexes Annex 6 – Call for Partner-driven Innovation projects summary" and Annex 7 – Call for Start-up driven Innovation projects summary" for details on the call content and eligibility criteria at each stage.

# 2.6. Summary of interactions between the activities in the Flagship Call

Flagship activities offer a palette of opportunities to interact with each other, strengthening the integration of the Knowledge Triangle through bringing about exchange among Education, Business Creation and Innovation type activities.

The below section summarises the identified interactions between activities called for in the Flagship Call.



Activity	Winter/Summer School	Modules towards a labelled fellowship programme	Module on advanced high value care principles	Start-up-driven and Partner-driven Innovation projects, and Fast Track Start-up driven Innovation (DiGinnovation)	Start-up-driven and Partner-driven Innovation projects: Service Quality Assessment	Bootcamp on VBHC models	Training module for healthcare professionals (non- degree)	Start-up-driven and Partner-driven Innovation projects: health registry or biobank-based
Winter/Summer School		1		2				
Modules towards a labelled fellowship programme	1		3				6	
Module on advanced high value care principles		3			4			
Start-up-driven and Partner-driven Innovation projects, and Fast Track Start-up driven Innovation (DiGinnovation)	2					5		



Activity	Winter/Summer School	Modules towards a labelled fellowship programme	Module on advanced high value care principles	Start-up-driven and Partner-driven Innovation projects, and Fast Track Start-up driven Innovation (DiGinnovation)	Start-up-driven and Partner-driven Innovation projects: Service Quality Assessment	Bootcamp on VBHC models	Training module for healthcare professionals (non- degree)	Start-up-driven and Partner-driven Innovation projects: health registry or biobank-based
Start-up-driven and Partner-driven Innovation projects: Service Quality Assessment			4			5		
Bootcamp on VBHC models					5			
Training module for healthcare professionals (non- degree)		6						7
Start-up-driven and Partner-driven Innovation projects: health registry or biobank- based							7	

Fellows from the Labelled Fellowship programme will have the opportunity to attend a Winter/Summer School as a requirement under the Label.

EIT Health will link as an administrator for the activities delivered under Winter/Summer School and the Labelled Fellowship programmes.

This interaction is applicable for activities under three flagships: New models to deliver healthcare, Facilitating the uptake of Digital Medical Devices and Diagnostics, and Harnessing the full potential of health data for innovation.

(2) Start-up driven and Partner driven Innovation projects (in either flagship) and Fast Track Start-up Driven Innovation (DiGinnovation)¹¹ projects 

Winter/Summer School

Representatives of Partner organisations from Innovation project consortia are encouraged to identify and commit to participation in a minimum of one option

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<sup>&</sup>lt;sup>11</sup> For DiGinnovation projects this requirement will consider the shorter timeline of the project, and therefore the selected activity or activities will need to be adjusted to take place accordingly.





among the following as appropriate to help facilitate Knowledge Triangle Integration under the flagship:

- Sit on the panel evaluating final pitches from learner participants at the end of the Winter / Summer School Track, and/or;
- Contribute to the development of challenges learner participants will address as part of the Winter / Summer School content, based on UN SDG3 related targets 3.1. to 3.9, and/or;
- Deliver a talk or lecture on the innovative technology or solution at the core of the innovation project, as well as the aims of the innovation project to Winter / Summer School learner participants as part of the learner curriculum, and/or;
- Offer a visit to Partner facilities to Winter / Summer school learning participants to facilitate understanding of how innovation is delivered on the ground

This interaction is applicable for activities under three flagships: New models to deliver healthcare, Facilitating the uptake of Digital Medical Devices and Diagnostics, and Harnessing the full potential of health data for innovation.

(3) Modules towards a labelled fellowship programme 

→ Module on advanced high value care principles

Non-degree education modules are expected to follow the quality criteria of UEMS EACCME for CPD accreditation, catering for healthcare professionals' national revalidation requirements. Furthermore, Non-degree education modules accredited under the European Credit Transfer and Accumulation System (ECTS) will feed into the EIT Labelled Fellowship journey, permitting continued professional development for module participants.

This interaction is applicable for activities under the flagship: New models to deliver healthcare.

(4) Module on advanced high value care principles 

⇒ Start-up-driven and Partner-driven Innovation projects: Service Quality Assessment

Healthcare professionals from innovation consortia (Service quality assessment Innovation project) will be invited to undertake the advanced module during the support programme of the innovation project. Completion of the advanced education module is mandatory for the clinical trial lead and data analysis lead in the consortium accordingly (as applicable based on consortium composition) and strongly recommended for the other consortium members. More information on





the Support Programme will be shared with selected proposals as they progress through the process.

This interaction is applicable for activities under the flagship: New models to deliver healthcare.

(5) Value-based Healthcare Bootcamp 

⇒ Start-up-driven and Partner-driven Innovation projects: Service Quality Assessment

Start-ups completing the bootcamp programme will be encouraged to further develop their business model and, with the support of the Regional Innovation Hubs, will be able to explore collaborative opportunities to bring their solutions and services to new markets in the form of Innovation projects.

Likewise, the start-ups participating in Innovation Projects on service quality assessment will be encouraged to apply for the bootcamp on VBHC models to speed up their business model validation.

This interaction is applicable for activities under the flagship: New models to deliver healthcare.

(6) Modules towards a labelled fellowship programme 

→ Training module for healthcare professionals (non-degree)

A non-degree education module is expected to follow the quality criteria of UEMS EACCME for CPD accreditation. Furthermore, Non-degree education modules accredited under the European Credit Transfer and Accumulation System (ECTS) will feed into the EIT Labelled Fellowship journey, permitting continued professional development for module participants.

This interaction is applicable for activities under the flagship: Harnessing the full potential of health data for innovation.

(7) Training module for healthcare professionals (non-degree) 

⇒ Start-up-driven and Partner-driven Innovation projects: health registry or biobank-based

Healthcare professionals from innovation consortia (registry-based innovation project) will be invited to undertake the non-degree education module during the





lifetime 12 of the Innovation project. Completion of the non-degree education module is mandatory for the clinical trial lead and data analysis lead in the Consortium accordingly (as applicable based on Consortium composition). Participation should therefore be a planned milestone in the project work programme.

This interaction is applicable for activities under the flagship: Harnessing the full potential of health data for innovation.

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<sup>&</sup>lt;sup>12</sup> Participation in the non-degree education module will be facilitated as part of the Support Programme for Start-up/Partner driven Innovation projects (health registry or biobank-based) applying under the 3rd Call cut-off (1st June 2023).





# 3. Flagships Call for BP2023 guidelines

# 3.1. 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 <a href="Strategic Agenda 2021-2027">Strategic Agenda 2021-2027</a> for details).

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 EIT Health's sustainability through different models which are explained in Annexes 10-12.

# 3.2. Eligibility, legal and financial provisions

This call is open to applications by EIT Health Core or Associate members as well as non-registered project partners. In order to be eligible for funding, 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<sup>13</sup> or countries associated to Horizon Europe as well as certain low- and middle-income countries.

A special consideration applies to legal entities established in the United Kingdom and Morocco. The transitional agreement<sup>14</sup> remains applicable, until association agreements start producing legal effects either through provisional application or their entry into force.

Non-registered project partners will only be eligible to receive funding after they have acceded to the relevant EIT Health legal framework. Individuals cannot apply for funding under this call.

Non-registered project partners, who have had their proposed activities selected for the EIT Health portfolio, and are requesting more than a €50,000 grant in one calendar year, must apply to become a member of the association <sup>15</sup> and pay the member-type appropriate membership

<sup>&</sup>lt;sup>13</sup> 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.

<sup>&</sup>lt;sup>14</sup> As set out in the General Annexes to the Horizon Europe Work Programme 2021-2022

<sup>&</sup>lt;sup>15</sup>In the unlikely event that a membership application is not approved at any point in the process, this shall have no further impact on selection, pay out or any other aspect of the call. The applicant will have fulfilled their obligation of applying for membership.





fee. Exceptions will be made for start-ups applying to Start-up-driven Innovation projects and Fast Track Start-up Driven Innovation projects (DiGinnovation) with the grant for option model.

The following rules surrounding consortium creation will be implemented at short proposal and full proposal stage:

- At the short proposal stage, any entity (whether EIT Health member or not) may apply
- At full proposal stage, each consortium should have at least one EIT Health Core/Associate Partner. In addition, Innovation activities should have at least 50% of its consortium composed of EIT Health Core/Associate Partners
- At full proposal stage, each consortium should have Partners coming from at least two different eligible countries coming from two different Regional Innovation Hubs.
- At full proposal stage, each consortium must involve organisations from two sides of the Knowledge Triangle.

The maximum amount of financial support provided to 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.

Financial support over EUR 60,000 provided to entities established in a third country not eligible under Horizon Europe can be granted, **only if the entity is not eligible for funding under a national guarantee**. They may receive EIT funding on an exceptional basis agreed with the EIT if the participation of the entity established in the third country is deemed essential for the action. In case the financial support is under EUR 60,000 within the 3-year duration of the Grant Agreement between EIT Health and EIT, namely 2023-2025, entities established in third countries may be awarded financial support, if duly justified.

What this means for UK entities:

- 1. Under the 60k threshold: UK entities are eligible for financial support (EIT Grant) up to EUR 60,000 within the 3-year grant duration
- 2. Over the 60k threshold and under the national guarantee: UK entities may still participate in proposals however budgets above EUR 60,000 within the 3-year grant duration must be covered own funding, and at the final reporting stage eventually reimbursed by the national guarantee. Important note: The guarantee will now cover all Horizon Europe calls that close on or before 31 December 2022. The official announcement is here Government extends Horizon Europe financial safety net GOV.UK (www.gov.uk). The UKRI website provides details on the scope and terms of the extension: Apply for Horizon Europe guarantee funding UKRI

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 of eligibility, you can reach out to <a href="mailto:eligibility@eithealth.eu">eligibility@eithealth.eu</a>





# 3.3. Societal impact

As explained in the introduction of this section, 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 patients and citizens 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 which 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.

In line with the journey towards designing solutions and programmes which bring value to citizens and patients, all activities in the EIT Health portfolio should more generally consider the principles of High Value Care transversally throughout programme development and implementation processes.





# Designing education and training activities that lead to demonstrable outcomes

Education activities must be need and data driven, evidence-based and relevant to targeted audiences. Demonstration of robust educational design is expected, through instructional design best practices and evaluation / outcome measurement framework defined from the outset, to ensure education and training activities have measurable outcomes. Outcome measurement data must be shared with EIT Health. Consortia should ensure the relevant GDPR requirements are covered to allow for such.

#### Complying with ethical, legal and social principles

Compliance with ethical rules and standards, relevant European legislation and international conventions is required.

## Contributing to the European Green Deal and the Sustainable Development Goals

One specific objective in the new EIT SIA 2021-2027 is to establish and foster appropriate synergies, complementarities and consistencies between EIT activities and other relevant European Union, national and regional initiatives, instruments, and programmes, including the European Green Deal. EIT Health is beginning to assess how the healthcare landscape is addressing the Green Deal objectives and which activities and drivers are key to accelerating innovation that supports addressing the key priorities. For this reason, EIT Health will collect information from its activities, not yet for evaluation purposes, on the steps they are taking to contribute to efforts aimed at tackling the climate challenge.

Similarly, in this view of synergies and complementarity with other initiatives, EIT Health will start to capture data on its portfolio contribution towards the achievement of the 2030 United Nations General Assembly goals for Sustainable Development which includes 17 Sustainable Development Goals (SDGs). Building on the principle of "leaving no one behind", the new agenda emphasises a holistic approach to achieving sustainable development for all. All activities aiming to enter the EIT Health portfolio will need to define in their short proposal submission on the EIT Health application platform (as the first step in the application process; see section '4. Selection process for Flagship Call BP2023') two of these goals that they will be working towards achieving.

# Implementing designed and tested innovations and claim IP rights

Each innovation proposal should aim during the activity lifetime to implement innovative products, services, and or approaches that will be filed for some form of intellectual property protection (i.e., patents, trademarks, registered designs, copyrights).

#### 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 proposals through dedicated KPIs (core KP and/or EIT health KPI), milestones and/or deliverables and should further be shown through reporting. Please see Annex 15 – KPIs list for the list of KPIs available.

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

## Contributing to the EIT and EIT Health Dissemination and Promotion

All EIT Health activities and programmes are required to undertake communication and dissemination activities to support the exploitation of programme results, as well as to promote and increase the visibility of the work undertaken by EIT Health, the EIT and its network community. Activities in the EIT Health portfolio will therefore be requested to follow EIT Health's guidelines for branding, communication, and dissemination, including but not limited to the application of appropriate EIT Health-EU co-branding on all dissemination material. Full proposals will need to present a dissemination and communication plan along with a corresponding budget, to specific target audiences and aligned to the challenge area. (MGA, Article 17).

# 3.4. Financial sustainability

All activities selected in EIT Health's portfolio must commit to contributing to the long-term financial sustainability targets of the KIC (EIT Health) by aiming at generating financial contribution back to the KIC.

Different models available depending on the type of the selected activity are outlined below.

# For innovation projects:

- Grant for option: only available to start-up-driven Innovation and Fast Track Start-up Driven Innovation (DiGinnovation) projects. Please see "Annex 10 – Financial sustainability model for Innovation activities: Grant for option model" for details
- Financial backflow: available to all Innovation projects. Please see "Annex 11 Financial sustainability model for Innovation activities: Backflow Model" for details of the backflow model.

If the backflow model is chosen by a Start-up driven Innovation or Fast Track Start-up Driven Innovation (DiGinnovation) project proposal, and the proposal is subsequently selected for funding, the start-up will be requested to apply for membership to the EIT Health association, and pay the member-type appropriate membership fee, in line with membership requirements for non-EIT Health partner organisations. Please see section, 'Note for non-EIT Health Core/Associate members' for full details of membership requirements for organisations in successfully selected proposals, including exceptions for Grant requests less than EUR 50,000 per calendar year.





Start-up-driven Innovation and Fast Track Start-up Driven Innovation (DiGinnovation) projects will need to choose and commit to progressing with either the "Grant for" option or the "financial backflow model" at the short proposal stage. Switching the model of choice will not be allowed at subsequent stages in the application and selection process. Partner-driven Innovation projects may only opt for the backflow model.

#### For Education activities:

- In case of KIC-driven and administered activity such as the EIT Health Labelled Fellowship programmes, as consortia deliver modules toward said programmes, the financial sustainability requirement lays with the KIC.
- In case of Partner-driven Education activities, such as summer schools, the consortium must submit a financial sustainability plan to ensure said summer schools become financially sustainable after the funding period. As stated in relevant sections on summer schools, EIT Health applies a decreasing funding model to summer schools.
- For all activities, the EIT Health revenue sharing model introduced in 2022 applies, thus opening mutually beneficial opportunities. Revenues will be shared at the following split: For Education activities driven by Partners: 70% Consortium 30% EIT Health ecosystem. For Education activities driven by EIT Health: 30% Consortium 70% EIT Health ecosystem. Please see Annexes 1-5 for details of different Education programmes and Annex 12 Financial sustainability model for Education and Business Creation activities" for details.
- Mandatory requirements of national law. It is acknowledged that Partners involved in EIT Health programmes may be subject to mandatory requirements of national law that are relevant to specific aspects of the guidelines, in particular the marketing of programmes and the generation of revenue. Nothing in the guidelines shall be deemed to require a Partner involved in an EIT Health programme to breach any mandatory requirement of national law under which the Partner is operating. In the case of conflict between the guidelines and mandatory requirements of national law, EIT Health aims at finding a coherent solution and to gain knowledge for the set-up of future calls. The affected Partner(s) are invited to 1) identify in their Expression of Interest (EOI) proposal any potential significant conflicts between the guidelines and mandatory requirements of national law under which the Partner is operating. 2) commit to working collaboratively with EIT Health and other Partners to co-create a compliant legal environment for the programme that respects mandatory requirements of national law while ensuring (a) achievement of the overall aims of the relevant programme; and (b) equitable treatment of Partners. Coherence of activity set-up with overall aims of the programme, especially financial sustainability contribution to the EIT Health ecosystem, shall be explored in due time after expression of interest, to avoid submission of non-compliant proposals.

# For Business creation activities:

 Please see Annex 12 – Financial sustainability model for Education and Business Creation activities for details.





# 3.5. Co-funding principles

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. EIT grant support (EIT Health resources) to EIT Funded Activities (EFAs)
- 2. Activity Partners co-funding with own resources
  - For Innovation activities, Winter / Summer School and Bootcamp programmes, a minimum co-funding level of 30% of the EIT Funded Activity (EFA) costs applies (70% maximum EIT Grant reimbursement of the EFA)
  - For other Education activities, co-funding contributions are encouraged but not mandatory. Please see Annexes 1-5 for details of Education programme requirements
  - Specific consideration will be given to consortia that exceed the 30% minimum co-funding level during the Portfolio Development process. Portfolio Development is described in Section 'Phase 3: Final selection (approx. 1.5 month)'
  - All mandatory co-funding contributions for all programmes will be an eligibility criterion during the application process. Additional co-funding beyond the mandatory requirement will be assessed during the portfolio development selection step
  - EIT Health must maintain a 30% co-funding rate on a portfolio level in the BP2023-25
- 3. Co-funding from external funding sources including regional, national or other EU funding streams
  - Other EU funding may be leveraged as non-EIT Funded Activities (NEFAs, see Annex 13 – NEFA guidelines) where appropriate.





 The 1/3 principle aims to exploit EIT Health funding by creating robust synergies with other public funding programmes and demonstrating the commitment of Partners through high impact achievements. Specific consideration will be given to consortia that bring such synergetic funds during the portfolio development process.

**Boundary condition**: The 1/3 funding requirement from Partners is crucial as the co-funding rate is a key criterion for EIT to release funding towards EIT Health and is obligatory to fulfil.

**Principle**: The additional 1/3 funding from other EU/national sources is **not mandatory**, but encourages Partners to secure co-funding on top of EIT Health and Partner resources, and will support the sustainability roadmap past 2025. EIT Health will provide support for Partners to help identify synergies and gain access to these additional sources of funding.





# 4. Selection process for Flagship Call BP2023

# 4.1. Introduction

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 Mar 2023	Cut-off 3 1 Jun 2023
New models to deliver healthcare			
Winter / Summer School	Yes	No	No
Modules towards a labelled Fellowship programme	No	Yes	Yes
Training Modules on Advanced High Value Care Principles	Yes	No	No
Start-up and Partner driven Innovation projects (Service Quality Assessment)	Yes	Yes	Yes
Bootcamp in VBHC	No	Yes	Yes
Facilitating the uptake of Digital Medical Devices & Diagnostics			
Winter / Summer School	Yes	No	No
Modules towards a labelled Fellowship Programme	No	Yes	Yes
Start-up and Partner driven Innovation 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
Modules towards a labelled Fellowship Programme	No	Yes	Yes
Training module for healthcare professionals (non-degree)	No	Yes	No





Training module for patients and citizens (non-degree)	No	Yes	No
Start-up- and Partner-driven Innovation projects (health registry or biobank based)	Yes	Yes	Yes

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

# 4.2. Selection process in details

The Flagship call introduces a new selection process. The refined process aims to ensure that applicants are asked to provide information for evaluation only at the necessary moment in the selection funnel, while strengthening proposals in an effort to maximise the success and impact of activities ultimately welcomed into the EIT Health portfolio.

The selection process will follow five phases outlined below.

A quality threshold of minimum 70% applies at the relevant selection steps. Proposals that reach a minimum of 85% at the hearings stage, but are not successfully selected to enter the portfolio, are offered a re-invitation for the next hearing round when applicable at another cut-off.

## Phase 1: Shortlisting (approx. 1 month)

Consortia will be invited to submit a short proposal form (accessible through EIT Health's application platform) as well as general information on their activity. At the short proposal stage, it will be accepted that consortia are still under construction and are not yet fully complete, and that details of the activity plan are not fully finalised. No commercialisation plan or sustainability plan will be expected at this stage.

The minimum requirements for applying (including eligibility criteria) are specified for the various flagship programmes under Annexes 1-9.

Submitted short proposals will be shortlisted through the following internal steps:

- Pre-filtering review including eligibility checking
- Filtering review to undertake an initial high-level assessment of general fit of the proposal into the flagship call based on strategic fit, potential future impact, and project feasibility. s

The pre-filtering and filtering steps will yield a yes/no decision on the progression of individual proposals further in the evaluation pipeline. Proposals that pass the internal review steps will go through a pre-selection process consisting of an online pitch in the case of Innovation and Education applications, or remote evaluation in the case of Business Creation applications.

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





# Shortlisting criteria

Project Excellence and Strategic Fit (50%)

# Implementation and Feasibility (10%)

Impact and Sustainability (40%)

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.

Important dates of the phase 1 process are outlined below:

	Cut off 1	Cut off 2	Cut off 3
Submission date of short proposal	2 Nov 2022	1 Mar 2023	1 Jun 2023
Eligibility check notification	10 Nov 2022	9 Mar 2023	8 Jun 2023
Filtering (internal review) notification and invitation to pre- selection round (if applicable)	24 Nov 2022	23 Mar 2023	22 Jun 2023
Pre-selection evaluation (if applicable)	12 – 14 Dec 2022	3 – 5 Apr 2023	10 – 12 Jul 2023
Pre-selection notification (external review)	22 Dec 2022	27 Apr 2023	20 Jul 2023

Important dates for a special case of Fast Track start-up driven Innovation project type (DiGinnovation) in cut-off 2 are outlined below:

	DiGinnovation
Submission date of short proposal	1 Mar 2023
Eligibility check notification	9 Mar 2023
Filtering (internal review) notification and invitation to pitch day	23 Mar 2023
Due diligence	24 Mar – 5 Apr 2023
Pitch day	5 Apr 2023
Pre-selection notification (external review)	6 Apr 2023





#### Phase 2: Support programme (approx. 1-2 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 principle implementation, and refine synergies with other activities (also part of the support programme or already in the portfolio). The support programme applies to all types of proposals and activities across the three flagships.

It is mandatory to take part, except for consortia who have already been through the programme, e.g. as a result of a previous application.

In parallel, start-ups that choose the grant for option model 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. Please see Annex 14 – Due Diligence" for details of the due diligence process.

Full proposals are expected to be submitted at the end of the support programme, and should incorporate any relevant feedback, learnings, recommendations and improvements gathered as a result of the support programme, with the ambition of producing a high-quality proposal to enter the final selection phase and help inform a thorough evaluation.

Expected dates for submission of the full proposal are given below. Those dates are subject to changes depending on the final definition of the support programme. They will be confirmed at the start of each support programme phase:

	Cut off 1	Cut off 2	Cut off 3
Full proposal deadline expectation	1 Mar 2023	14 Jun 2023	11 Oct 2023

Expected date for submission of the full proposal for Fast Track Start-up Driven Innovation project type (DiGinnovation) in cut-off 2 is outlined below:

	DiGinnovation
Full proposal deadline expectation	19 May 2023

NB: Full content details of the support programme will be disclosed early November 2022.





# Phase 3: Final selection (approx. 1.5 month)

The final selection phase will be facilitated for all consortia who submit full proposals. The phase will consist of an evaluation process, a portfolio development step and an Ethical, Legal and Social Issues (ELSI) review, as further outlined in this section.

#### **Evaluation**

Evaluation will take the form of a hearings review for all types of activities. The hearings will take place within two weeks following the submission of full proposals. An exception applies for Fast Track Start-Up driven Innovation (DiGinnovation) projects, where final selection will be based on the outcome of a remote external review ranking.

Details on the organisation of the hearings or the remote review will be communicated by the end of December 2022. Evaluation will be based on the following criteria:

#### **Evaluation Criteria**

Project Excellence and Strategic Fit (20%)

Implementation and Feasibility (40%)

Impact and Sustainability (40%)

#### Portfolio development

Full proposals will be ranked based on evaluation scores assigned as a result of the hearings review and will enter a portfolio development process. The purpose of portfolio development is two-fold. Firstly, the analysis serves to quantify the impact expected from prospective activities, thereby building a strong portfolio of high-potential activities of sufficient return. Secondly, portfolio development allows to inform selection decisions in a scenario where competing proposals receive similar evaluation scores.

The portfolio development process will consider both the outcomes of the hearings, as well as key promises in proposals linked to societal impact, financial contribution models and 1/3 cofunding. Ranked proposals may receive up to 3 additional points as a result of portfolio development.

#### **Evaluation Criteria for Portfolio Development**

Societal Impact (+1 point)

Financial contribution models (+1 point)

1/3 co-funding (+1 point)





#### **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.

Final notification of acceptance into the portfolio will be communicated around one month after submission of full proposal i.e., following the below calendar:

	Cut off 1	Cut off 2	Cut off 3
Final selection notification	6 Apr 2023	20 Jul 2023	16 Nov 2023

Final notification of acceptance into the Fast Track Start-up Driven Innovation project type (DiGinnovation) in cut-off 2 will also be communicated around one month after submission of full proposal i.e., following the below calendar:

	DiGinnovation
Final selection notification	22 Jun 2023

NB: These dates are subject to changes depending on the final date of full proposal submission and on the EIT Health Supervisory Board meeting to confirm the final selection.

#### 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 for option model, 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, i.e. depending on the planned timeframes in the selected activity proposal, activity start and end need not coincide with a January to December timeframe.

# Phase 5: Monitoring (project lifetime + 5 years)

Once per year, all projects are subject to a formal review. The review is a go/no-go point for the continuation for the project and EIT funding, and is established on the basis of a critical time point in the project's life cycle, serving to either fast-track, support, redirect, or stop the project





in cases of improper implementation or severe underperformance.

Post-funding monitoring will also be required up until five years after project closure to capture impact which exceeds the project 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 special attention will be given to projects to continuously capture EIT Core KPIs in post-funded years. In addition, post-funding monitoring will help to identify potential success stories or lessons learnt 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).





### 4.3. How to apply?

### Application platform

At each relevant submission step in the application and evaluation process (short proposal and full proposal) activity proposals must be completed and submitted via the new EIT Health application system: <a href="here">here</a> until the deadline date 4pm CET.

Please see section '4.2. Selection process in details' to find deadline dates related to each application cut off.

The activity leader of a proposal is responsible for obtaining commitment from the consortium participating in the proposal before submission. The activity leader remains the single point of contact for official communication throughout the submission and review process and is responsible for the subsequent tasks that may ensue.

Step by step application platform guidance on proposal submission is available on EIT Health's application platform.

### Registration of project participants

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

If your organisation is already an EIT Health member or has registered as an External Project Partner in previous Call(s) in our platform PLAZA, you should be able to find the corresponding data of your organisation in the application platform.

However, you will need to still create a new account for you as an individual and link yourself to your organisation. Please bear in mind that the approval of this link might take 48 hours. Please be also aware that you will have to fill out additional fields on your organisation profile.

#### Note for non-EIT Health Core/Associate members

In line with Horizon Europe principles for openness, this call is open for applications from all organisations, external and internal to the EIT Health network, following the eligibility criteria of 3.2. Eligibility, legal and financial provisions.

Non-EIT Health Partner organisations who have had their proposed activities selected for the EIT Health portfolio, and are requesting more than €50,000 grant in one calendar year, must apply to become a member of the association and pay the member-type appropriate membership fee (Core or Associate Partner, depending on the amount of Grant award). Processing of the membership request will attract administration and management fees irrespective of the outcome of the request.





Please refer to the 'Become an EIT Health Partner' section of the EIT Health website for details of the process on requesting membership. Please contact your Regional Innovation Hub for support (see section Where to get help).

Exceptions will be made for organisations with a requested Grant lower than 50.000 €, and for start-ups applying to Start-up driven Innovation projects and Fast Track Start-up driven Innovation projects (DiGinnovation) with the grant for option financial sustainability model.

### Note for EIT Health Core/Associate members

As in previous years, EIT Grant funding is limited to €350,000 per annual BP for Associate Partners, including their Affiliated Entities.

Considering the new opportunities and the new strategic course of EIT Health, an exception has been granted to allow Partners who have left in the last two years (in 2021 and 2022) to reconsider and re-join, despite the EIT Health AoA section 5.3 and By-Laws section 4.16 Applying before the 31st of October 2022 waives the administration fees of 5,000 € due as of 2023, and keeps the years of membership intact.

There is no limitation on the number of proposals Partners in any Partner type may participate in.

### EIT Regional Innovation Scheme (EIT RIS)

The EIT Regional Innovation Scheme (EIT RIS) was introduced in 2014 to advance the innovation performance of more countries and associated regions across Europe, especially countries with moderate or modest innovation scores as defined by the European Innovation Scoreboard.

Entities from RIS eligible countries or regions can participate in this Flagship Call. The EIT budget devoted to implementing EIT RIS activities, in the 2021-2027 period, will be at least 10% and maximum 15% of the overall EIT funding for existing and new KICs.

EIT Health encourages the participation of entities from RIS regions with the goal of improving the knowledge triangle integration and the innovation capacity of local ecosystems in the RIS countries and regions and attract new RIS Partners.

#### Webinars – presentation of the Call

EIT Health will be offering a series of online webinar sessions, organised by Regional Innovation Hubs, to present the Call for projects and offer an opportunity to applicants to ask any questions:

<sup>&</sup>lt;sup>16</sup> AoA section 5.3: "After a Member has withdrawn, it may rejoin the Association at the earliest two years after the withdrawal has become effective." By-Laws section 4: "An upgrade (Associate to Core) is not possible within a period of 2 years after a downgrade"





Please find below the list of webinars:

Regional Innovation Hub	Date	Time
Scandinavia	19 September 2022	3pm CET
Spain	23 September 2022	1pm CET
Belgium-Netherlands	27 September 2022	11am CET
France	28 September 2022	9am CET
InnoStars	30 September 2022	2pm CET
Ireland/UK	4 October 2022	1pm CET
Germany/Switzerland	5 October 2022	9.30am CET
Austria	30 September 2022	11am CET

Please reach out to your Regional Innovation Hub if you would like to attend.

### Note on access to the EIT Health Connections Community Platform and to EIT Health website

Supporting guidance and information documents regarding this call, including proposal guidance, recordings and other materials, are available through the EIT Health Community platform, <u>Connections</u>. Only EIT Health members can have access to Connections.

Organisations that are not EIT Health Partners will have access to all material through the EIT Health website here: <a href="mailto:eithealth.eu/opportunity/call-for-activities-related-to-the-flagships/">eithealth.eu/opportunity/call-for-activities-related-to-the-flagships/</a>

### 4. 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 the assigned external evaluators, who are bound to confidentiality by contract. 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. These third parties are also bound by confidentiality provisions.

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





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

Applicants and potential beneficiaries of the EIT grant in selected projects must avoid any conflict of interest and comply with the principles of transparency, non-discrimination, and sound financial management.

### 4.4. Grounds for appeal and appeal 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., technical failure of the electronic application platform).
- Human/technical errors made by EIT Health staff.

What does not constitute grounds for appeal:

Scores awarded in the course of the evaluation process.

#### **Appeal process:**

- Partners should send their appeals in writing to the EIT Health Executive Management
  Team at <a href="mailto:appeals@eithealth.eu">appeals@eithealth.eu</a> (addressing the CEO) as soon as they identify an error,
  but no later than 21 days after the error occurred
- EIT Health staff at the Central Office assess the claim and deliver a first response with the regional Innovation Hub/InnoStars in copy
- 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, a late submission may still be accepted as eligible)
- The EIT Health Supervisory Board is notified about the matter if:
  - o the Partner does not accept that the Executive Management Team rejects the appeal, or;
  - o there are grounds for appeal, but the problem cannot be remedied any more without disrupting the process.





### 4.5. 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 Vaitsis	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	Regional Innovation Hub Germany- Switzerland	clc.germany@eithealth.eu
	Other	Jeff Wilkesmann	jeff.wilkesmann@eithealth.eu
InnoStars	All	Chiara Maiorino Manal Al-Hammadi Marta Passadouro Zsolt Bubori	chiara.maiorino@eithealth.eu manal.al-hammadi@eithealth.eu marta.passadouro@eithealth.eu 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-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

Please refer to the website for the most updated application of the call document.





## Annex 1 – Call for Summer/Winter School summary

Type of Education	Winter or Summer School (W/S School)
projects	
Definition	Delivery of Winter or W/S School programme to cover 5 ECTS.
	Themes correspond to each of the Flagships.
Goal	EIT Health W/S School Series is meant to become a reference in short courses for entrepreneurship education, carving the path toward start up creation for aspiring entrepreneurs.
	W/S Schools expose students to innovation and entrepreneurship in a dynamic, intense and hands-on short and comprehensive course, preparing learners to continue on a path toward further I & E pursuits.
	As I & E education sprints, W/S Schools merge active learning methodologies aimed at concluding with learners pitching their own business / service idea. Prototyping is strongly encouraged.
	The Challenges to be solved directly relate to the Flagship initiatives and are developed in collaboration within the KIC.
	The first edition takes place in winter or summer 2023.
Duration	A W/S School can apply for a maximum 3-year funding cycle.
	EIT Health calls for a multi-annual proposal, up to 3 years. Proposals shall present full budgets for the whole granting period.
Indicative grant amount	Up to €160,000 will be awarded for Year One of a W/S School, considering the following costs as the maximum eligible for each category:
per project	<ul> <li>Up to €70,000 for mobility travel expenses.</li> </ul>
	<ul> <li>Up to €4,500 for event catering.</li> </ul>
	<ul> <li>Up to €60,000 for trainers and mentors.</li> </ul>
	<ul> <li>Up to €25,500 for trainers and mentors (travel).</li> </ul>
	The decreasing funding model will function as follows over a 3-year period:
	• Year One: Up to €160,000
	• <b>Year Two</b> : Up to €115,000
	<ul> <li>Year Three: Up to €70,000 (final year of funding)</li> </ul>
	Programme developed and implemented in collaboration with EIT Health team.
	EIT Health assumes costs for marketing, prizes on Mentoring & Coaching.
	One team – to be chosen based on academic guidelines – will be awarded a set of sessions with mentors and experts of the <u>EIT Health Mentoring &amp; Coaching Network</u> .





	After the grant period, it is expected that the W/S School will continue its activities and, if agreed, can extend its collaboration with EIT Health by applying to the Recognition Programme.
Target Learner	Motivated and aspiring entrepreneurs who are ready to advance their I & E journey in a STEM field. The learners should be looking to take the next step with their entrepreneurial ideas.
	For example, any of the following learners could be the target audience:
	<ul> <li>Master students</li> <li>PhD students</li> <li>Post-doctoral students</li> <li>Multidisciplinary students</li> </ul>
	Each of the W/S Schools will be directly linked to the corresponding EIT Labelled Fellowship pathway. Fellows will be invited to attend W/S as part of their personalised learning pathway and vice versa, W/S learners will be invited to upgrade and become EIT Fellows.
	The programme must enrol a minimum of 70 learners per year.
	All participants will be invited to join the EIT Health Alumni Community.
Standardised data	Participant registration and a post-programme survey will be led by EIT Health, with collaboration from the Activity Lead and the participating institutions. Access to participants' data will be shared.
Co-funding request	Mandatory co-funding: 30%
Rules of participation	<ol> <li>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.</li> <li>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.</li> <li>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</li> <li>Consortium rules apply. Visit Partnership specificities to learn more.</li> </ol>
Partnership specificities	Must include a minimum of two Higher Education Institutions (HEI), from two different eligible countries, whereby:  One HEI must be an EIT Health Core or Associate Partner  One HEI must belong to a RIS region.
	There must also be at least one non-academic or industry partner.
Learning formats	In-person, online or blended formats are acceptable.  Given that the W/S School is delivered in a minimum of two host institutions, the learning must be synchronised in the delivery of key content. For example, master classes, a final event, etc.
Digitalisation	As a component of the W/S School, an online, pre-learning course is encouraged to facilitate W/S School participants in starting off at the same level and allowing them to make the most





	of the learning experience. Please note that EIT Health can ease the Entrepreneurship 101 for this levelling exercise.
EIT Learning Objectives	As W/S Schools are linked to EIT Labelled Fellowship pathways, its design shall directly contribute to the EIT Learning Outcomes: <u>EIT Learning Outcomes   European Institute of Innovation &amp; Technology (EIT) (europa.eu)</u>
European Credit Transfer and Accumulation System (ECTS	The W/S School must offer a minimum of 5 ECTS.
EIT Health Certificates of completion	Certificates of Completion provided by EIT Health must be issued to eligible participants.
Mandatory evaluation of	The Activity Lead, in collaboration with EIT Health, will perform the impact evaluation of the programme on a yearly basis.
EIT Health funded programmes // EIT Learning Objective	A pre- and post-questionnaire – to demonstrate the variation in levels of confidence, performance, skills, knowledge and/or behaviour around the W/S School– will be provided by EIT Health.
	A retrospective action for measurement of entrepreneurial intentions and innovations skills development among previous years' participants will be developed by EIT Health. Potential start-ups created, jobs created and other relevant KPIs will be monitored in the 5 years following completion.
Sustainability	The W/S School must outline a well-defined sustainability strategy for continuing the education programme beyond EIT Health funding.
	The W/S School shall work toward sustainability, with a multi-annual strategy included in the proposal. Each of the identified mechanisms requires a clear action plan.
	After the grant period, it is expected that the W/S School will continue its activities and, if agreed, can extend the collaboration with EIT Health by applying to the Recognition Programme, which allows the programme to benefit from being part of the portfolio. While the programme will not receive a direct grant, it will receive other benefits.
	Please note that letters of intent (institutional commitment) and of interest (sponsoring seats, master thesis, scholarships, etc.) are required.
Financial return to EIT Health	- Revenue sharing model: 70% to consortium / 30% stays within EIT Health ecosystem.
KPIs	Mandatory KPIs:
(Mandatory)	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).
	Optional KPIs (it is mandatory to select at least one):





KIC03: Number of students trained by EIT Health (non-degree) education programmes.

KIC04: Number of professionals trained: Number of healthcare professionals trained by EIT Health non-degree education programmes; or, Number of executives trained by EIT Health non-degree education programmes.

KIC07: Number of Start-ups created by participants in (non-degree) Education programmes.

KIC05: Employment success.

KIC08: Number of start-ups engaged.

KIC10: Number of citizens/patients reached.

KIC11: Number of citizens/patients involved.

#### **Work Plan**

The first edition can take place late winter or summer 2023.

A W/S School includes:

A. Development of the programme, including:

- arranging consortium meetings;
- developing education content (including developing challenges connected to those described under each of the Flagships and based on UN SDG3 related targets 3.1. to 3.9, as stated on EIT Health's Strategic Agenda);
- sourcing coaches, mentors and speakers;
- arranging hosting logistics (agenda, venues, supporting technology, etc.).

B. Delivery of a two-to-three-week W/S 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 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.

C. End of year programme reporting and financial reporting.

Expected deliverables:

To be described by the Activity Leader.

 $\hbox{OUT 01: Recruitment and promotion.}\\$ 

OUT 02: Delivery of the W/S School

OUT 03: Sustainability models to continue the W/S School beyond EIT Health funding.





DEL 01: Recruitment and marketing plan. DEL 02: Report outlining the agenda, curriculum, and methodology planned for delivery of the W/S School. DEL 03: Report outlining the sustainability model that will be implemented to continue the W/S School beyond EIT Health funding. DELO4: Final report including structured learner data, lessons learned, achievements (template to be provided). DELO5: Impact assessment in year 3, exposing changes in the mindset of Alumni, potential and confirmed start-up creation cases, etc. MS 01: (Critical) Confirmation of programme dates. MS 02: (Project) Launch of learner recruitment. EIT Health will lead the marketing of the programme, ensuring its visibility through the Marketing relevant channels, so the recruitment of the yearly targets is successful. The programme will follow the general communication and marketing guidelines of EIT Citizen and The proposal must include completion of the mandatory questions on citizen and patient **Patient** engagement and outcomes that matter to patients as well as the ELSI self-assessment form Engagement, High-Value Citizens and patients are expected to be involved in the activity development. Care, Ethical, **Legal and Social** Issues (ELSI) **Evaluation** Common scorecard for all projects – overall criteria identic for all archetype: criteria and Project Excellence and Strategic Fit weights Implementation and Feasibility Impact and Sustainability The weight of each criterion will be different on each phase of the Selection process\_ Monitoring Education and Activity Leads will meet regularly to coordinate the collaboration within the KIC and to review progress in implementation. All EIT Health activities are subject to formal monitoring from the EIT Health Project Management Office to determine progression towards critical milestones. Please note that the continuation of the programme is directly related to KPIs and outcomes

achievement. Funding can be discontinued in the event of underachievement.









# Annex 2 – Call for modules toward a labelled fellowship programme summary

Type of Education projects	EIT Labelled Fellowships	
Definition	Modules that enable individual learning pathways around the challenges that each of the flagship refers to.	
Goal	EIT Health aims at developing 3 Labelled Fellowships, one per flagship. For that, it is calling for some common elements to respond to the 3 pathways and some specific contents that would be flagship-related:	
	Common elements:	
	<ul> <li>A) Consortia aiming to cover the Recognition of Prior Learning (RPL)_to support the definition of the personalised pathway and to identify entrepreneurial potential. I.e. using relevant tools, platforms; relevant self-assessment surveys, etc.</li> <li>B) Consortia aiming to deliver mandatory Innovation &amp; Entrepreneurship (I &amp;E) and Leadership competencies, which are mandatory in every personalised pathway. This module/s aims at being essential in the field for those not opting to include a W/S School and shall work in complementarity with the learners that will. It should be equivalent at least to 5 ECTs.</li> </ul>	
	Flagship-related contents:	
	<ul> <li>C) Consortia offering modules to be repurposed aimed at upskilling / reskilling learners in each of the flagships' fields.</li> <li>D) Establishing and conducting content-based assessment. This will be complementary to the competency-based and impact-based assessments that the KIC will lead and carry out.</li> </ul>	
	For consideration:	
	<ul> <li>A fellow shall cover at least the equivalent to 30 ECTs by following a journey where the W/S School (5 ECTS) can be optional, but the contents on I &amp; E will remain as mandatory (at least 5 ECTS) as well as the collaboration with a non-academic setting to solve real-life challenges (cross-organisational collaboration to be equivalent to 3 ECTs).</li> <li>The cross-organisational activity will be KIC-lead through the collection of challenges from non-academic partners in a shared space or pool.</li> </ul>	
	<ul> <li>The content of the modules shall support the learner to respond to the above-mentioned challenges.</li> <li>The development of solutions for these challenges can lead to the submission of the required learner assessment.</li> </ul>	





	<ul> <li>The modules shall work independently –avoid as much as possible interdependent and series (I and II, etc) in order to maximise the personalised progress of the learners.</li> </ul>
Duration	The grant covers the repurposing of the above-mentioned contents during 2023 and the continued work during the RPL and content-based assessment activities until the end of 2025.
Indicative	900K available for the 3 Labelled Fellowships; up to 300K€ per flagship pathway.
grant amount per project	Consortia aiming at responding for common elements can submit proposals with budgets covering the 3 flagships over 2023-25.
	Consortia aiming at responding for flagship-related contents can submit proposals with budgets covering the 3 flagships over 2023-25, attaining the contents shall be ready for the 2023-24 academic year.
	Indicative amounts:
	Common elements for the 3 flagships: up to 150K for I $\&$ E and Leadership modules and up to 150K for Recognition of Prior Learning.
	Flagship-related contents and assessment: max. 200K.
	Grant cannot be used for LMS platform, challenges definition and recruitment / marketing related costs.
	Proposals shall present full budgets for the whole granting period.
Target Learner	-Master and Doctoral level learners having completed or not their studies.
	-Professionals willing to upskill / reskill themselves in the related fields.
	First learners will be recruited to start their pathways in 2023 Fall.
Co-funding request	Co-funding is recommended, not mandatory. Proposals with co-funding will be evaluated favourably.
Rules of participation	<ol> <li>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.</li> <li>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.</li> <li>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</li> <li>Consortium rules apply. Visit Partnership specificities to learn more</li> </ol>
Partnership specificities	Must include a minimum of two Higher Education Institutions (HEI), from two different eligible countries, whereby:
	<ul> <li>One HEI must be an EIT Health Core or Associate Partner</li> <li>One HEI must belong to a RIS region.</li> </ul>
	There must also be at least one non-academic or industry partner that is expected to contribute to the curriculum / modules repurposing as well as assessment supervisors.





Learning formats	Online – as self-paced as possible.
EIT Learning Objectives	EIT Labelled Fellowship pathways_directly relate to the EIT Learning Outcomes: <u>EIT Learning</u> Outcomes   European Institute of Innovation & Technology (EIT) (europa.eu)
European Credit Transfer and Accumulation System (ECTS)	Both the Entrepreneurship & Innovation and Leadership modules as well as the specific flagship-related modules are expected to offer ECTs.
Mandatory evaluation of EIT Health funded programmes EIT Learning Objective	The awarded consortiums will conduct content-based assessment, while EIT Health will conduct competencies and impact-based assessment on a regular basis.
Sustainability	-Revenue generated by EIT Health will be shared following the model: 30% to consortium / 70% to EIT Health ecosystem
	-Programmes hosted on EIT Health platform (Academy)
	-IP ownership remains with the consortium
KPIs	KPIs will be managed and reported by the KIC. Still, it is important that proposals acknowledge them since they are expected outcome of the personalised pathways.
	EITHE07.5 Students enrolled in EIT-labelled programmes
	EIT07.1 Graduates from EIT-Labelled programmes
	EITHE07.2 EIT RIS Graduates from EIT labelled programmes.
	EITHE05.1 Start-ups created by students enrolled and graduates from EIT-labelled programme
	EITHE05.2 EIT RIS Start-ups created by students enrolled and graduates from EIT-labelled programme.
	EITHE09.1 Students and graduates from EIT labelled programmes who joined start-ups
	EITHE09.2 EIT RIS Students and graduates from EIT labelled programmes who joined start-ups.
	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 around the topic information.
Work Plan	The first edition takes place in 2023-24 academic year.
	Each consortia shall identify which WP they contribute to:
	WP1: Recognition of prior learning. Ongoing 2023-2025
	WP2. Modules to be repurposed -to be developed in 2023 & Content- based assessment definition and implementation - ongoing 2023-2025.





#### Expected deliverables:

OUT 01: Methodology-Recognition Prior Learning

OUT 02: Modules to be repurposed for the learning pathways

OUT 03: Content-based assessment method

DEL 01: Methodology for the Recognition of Prior Learning and implementation definition.

 ${\tt DEL~02:} \ Curriculum\ of\ the\ learning\ pathway.\ Visualisation\ of\ potential\ journeys.$ 

DEL 03: Definition of content-based assessment definition.

DEL 04: Report to identify the contribution of the non-academic partner/s in the curriculum

development as in the supervision of the assessment.

MS 01: (Critical) Availability for action of the RPL process.

MS 02: (Project) Availability of the repurposed modules.

MS 03: (Critical) Availability of content-based method.

EIT Health can require some information in 2024 and 2025 with regards to RPL delivery and content-based assessment to complete the KIC reports for the whole activity









## Annex 3 – Call for training module for professionals summary

Type of Education projects	Online Training module for professionals
Definition	Design, creation, and delivery of innovative, impactful, and high-quality 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
Goal	To raise awareness, knowledge and technical skills in digital health for successful deployment of innovation.  Future participants to receive European certification from EIT Health via EIT Label system when label is approved by EIT.
Audience/targe t learners	The module must precisely define the healthcare professionals target audiences. Professionals are defined as all actors in healthcare systems.
Duration	4 weeks
Duration of the grant	Proposals must commit to multi-annual delivery of the implemented training programme for up to 3 years. Proposals shall present full budgets for the whole granting period.
Indicative grant amount per project	Max 50k€ for three years
Co-funding request	Co-funding recommended, not mandatory. Proposals with co-funding will be evaluated favourably.
Rules of participation	1. This call is open to applications from EIT Health Associate or Core members as well as new organisations.





	2. Projects must involve members from a minimum of two countries and from two different Regional Innovation Hubs.
	3. The geographical origin of applicant is limited to EU Member States or countries associated to Horizon Europe.
	4. 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.
	5. Training module must be need- and data-driven, evidence-based and relevant to target audiences. Demonstration of robust educational design is expected through instructional design best practices and evaluation / outcome measurement framework defined from the outset.
	6. Consortia should ensure the relevant GDPR requirements are covered to allow for such.
	7. Target audiences must be precisely defined
	8.Proposals must commit to multi-annual delivery of the implemented training programme for up to 3 years
	9.Training module will be hosted and delivered on the EIT Health Academy Platform
	10. Training module to follow quality criteria of UEMS EACCME for CPD accreditation
	11. Consortium will apply for UEMS EACCME credits
Standardised data	Participants registration will be done on the EIT Health Academy Platform. Access to participants' data will be shared (registration, evaluation, outcomes measures).
Intellectual	Intellectual Property is owned by the consortium
Property	• •
Mandatory Evaluation of activity	Outcome measurement framework must be defined to ensure the training has measurable outcomes. Outcome measurement data will be collected on the EIT Health Academy Platform and shared with the consortium.
	A post activity test in the form of a multiple-choice questionnaire (MCQ) will be included in the module. Content of the MCQ will be provided by the activity lead. A pass score will be defined for learners willing to obtain the UEMS EACCME certificate. UEMS EACCME certificate will be delivered via the EIT Health Academy Platform.





EIT Health Certificate of completion	EIT Health Certificates of Completion must be issued to eligible participants.		
Financial return to EIT Health	Revenue sharing model: 30% to consortium / 70% to EIT Health ecosystem		
KPIs (Mandatory)	KIC04.1: Healthcare professionals trained by EIT Health (non-degree) education programmes EITHE08.1: Participants in (non-degree) education and training (including EIT RIS)		
Sustainability	The consortium must outline a well-defined sustainability strategy for continuing the training module beyond EIT Health funding.  After the grant period, it is expected that the consortium will continue the training programme and, if agreed, can extend the collaboration with EIT Health by applying to the Recognition Programme (type B) which allows the programme to remain in the portfolio and benefit from EIT Health services. In return Recognised programmes will continue to share their KPIs with EIT Health.		
Marketing	EIT Health will lead the marketing of the programme, ensuring its visibility through the relevant channels, so the recruitment of the yearly targets is successful.  The programme will follow the general communication and marketing guidelines of EIT Health.  Activity lead and the consortium are not allowed to market their training modules using their own communications channels such as websites.		
Recruitment of participants	The programme must enrol a minimum of 1600 learners by 2025.  All learners will be invited to join the <u>EIT Health Alumni Community.</u>		
Monitoring	EIT Health Project Management Office (PMO) will conduct a mandatory monitoring meeting per year.  Mid-term review: once per year connected to deadline of critical milestone of the project.		









### Annex 4 – Call for training module for patients and citizens summary

Type of Education projects	Online Training module for patients and citizens		
Definition	Design, creation, and delivery of innovative, impactful, and high-quality training module to educate and equip patients and citizens with the skills needed to successfully deploy innovation and digital transformation in healthcare delivery, including through the re-use of health data		
Goal	To raise awareness, knowledge and technical skills in digital health for successful deployment of innovation.  Future participants to receive European certification from EIT Health via EIT Label system when label approved by EIT.		
Audience/targe t learners	The module must precisely define the groups of patients and citizens which will benefit from this training.		
Duration	4 weeks training module across 3 years		
Duration of the grant	Proposals must commit to multi-annual delivery of the implemented training programme for up to 3 years. Proposals shall present full budgets for the whole granting period.		
Indicative grant amount per project	Max 50k€ for three years		
Co-funding request	Co-funding recommended, not mandatory. Proposals with co-funding will be evaluated favourably.		
Rules of participation	1. This call is open to applications from EIT Health Associate or Core members as well as new organisations.		
	2. Projects must involve members from a minimum of two countries and from two different Regional Innovation Hubs.		





	3. The geographical origin of applicant is limited to EU Member States or countries associated Horizon Europe.			
4. Organisations will not be eligible to receive funding until they have acceded to the Horizon Europe legal framework and are eligible to receive EIT-funding as grant rec Individuals cannot apply for funding under this call.				
	5. Training module must be need- and data-driven, evidence-based and relevant to target audiences. Demonstration of robust educational design is expected through instructional design best practices and evaluation / outcome measurement framework defined from the outset.			
	6. Consortia should ensure the relevant GDPR requirements are covered to allow for such.			
	7. Target audiences must be precisely defined			
	8.Proposals must commit to multi-annual delivery of the implemented training programme for up to 3 years			
	9.Training module will be hosted and delivered on the EIT Health Academy Platform			
Standardised data	Participants registration will be done on the EIT Health Academy Platform. Access to participants' data will be shared (registration, evaluation, outcomes measures).			
Intellectual Property	Intellectual Property is owned by the consortium			
Mandatory Evaluation of activity	Outcome measurement framework must be defined to ensure the training has measurable outcomes. Outcome measurement data will be collected on the EIT Health Academy Platform and shared with the consortium.			
EIT Health Certificate of completion	EIT Health Certificates of Completion must be issued to eligible participants via the EIT Health Academy Platform.			
Financial return to EIT Health	Revenue sharing model: 30% to consortium / 70% to EIT Health ecosystem			
KPIs (Mandatory)	EITHE08.1: Participants in (non-degree) education and training (including EIT RIS)			





Sustainability	The consortium must outline a well-defined sustainability strategy for continuing the training module beyond EIT Health funding.  After the grant period, it is expected that the consortium will continue the training programme and, if agreed, can extend the collaboration with EIT Health by applying to the Recognition Programme (type B) which allows the programme to remain in the portfolio and benefit from EIT Health services. In return Recognised programmes will continue to share their KPIs with EIT Health.	
Marketing	EIT Health will lead the marketing of the programme, ensuring its visibility through the relevant channels, so the recruitment of the yearly targets is successful.  The programme will follow the general communication and marketing guidelines of EIT Health.  Activity lead and the consortium are not allowed to market their training modules using their own communications channels such as websites.	
Recruitment of participants	The programme must enrol a minimum of 1600 learners by 2025.  All learners will be invited to join the EIT Health Alumni Community.	
Monitoring	EIT Health Project Management Office (PMO) will conduct a mandatory monitoring meeting per year.  Mid-term review: once per year connected to deadline of critical milestone of the project.	





# Annex 5 – Call for training Modules on Advanced High Value Care Principles summary

Type of Education projects	Online Training module on advanced high value care principle			
Definition	Design, creation, and delivery of innovative, impactful, and high-quality training module to skill, upskill and reskill Master and PhD-level students and graduates, healthcare and medical professionals in the field of value-based healthcare transformation.			
Goal	The advanced high value care principles module is meant to provide advanced training to individuals and professionals already introduced to the concept of high value care.			
	Future participants will receive European certification from EIT Health via EIT Label system once the label is approved by EIT.			
	The module will also serve as part of the support programme for innovation collaborative projects under the Service Quality Assessment call for projects, meaning that in 2023 the module could be delivered twice.			
Topics	Topics to be covered:			
	<ul> <li>Outcomes</li> <li>IT Platform – integration</li> <li>Establishment and nurturing of Learning communities</li> <li>Rewards - incentives</li> <li>VBHC Contracts</li> </ul>			
	o Citizen and patient involvement & engagement o ELSI importance			
	o Holistic perspective – patient journey and added value  The applicants can suggest additional content based on the HVC expertise. Such topics could be for instance:  o use of patient registries or real-world data, o federated networks approach for benchmarking, o health technology assessment, o Digital Medical Devices fast-track reimbursement based on value,			





	o etc.			
Audience/targe	Individuals and professionals working in healthcare transformation projects.			
t learners	Master and PhD-level students and graduates, healthcare and medical professionals			
Format	Online format preferred – where modules are made available on the EIT Health Academy.			
Duration	Max. 8 weeks programme to be delivered in a specific timeframe as of 2023.			
Duration of the grant	Proposals must commit to multi-annual delivery of the implemented training programme for up to 3 years. Proposals shall present full budgets for the whole granting period.			
Indicative grant amount per project	Max 50k€ for three years			
Co-funding request	Co-funding recommended, not mandatory. Proposals with co-funding will be evaluated favourably.			
Rules of participation	1. This call is open to applications from EIT Health Associate or Core members as well as organisations.			
	2. Projects must involve members from a minimum of two countries and from two different Regional Innovation Hubs.			
	3. The geographical origin of applicant is limited to EU Member States or countries associated to Horizon Europe.			
	4. 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.			
	5. Training module must be need- and data-driven, evidence-based and relevant to target audiences. Demonstration of robust educational design is expected through instructional design best practices and evaluation / outcome measurement framework defined from the outset.			
	6. Consortia should ensure the relevant GDPR requirements are covered to allow for such.			
	7.Proposals must commit to multi-annual delivery of the implemented training programme for up to 3 years			
	8. The training module will be hosted and delivered on the EIT Health Academy Platform			





	9. Training module to follow quality criteria of UEMS EACCME for CPD accreditation			
	10. Consortium will apply for UEMS EACCME credits			
Standardised data	Participants registration will be done on the EIT Health Academy Platform. Access to participants' data will be shared (registration, evaluation, outcomes measures).			
Intellectual Property	Intellectual Property is owned by the consortium			
Mandatory Evaluation of activity	Outcome measurement framework must be defined to ensure the training has measurable outcomes. Outcome measurement data will be collected on the EIT Health Academy Platform and shared with the consortium.			
	A post activity test in the form of a multiple-choice questionnaire (MCQ) will be included in the module. Content of the MCQ will be provided by the activity lead. A pass score will be defined for learners willing to obtain the UEMS EACCME certificate. UEMS EACCME certificate will be delivered via the EIT Health Academy Platform.			
EIT Health Certificate of completion	EIT Health Certificates of Completion must be issued to eligible participants via the EIT Health Academy Platform.			
Financial return to EIT Health	Revenue sharing model: 30% to consortium / 70% to EIT Health ecosystem			
KPIs (Mandatory)	EITHE08.1: Participants in (non-degree) education and training			
Sustainability	The consortium must outline a well-defined sustainability strategy for continuing the training module beyond EIT Health funding.  After the grant period, it is expected that the consortium will continue the training programme and, if agreed, can extend the collaboration with EIT Health by applying to the Recognition Programme (type B) which allows the programme to remain in the portfolio and benefit from EIT Health services. In return Recognised programmes will continue to share their KPIs with EIT Health.			





Marketing	EIT Health will lead the marketing of the programme, ensuring its visibility through the relevant channels, so the recruitment of the yearly targets is successful.  The programme will follow the general communication and marketing guidelines of EIT Health.  Activity lead and the consortium are not allowed to market their training modules using their own communications channels such as websites.
Recruitment of participants	For information, a minimum of 30 participants will come from the pre-selected innovation projects pre-proposals.  All learners will be invited to join the <u>EIT Health Alumni Community.</u>
Monitoring	EIT Health Project Management Office (PMO) will conduct a mandatory monitoring meeting per year.  Mid-term review: once per year connected to deadline of critical milestone of the project.





## Annex 6 – Call for Partner-driven Innovation projects summary

Type of Innovation projects	Facilitating the uptake of Digital Medical Devices & Diagnostics	Harnessing the full potential of health data for Innovation	Service Quality Assessment Innovation projects
Definition	Collaborative industry-driven project Consortia that focus on validating, certification, and introduction to the market of patient-centred innovative Digital Medical Devices solutions and innovations.	Collaborative industry, 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 the new innovation developed in the project to the market.	Collaborative projects that aim to promote the market uptake of innovative products and services of added value for patients, by assessing the quality of the healthcare service improvement, to generate sufficient evidence to convince payors to reimburse based on value.
Goal	Launch innovative patient centered Digital Medical Devices into the market	Unleash the full potential of health data by exploring the secondary use of data for the development of innovative technologies or solutions that deliver outcomes that matter to patients	Build more resilient healthcare systems that work based on value, not on volume.
Duration	Max 24 months (may be shorter		Max 30 months (may be shorter) until 31 December 2025 at latest
Indicative grant amount per project	Max 1.5M€ Grant for the EIT Funded Activity (EFA), with max 850k€ Grant per year		Max 2M€ Grant for the EIT Funded Activity (EFA), with max 850k€ Grant per year
Co-funding request	Minimum co-funding level of 30% of EIT Funded Activity (EFA) costs (70% maximum EIT Grant reimbursement of EFA).		
Rules of participation	At Short Proposal stage At least two entities must be involved.  At full proposal stage  At least 50% of the project entities must be EIT Heath registered members at the full proposal submission stage.  Involvement of industry, healthcare provider and other stakeholders from a minimum of two countries from two different Regional Innovation Hubs.		





Type of Innovation	Facilitating the uptake of Digital Medical Devices & Diagnostics	Harnessing the full potential of health data for Innovation	Service Quality Assessment Innovation projects
projects	Wiedical Devices & Diagnostics	of ficaltif data for filliovation	illiovation projects
	<ul> <li>A dossier for the relevan submitted and approval multicentric studies, eth before project start).</li> </ul>	efore project start (for	
	N/A	At Full Proposal stage: Relevant privileges to access health registry or biobank (to facilitate health registry- or biobank-based clinical study) in place before project start.	At Short Proposal Stage The participants must come from at least two different countries where the clinical partners should be already identified.
Partnership specificities	NA		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  a Partner taking care of the IT platform integration  a commercialising entity taking care of the replicability of the approach in third countries and beyond  a Partner with health economics expertise capable to support the development of the required evidence.
Supporting Framework	CIMIT Innovation maturity Levels (IMLs)  Milestones Framework		HVC Implementation Framework (From "Handbook for Pioneers" report)
Project maturity	Solution or technology maturity level between IML5 (Proof of Value), and IML6 (Initial Clinical Trials) as defined by the CIMIT Maturity Innovation Cycle for Healthcare and Life Sciences, at proposal submission.  The project should achieve advance through IML7 (Validation of Solution) and IML8 (Approval & Launch) within project timeframe.		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.
Impact	Critical milestones for each year (link to the Milestones Framework). Reaching regulatory approval and market launch maximum 1 year after the end of the project.		Critical implementation milestones for each year, plus number of patients that benefitted from the solution.





Type of Innovation projects	Facilitating the uptake of Digital Medical Devices & Diagnostics	Harnessing the full potential of health data for Innovation	Service Quality Assessment Innovation projects
projects		Year 3 focus on large scale implementation (a different region/country from where the test/pilot took place)	
Grant spent on technology development	Yes	Yes	No. Only platform integration developments to capture/incorporate/analyse patient outcomes into the IT systems are envisioned.
Commercial agent	Technology provider, part of the  Every innovation activi		
Financial return to EIT Health			
KPIs (Mandatory)	Financial backflow  KIC13: Number of citizens/patients that benefitted from solutimplemented in KAVAs  At least one customised KPI linked to Patient Reported Outco  EITHE02.4: Innovations launched on the market with a sales revenue of at least 10 000 EUR documented; to be reported during the KAVA duration or within 1 year after completion. Innovations include new or significantly improved products (goods or services) and processes sold.		·





## Annex 7 – Call for Start-up driven Innovation projects summary

Type of Innovation projects	Facilitating the uptake of Digital Medical Devices & Diagnostics	Harnessing the full potential of health data for Innovation	Service Quality Assessment Innovation projects
Definition	Collaborative start-up driven project Consortia that focus on validating, certification, and introduction to the market of patient-centred innovative Digital Medical Devices solutions and innovations.	Collaborative start-up driven 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 the new innovation developed in the project to the market.	Collaborative start-up driven projects that aim to promote the market uptake of innovative products and services of added value for patients, by assessing the quality of the healthcare service improvement, to generate sufficient evidence to convince payors to reimburse based on value.
Goal	Launch innovative patient centred Digital Medical Devices into the market	Unleash the full potential of health data by exploring the secondary use of data for the development of innovative technologies or solutions that deliver outcomes that matter to patients	Build more resilient healthcare systems that work based on value, not on volume.
Duration	Max 2,5 years (may be Max 24 months years (may be shorter) shorter) until 31 December 2025 at latest		
Indicative grant amount per project	Max 2M€ Grant for the EIT  Max 1.5M€ Grant for the EIT Funded Activity (EFA), with max  850k€ Grant per year  The grant allocated for start-up must be included in the range  [300k€-500k€]  Max 2M€ Grant for the EIT  Funded Activity (EFA), with  max 850k€ Grant per year.  The grant allocated for start-  up must be included in the  range [300k€-500k€]		
Co-funding request	Minimum co-funding level of 30% of EIT Funded Activity (EFA) costs (70% maximum EIT Grant reimbursement of EFA).		
Rules of participation	At Short Proposal stage At least two entities must be involved.  At full proposal stage  At least 50% of the project entities must be EIT Heath registered members at the full proposal submission stage.  Involvement of industry, healthcare provider and other stakeholders from a minimum of two countries from two different Regional Innovation Hubs.  A dossier for the relevant ethics committee approvals to facilitate clinical study submitted and approval to commence study foreseen before project start (for		





Type of Innovation projects	Facilitating the uptake of Digital Medical Devices & Diagnostics	Harnessing the full potential of health data for Innovation	Service Quality Assessment Innovation projects	
	multicentric studies, ethics committee approval in place for at least one centre before project start).			
	N/A	At Full Proposal stage: Relevant privileges to access health registry or biobank (to facilitate health registry- or biobank-based clinical study) in place before project start.	At Short Proposal Stage The participants must come from at least two different countries where the clinical partners should be already identified.	
Partnership specificities	NA		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 a Partner taking care of the IT platform integration a commercialising entity taking care of the replicability of the approach in third countries and beyond a Partner with health economics expertise capable to support the development of the required evidence.	
	<ul> <li>The start-up is at the core of the project – without the start-up, there is no Innovation project.</li> <li>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.</li> <li>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.</li> <li>Have at least 2 paid FTEs working in a start-up at the time of submission.</li> <li>Have a CEO working full-time in a start-up at the time of submission.</li> </ul>			
Supporting Framework	CIMIT Innovation maturity Levels (IMLs)  Milestones Framework		HVC Implementation Framework (From "Handbook for Pioneers" report)	
Project maturity	Solution or technology maturity le Value), and IM Clinical Trials) as defined by the CIN for Healthcare and at proposal sub	L6 (Initial /IIT Maturity Innovation Cycle Life Sciences,	The technology to be used should be readily available, in the market, if needed with CE mark granted. Only platform integration developments to	





Type of Innovation projects	Facilitating the uptake of Digital Medical Devices & Diagnostics	Harnessing the full potential of health data for Innovation	Service Quality Assessment Innovation projects	
	The project should achieve advance through IML7 (Validation of Solution) and IML8 (Approval & Launch) within project timeframe.		capture/incorporate/analyse patient outcomes into the IT systems are envisioned.	
Impact	Critical milestones for each year (link to the Milestones Framework). Reaching regulatory approval and market launch maximum 1 year after the end of the project.		Critical implementation milestones for each year, plus number of patients that benefitted from the solution. Year 3 focus on large scale implementation (a different region/country from where the test/pilot took place)	
Grant spent on technology development	Yes	Yes	No. Only platform integration developments to capture/incorporate/analyse patient outcomes into the IT systems are envisioned.	
Commercial	Technology provider/ start-up, part of the consortium			
agent  Financial  return to EIT  Health	Every innovation activity should have a clear commercialisation strategy  To be chosen by the consortium at Short Proposal stage:  Grant for option  Financial backflow  If consortium chooses backflow model, the start-up will be requested to apply for membership to the EIT Health association, and pay the member-type appropriate membership fee, in line with membership requirements for non-EIT Health partner organisations. Exceptions for Grant requests less than EUR 50,000 per calendar year apply.  Changing the chosen return model will not be permitted in subsequent stages of the application and selection process			
KPIs (Mandatory)	KIC13: Number of citizens/patier in KAVAs     At least one customised KPI links  EITHE02.4: Innovations launched revenue of at least 10 000 EUR d during the KAVA duration or with Innovations include new or significat	on the market with a sales ocumented; to be reported hin 1 year after completion. ntly improved products (goods		





Type of Innovation projects	Facilitating the uptake of Digital Medical Devices & Diagnostics	Harnessing the full potential of health data for Innovation	Service Quality Assessment Innovation projects
			improved products (goods
			or services) sold.





### Annex 8 – Call for Fast Track Start-Up driven Innovation projects (DiGinnovation)

Type of	Fast Track Start-Up Driven Innovation Project (DiGinnovation)	
Innovation projects		
Definition Definition	DiGinnovation selects top digital health start-ups/scale-ups 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	
Goal	Receive reimbursement for innovative patient-centered Digital Medical Devices and launch these innovations on the market	
Duration	Max 9 months	
Indicative grant amount per project	Max 350k€ Grant for the EIT Funded Activity (EFA)  The grant allocated for start-up must be included in the range [150k€ - 350k€]. Start-up may receive the full Grant of 350k€ provided additional partners part of the project bring co-funding in line with co-funding requirements.	
Co-funding request	Minimum co-funding level of 30% of EIT Funded Activity (EFA) costs (70% maximum EIT Grant reimbursement of EFA).	
Rules of participation	At Short Proposal stage One participant ONLY – the start-up. At full proposal stage  • At least two project partners must be involved (minimum one must be an EIT Health member).  • At least 50% of the project entities must be EIT Heath registered members at the full proposal submission stage.  • The participants must come from at least two different countries from two different Regional Innovation Hubs.  • A dossier for the relevant ethics committee approvals to facilitate clinical study submitted and approval to commence study foreseen before project start (for multicentric studies, ethics committee approval in place for at least one centre before project start).	
Partnership specificities	<ul> <li>The start-up is at the core of the project – without the start-up, there is no Innovation project.</li> <li>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.</li> <li>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.</li> <li>Have at least 2 paid FTEs working in a start-up at the time of submission.</li> <li>Have a CEO working full-time in a start-up at the time of submission.</li> </ul>	





	Start-up applying for at least 150k€ EIT Health grant.  The start of the star
	• The start-up's DMD solution must be already CE-marked and classified as I-lla or IIb in case of France as targeted market.
	• The start-up's DMD solution must meet the requirements for reimbursable applications in the targeted country.
Supporting Framework	CIMIT Innovation maturity Levels (IMLs) <u>Milestones Framework</u>
Project maturity	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
Impact	Critical milestones for each year (link to the Milestones Framework).  Reaching market and reimbursement by maximum 1 year after the end of the project.
Grant spent on technology development	No
Commercial agent	Start-up/scale-up applicant Every innovation activity should have a clear commercialisation strategy
Financial return to EIT Health	<ul> <li>To be chosen by the consortium at Short Proposal stage:</li> <li>Grant for option</li> <li>Financial backflow</li> <li>If consortium chooses backflow model, the start-up will be requested to apply for membership to the EIT Health association, and pay the member-type appropriate membership fee, in line with membership requirements for non-EIT Health partner organisations. Exceptions for Grant requests less than EUR 50,000 per calendar year apply. Changing the chosen return model will not be permitted in subsequent stages of the application and selection process.</li> </ul>
KPIs (Mandatory)	<ul> <li>EITHE02.4: Innovations launched on the market with a sales revenue of at least 10 000 EUR documented; to be reported during the KAVA duration or within 1 year after completion. Innovations include new or significantly improved products (goods or services) and processes sold.</li> <li>KIC13: Number of citizens/patients that benefitted from solutions developed or implemented in KAVAs</li> <li>At least one customised KPI linked to Patient Reported Outcome Measure (PROM)</li> </ul>





## Annex 9 – Call for Bootcamp in VBHC summary

Type of Programme	Value-Based Healthcare Bootcamp
Definition	Development and delivery of a Bootcamp programme. Bootcamp programme will implement an eight-to-ten-week programme delivering expert mentoring and knowledge, skills, and competencies. Following participation in the Bootcamp, teams/start-ups should be ready to take the next steps in securing funding for developing their idea and/or entering other European markets. The Bootcamp curriculum shall be based on practical implementation of frameworks and methodologies for the idea that the team/start-up put forward for Bootcamp participation. Teams/start-ups must strengthen their business case and be able to use acquired knowledge and skills in their venture's future development.  Themes correspond to the New Healthcare Delivery Models Flagships.
Goal	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).  The first edition of the Bootcamp is expected to take place in 2024 calendar year.
Duration	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.
Indicative grant amount per project	The decreasing funding model will function as follows over a 2-year period:  Year One: Up to €120,000 Year Two: Up to €70,000 (final year of funding)  EIT Health assumes costs for programme marketing and infrastructure necessary to facilitate recruitment and selection process.  After the grant period, it is expected that the Bootcamp will continue its activity and, if agreed, can extend its collaboration with EIT Health by applying to the Recognition Programme.





Target	Innovation provided by companies or start-ups with:
Target	illilovation provided by companies of start-ups with:
Audience	Product/service CE marked to ensure the safety, health and environmental
	protection, except for those product/services that the EU has not specifications.
	Demonstrated high level of analytical and/or clinical performance.
	Demonstrated clinical evidence (outputs and outcomes)
	Demonstrated direct impact in patients' outcomes
Standardised data	Participant registration and a post-programme survey will be led by EIT Health, with collaboration from the Activity Lead and the participating institutions. Access to participants'
uata	data will be shared.
Co-funding	-co-funding: 30%
request	-Revenue sharing model: 70% to consortium / 30% to EIT Health ecosystem
	-Programme developed and implemented in collaboration with EIT Health team
	-Access to EIT Health platform to host and/or deliver virtual parts of the programme, if applicable
	-IP ownership with consortium
Rules of	This call is open to applications from EIT Health Associate or Core members as well
participation	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.
	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
	Involvement of industry, healthcare provider and/or start-up stakeholders from a
	minimum of 2 countries from two different Regional Innovation Hubs.
	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).
Partnership	Programme consortia must include a minimum of two institutions, from two different eligible
specificities	countries.
	We anticipate that lead partners are incubators, innovation clusters, universities and/or

industry partners with experience in designing programmes to support start-ups.

All Bootcamp consortia partners must have a good track-record in supporting health start-ups. We expect that healthcare institutes, business partners – such as insurance companies,





	innovation networks, and government organisations – are likely to be part of the proposal, to provide access to their network.
Programme format	Bootcamps are encouraged to plan modules according to best content-to-format principles. Format could include:
	Online, pre-learning and levelling course: delivery of an online, pre-learning course is encouraged, to help Bootcamp participants start off at the same level, allowing them to make the most of the learning experience.  Seminars, workshops, presentations and meetings with relevant stakeholders and experts.  Mentoring and coaching sessions.  In-person/online peer learning sessions.  In person/online final pitch and winner selection.
Digitalisation	As a component of the Bootcamp, an online, pre-learning course is encouraged to facilitate Bootcamp participants' in starting off at the same level and allowing them to make the most of the learning experience.
Mandatory evaluation of EIT Health funded programmes EIT Learning Objective	The Activity Lead, in collaboration with EIT Health, will perform the impact evaluation of the programme on a yearly basis.  A pre- and post-questionnaire – to demonstrate the variation in levels of confidence, performance, skills, knowledge and/or behaviour around the Bootcamp – will be provided by EIT Health.  A retrospective action for measurement of entrepreneurial intentions and innovations skills development among previous years' participants will be developed by EIT Health. Potential start-ups created, jobs created and other relevant KPIs will be monitored in the three years following completion.
Sustainability	The Bootcamp consortia must outline a well-defined sustainability strategy for continuing the programme beyond EIT Health funding.  The Bootcamp work towards sustainability, with a multi-annual strategy included in the proposal. Each of the identified mechanisms requires a clear action plan.  After the grant period, it is expected that the Bootcamp will continue its activities and, if agreed, can extend the collaboration with EIT Health by applying to the Recognition Programme, which allows the programme to benefit from being part of the portfolio. While the programme will not receive a direct grant, it will receive other benefits.  Please note that letters of intent (institutional commitment) and of interest (sponsoring seats, master thesis, scholarships, etc.) are required.





**Financial return** EIT Health requires consortia to follow a revenue sharing model of: 70% to consortium / 30% to EIT Health ecosystem.

KPIs

**Mandatory KPIs:** 

(Mandatory)

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

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

**Recommended KPIs:** 

KICO9: Programme Attractiveness and Demand Citizen-, Patient- and societal impact related KPIs (KIC 10-13)

KICO1: Number of jobs created in new businesses organisations as a direct result of your project

KIC19: Number of pre-prototype ideas/concepts validated

KIC14: Number of non-EIT Health events/fairs/conferences where EIT Health partners are presenting

EITHE02.1: Marketed Innovations

EITHE02.2: -EITRIS EIT RIS Marketed Innovations

EITHE04.1: Start-ups created of/for innovation

**Work Plan** 

The first edition takes place in 2024 calendar year.

A Bootcamp includes:

A. Development of the programme, including:

arranging consortium meetings;

developing training content (connected to those described under each of the Flagships and based on UN SDG3 related targets 3.1. to 3.9, as stated on EIT Health's Strategic Agenda);

sourcing coaches, mentors and speakers;

arranging hosting logistics (agenda, venues, platforms and tools (supporting technology), etc.).

B. Delivery of an eight-ten-week Bootcamp for a minimum of 10 start-ups, including a good mix of:

Theory and practice:

Online pre- and in-course learning Expert and faculty seminars





Fieldwork and development/project time

Interactive sessions:

Workshops

Office hours

Expert coaching and mentoring sessions
Stakeholder access and peer learning:
Facilitated access to relevant stakeholders
Reverse pitch sessions and 1:1 feedback
Final pitch and winner selection.

C. End of year programme reporting and financial reporting.

### **Expected outputs and deliverables:**

To be described by the Activity Leader.

OUT 01: Recruitment and promotion.

OUT 02: Delivery of the Bootcamp

OUT 03: Sustainability models to continue the Bootcamp beyond EIT Health funding.

DEL 01: Recruitment and marketing plan.

DEL 02: Report outlining the agenda, curriculum, and methodology planned for delivery of the Bootcamp.

DEL 03: Report outlining the sustainability model that will be implemented to continue the Bootcamp beyond EIT Health funding.

DELO4: Final report including structured participants' data, lessons learned, achievements (template to be provided).

DEL05: Impact assessment in year 2, exposing changes in the business models and/or market access strategies, new jobs created, etc.

MS 01: (Critical) Confirmation of programme dates.

MS 02: (Project) Launch of participants' recruitment.

### Marketing

EIT Health will lead the marketing of the programme, ensuring its visibility through the relevant channels, so the recruitment of the yearly targets is successful.





	The programme will follow the general communication and marketing guidelines of EIT Health.
Citizen and Patient Engagement, High-Value Care, Ethical, Legal and Social Issues (ELSI)	The proposal must include completion of the mandatory questions on citizen and patient engagement and outcomes that matter to patients as well as the ELSI self-assessment form in the form system.  Citizens and patients are expected to be involved in the activity development.
Evaluation criteria and weights	Common scorecard for all projects – overall criteria identic for all archetype:  Project Excellence and Strategic Fit Implementation and Feasibility Impact and Sustainability  The weight of each criterion will be different on each phase of the Selection process
Monitoring	EIT Health Programme Manager and Activity Leads will meet regularly to coordinate the collaboration within the KIC and to review progress in implementation.  All EIT Health activities are subject to formal monitoring from the EIT Health Project Management Office to determine progression towards critical milestones.  Please note that the continuation of the programme is directly related to KPIs and outcomes achievement. Funding can be discontinued in the event of underachievement.





# Annex 10 – Financial sustainability model for Innovation activities: Grant for option model

In the case of start-up-driven projects, EIT Health is committing to support the development of the selected Start-ups by granting funds and in-kind contributions to support innovation activities of a project. In return, EIT Health shall participate in the start-up by way of receiving options to assume shares in the start-up upon the occurrence of pre\_defined Exit Events (as defined below). In such Exit Events, EIT Health has the right to subscribe to shares in the start-up and subsequently be treated as a shareholder of the company. The total value of EIT Health's investment shall be the total amount of the grant paid to the Start-up and the nominal value of in-kind contributions of EIT Health to the Start-up prior to and during the project.

## Main principles:

- Upon selection, EIT Health is committing to support the development of the Start-up by granting funds to support innovation activities in a said project:
  - In a start-up driven project: min €300,000 grant within a maximum €1.5 million grant going to a project and fixed in-kind in the value of €150,000.
  - In Fast-Track start-up driven project (DiGinnovation): min €150,000 grant within a maximum €350,000 grant going to a project and fixed in-kind in the value of €100,000.
- In return for a grant and in-kind contribution EIT Health will receive option in a start-up which shall entitle EIT Health to subscribe to a certain number of shares in a start-up in case of an Exit Event (defined below).
- In-kind contributions are defined as services and non-financial resources provided to selected start-ups, that EIT Health delivers in addition to the direct grant payments. Including but not limited to, in kind contributions include access to EIT Health members network, assignment of a dedicated EIT Health's Single Point of Contact to ensure follow-up, ongoing support of in project management and link with the main stakeholders/partners. The value of in-kind contributions is fixed at the project level (€150,000 in Start-up driven projects and €100,000 in the Fast Track Start-up driven project)
- In addition to the fixed in-kind contribution per project type, direct grant and/or service-specific in-kind contributions may be added on top, in case the project benefits from additional EIT Health's Accelerator services in the framework of a Flagship. Depending on services, the value of such additional in-kind contributions is ranging from €1,200 for access to the Finance Booster training to €40,000 for market access support through Bridgehead.





- By using options, EIT Health intends to be treated comparable to a shareholder and participate in future financial successes of the start-up without assuming immediate equity.
  - Importantly, if the option is not yet exercised or surrendered, EIT Health holds no equity in the start-up and have no shareholder rights.
- EIT Health shall be entitled to appoint one (1) member of the advisory board, as long as EIT Health holds options or shares which on a fully diluted basis correspond to at least 8.00 % of the share capital.
- EIT Health's options will dilute in financing rounds in the same ratio as equity-shares.
- In Exit Events, EIT Health has the right but not the obligation to purchase shares upon surrender of the options and such shares shall be granted by the Start-up.
- Exit events are defined as follows:
  - Sale of more than 50% of the shares in the Start-up
  - Sale of more than 50% of assets as well as licensing of substantial IP rights of Start-up
  - Initial Public Offering (IPO)
  - Liquidation
- Alternatively, the Start-up is entitled to directly settle EIT Health's claim to shares by paying to EIT Health a Compensation Payment equal to the amount EIT Health would have received in such Exit Event as pro rata shareholder
- In the event of a merger, the option of EIT Health shall be converted into new options on the level of the new entity. The conversion shall occur on the same economic conditions as the shareholders.
- The number of shares EIT Health is entitled to purchase by surrendering the options corresponds to the price per share which shall be determined by either of the following:
  - i. The post-money valuation of the last qualified financing round <sup>17</sup> if the financing round was concluded no later than one year prior to application
  - ii. The pre-money valuation of the current external funding round if it is closed prior to the conclusion of the Option Agreement
  - iii. The pre-money valuation obtained as a part of a valuation analysis performed by an independent third party contracted by EIT Health.

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<sup>&</sup>lt;sup>17</sup> "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.





- In case of (i) and (ii) the start-up will have to provide proofs of the valuation prior to the project start. In cases, where the start-up is not able to evidence the conclusion and the respective post-money valuation of the Qualified Financing Round, EIT Health will only accept the valuation of (iii). In case of (iii), valuation analysis will be performed and communicated to the Start-up prior to the project start. If the valuation of (iii) is not accepted by the Start-up, the full Innovation project will not be considered for funding. Please note that in case the start-up has received a valuation through another EIT Health programme no more than one year prior to application, it will also be accepted under Start-up Amplifier alternative (i), should the supporting documentation be provided.
- For start-up driven projects with a duration of two years, it will be possible to reconsider
  the valuation of a start-up during the project lifetime, though this step is not required.
  Should the Start-up wish to adjust its valuation during the lifetime of the project, it shall
  follow the principles of the <u>CIMIT Healthcare Innovation Cycle Milestone framework</u> to
  define significant value inflection points that leads to a valuation increase.

The revenue received by EIT Health from these projects will be invested in future innovation opportunities for the network.





## Annex 11 – Financial sustainability model for Innovation activities: Backflow Model

The model of backflow can apply to Partner-driven and Start-up driven Innovation projects, including Fast Track Start-up driven Innovation projects (DiGinnovation).

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 project.

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.

The definition of successful commercialisation of the project is linked to the achievement of KPI EITHE02.4: Innovations launched on the market or EITHE02.1: Innovations launched on the market with a sales revenue of at least 10 000 EUR documented, and shall be defined in detail at the time of full proposal submission. Additional parameters to be defined by the consortium are: the amount (mark-up in addition to the total project funding received), timing of payments and conditions for the backflow (eg: percentage of revenues, fixed yearly amount).

The Net Present Value (NPV) of the model proposed by the consortium will be crucial criteria for the portfolio analysis phase in 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.

The consortium agrees to commit to the financial sustainability contract to be completed under the conditions expressed in the proposal with EIT Health after project approval.

A shared revenue plan will be defined at full proposal stage submission, with the assistance of EIT Health services during the Support Programme, and this will include:

- Fixed amount per year or Percentage of shared revenue (use of operating profit or free cash flow instead of revenue as baseline is possible. In this case, a mark-up of minimum 5% is compulsory)
- Extra 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)





- 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.

Understanding the complexity of the return forecast of the solutions in the market with a timeline of three years, EIT Health will accept a re-negotiation of the backflow model 6 months prior to project finalisation, as long as commitments from the consortium will bring similar revenues to the network.

The revenue received by EIT Health from these projects will be invested in future innovation opportunities for the network.





## Annex 12 – Financial sustainability model for Education and Business Creation activities

All Partners involved in EIT Health programmes will need to support the financial sustainability of EIT Health and its ecosystem by providing co-funding in line with the requirements of the relevant programme stream.

In addition, co-funding is mandatory for EIT Health programmes included in the EIT Health portfolio. Summer/Winter Schools and Bootcamps fall in this category.

EIT Health requires consortia to follow a revenue sharing model of 70% to consortium / 30% to EIT Health ecosystem, or 30% to consortium / 70% to EIT Health ecosystem, depending on the programme type.

For KIC-driven programmes (i.e. EIT labelled fellowship, EIT labelled certification for lifelong learning), revenue sharing model will be around content IP and ownership. This includes under the Flagship call the Modules towards a labelled Fellowship programme, Training Modules on Advanced High Value Care Principles, Training module for healthcare professionals (non-degree) and Training module for patients and citizens (non-degree).

The revenue received by EIT Health from these prorammes will be invested in future education and Business Creation opportunities for the network.









## Annex 13 – NEFA guidelines

### Non EIT Funded Activity (NEFA) model

NEFAs are activities that are fully implemented without any EIT funding — they may be completely self-funded by the KIC, or funded by other EU programmes, regional funds etc. NEFAs must comply with the same operational principles as EIT Funded Activities (EFAS).

In accordance with the EIT SIA (<u>Strategic Innovation Agenda</u>), the funding model introduces formally decreasing funding rates with the objective that over time, the EIT financed parts of any KIC activities are replaced by the KIC's own revenues and funds from third parties to maintain activities. The overall goal is that a KIC's innovation ecosystem becomes financially sustainable and that a KIC no longer requires EIT funding to carry out its activities at the latest in year 15.

NEFAs are a way for EIT to recognise increasing amounts of additional funding of KICs through activities fully implemented without any EIT funding (NEFAs). Considering KIC activities that are financed from own funds, or third parties may incentivise the KICs to diversify their sources of funding while helping KICs to comply with decreasing funding rates.

The ultimate objective of this funding model is that after year 15, KICs have the capacity to implement KTI (Knowledge Triangle Integration) activities without EIT funding, resulting in a complete NEFA portfolio.

The EIT will closely monitor both EIT and non-EIT financed activities. The EFAs need to fulfil all requirements of the EIT and Horizon Europe legal framework including planning, reporting, cost eligibility and control requirements. While NEFAs would be subject to the same requirements in terms of planning and reporting, they will be funded by the KICs' own resources or funding received from other programmes/ donors. Therefore, the eligibility rules and control/ audit requirement for the NEFAs shall be driven by the rules and requirements of the funding bodies (e.g., KIC's internal rules for their own funds, other EU programmes, national funding schemes, private funds, investors and donors, etc.).

In order to be recognised at the reporting stage and to be considered as contribution to the funding rates from non-EIT sources, as defined in the SIA, KICs must provide evidence that costs behind NEFAs have actually been incurred and been found eligible by the provider of the funding source.

## **Operational Conditions**

NEFAs need to comply with the same operational conditions as EFAs:





- 1. contribute to the KIC's Strategic Agenda in line with the EIT Impact Framework, including a contribution to EIT core KPIs (core KPIs are marked in red in the EIT Impact Framework)
- 2. derive from and contribute to Knowledge Triangle Integration (KTI);
- 3. objectives and expected results have been adequately described in the KIC's Business Plan;
- 4. have been implemented by the KIC and its partners (incl. KIC Legal Entity); and
- 5. fulfil the reporting and data requirements of the EIT in terms of content and impact and IT tools.

## **Reporting Requirements**

Progress Reporting: Progress and achievement against the Business Plan, description of the work implemented., Key Performance Indicators (KPIs) and Deliverables (DELs) reporting and provision of supporting documentation

Cost Reporting: EIT Health will need to provide evidence that costs behind NEFAs (non EIT Funded Activities) have been incurred and found eligible by the funding body. The reports approved by the funding bodies or similar evidence will need to be submitted by the NEFA activity leader. The eligibility of cost will not be checked by EIT Health, the evidence will be requested for audit trail purposes.

This evidence will be required at the interim report and final report stage. Should timelines between the funding body and EIT Health not converge, the evidence may be provided when it is available.

It is critical to ensure an appropriate level of transparency, therefore all activities, regardless of their funding source, shall be subject to EIT's review and validation processes:

- 1. at the planning stage, as part of the multi-annual Business Plan assessment;
- 2. during implementation, via the reinforced strategy for continuous monitoring; and
- 3. at reporting stage, including data provision via the eGrants and CORDA tools

Reporting timeframe for NEFAs will be considered from the start of the EFA.





## Annex 14 – Due Diligence

Should a project be invited to the Support Programme (for start-up driven projects) or Pitch Day (for Fast Track start-up driven projects) and select grant for optoin model, the start-up at core of the project will go through due diligence.

Due diligence is put in place to make sure that:

- The start-up is a solid partner that can contribute to the partnership and commercialise the product/service.
- The numbers provided are valid, claims are real and there are no legal issues.
- The start-up team has the required core competencies for performing the planned work.
- The start-up is a suitable investment for EIT Health.
- EIT Health looks to invest in start-ups that have:
  - clear unmet patient and institutional need which has been validated through stakeholders' interviews and sizable market (not only a problem exists, but also the people ready to pay for having this problem solved);
  - o fully spun out of the university, with the IP agreements in place/about to be concluded;
  - o reached certain level of maturity minimum IML 5 for start-up driven projects and IML7 for Fast Track Start-up driven projects
  - o have a strong team already working at the core of a start-up, receiving salaries;
  - o have a strong businessperson in the core team;
  - o have balanced cap table, with founders and key employees being sufficiently incentivised.

At the heart of due diligence assessment approach lies a systematic and standardized assessment of key elements of successful start-ups:

- Team (team complementarity, education/skills, working experience, team commitment, advisory board, prior start-up experience);
- Product (technology and IP, customer need, competitive advantage, development stage, development/production costs, scalability);
- Market (market size/potential, level of competition, entry barriers, market growth and trends, competition, exit potential);
- Business model (revenue model/unit economics, milestones/roadmap, customer acquisition, go-to-market strategy, business plan logic, partnerships);

The criteria are weighted equally within a dimension. As a results of the assessment of these four dimensions, rating on a scale of 1% to 100% is produced. Start-up cases with the score of at least 70% or above are recommended. Additionally, legal and financial aspects are reviewed





highlighting additional risks and red flags. Finally, the overall recommendation to invest or not is provided.

The start-up needs to provide additional information and documentation in English (except for the registration certificate) during the Short Proposal and Due Diligence phase, to enable due diligence and (if further needed) valuation analysis. Documentation includes:

At the Short Proposal phase:

- Registration certificate
- Start-up website
- Pitch deck

## At the Due Diligence phase:

- Business plan
- Historic financials
- Financial projections in excel, with the financial summary using a specific template (to be provided)
- List of shareholders
- Legal Self-Assessment Certificate
- Other relevant documents

Submitted documents will be treated as confidential. An Independent third party performing due diligence and valuation analysis will have calls with start-ups in the framework of this process. EIT Health or an independent third party performing due diligence and valuation analysis may reach out to the Start-up in case more information is required to finalise the due diligence and/or valuation analysis.

As a result of due diligence, one of the following scenarios will be possible:

- 1. Start-up passes the due diligence (none or minor issues identified during due diligence) and will be considered for EIT funding as a part of an Innovation proposal.
- 2. Start-up does not pass the due diligence (major issues identified during due diligence) and Innovation proposal will not be considered for EIT funding.

The start-up will be **excluded** from Due Diligence process in the following cases:

- The start-up has already passed through one or several of the following EIT Health programmes:
  - Wild Card (funded venture)
  - Start-up Amplifier (funded venture or having passed Due Diligence previously)
  - DiGinnovation (funded venture or having passed Due Diligence previously)
  - EIT Health Catapult (finalist)





- Bridgehead (funded venture)
- Rescue Instrument (funded venture)
- Gold Track (successfully vetted by the Gold Track programme)

Please note that the proofs of the relevance of the exclusion criteria will be requested at the application stage.





## Annex 15 – KPIs list

EIT Core KPIs are indicated in red.

EIT Health KPIs are indicated in black.

In some cases, structured data is needed as well as additional supporting evidence. Detailed information per KPI is included in the table below.

KIC Categ ory	KPI Title	KPI Code	Definition and Structured Data required	Supporting evidence required
Product s and services	Innovations launched on the market with a sales revenue of at least 10 000 EUR documented	EITHEO 2.4	Number of innovations introduced on the market during the KAVA duration or within 3 years after completion with a sales revenue of at least 10 000 EUR documented. Innovations include new or significantly improved products (goods or services) and processes sold.  Structured data:  • Year of reporting • Name of the innovation • Type of innovation (e.g. new product, new service) • Market (country) • Country of origin of the company commercialising the innovation • Reference to a specific KIC KAVA • Was the innovation developed and launched on the market as a result of the capacity building activities delivered as part of the HEI	Innovations introduced on the market must be directly linked with the KAVA and reported in the year when they reached the first revenue (but not later than  three years after completion of the KAVA).  Supporting evidence:  • Description of product or process with specified performance characteristics/ physical parameters/ functionalities demonstrating novelty (new or  significant improvement) of the product/process  • Declaration demonstrating link with a specific KIC KAVA (indication of the specific output of KIC KAVA(s))





		Was the innovation launched by learners/graduates from labelled programmes (or with direct link to participating in the labelled activity)?	and financial proof of the KAVA investment  in the innovation development  • Documented proof such as an invoice or an online sales record demonstrating that the purchase has been made by a customer
Innovatio ns launched on the market	EITHEO 2.1	Number of innovations introduced on the market during the KAVA duration or within 3 years after completion.  Innovations include new or significantly improved products (goods or services) and processes sold.  Structured data:  • Year of reporting • Name of the innovation • Type of innovation (e.g. new product, new service) • Market (country) • Country of origin of the company commercialising the innovation • Reference to a specific KIC KAVA • Was the innovation developed and launched on the market as a result of the capacity building activities delivered as part of the HEI CBI? • Was the innovation launched by learners/graduates from labelled programmes (or with direct link to participating in the labelled activity)?	Only EITHE02.4 Innovations launched on the market with a sales revenue of at least 10 000 EUR documented should be used in projects and project proposals and counts for Strategic Agenda achievement targets. EITHE02.1 Number of innovations launched on the market represent the encompassing KPI, used for statistical purposes (counts innovations with or without sales of 10k).  No supporting evidence is required.



EIT RIS Innovatio ns Iaunched on the market	EITHEO 2.2- EITRIS	Number of products or processes (as per EITHE02.1 definition) launched on the market by organisations from the EIT RIS countries (as per EITHE02.1 definition)  Structured data:  • Year of reporting • Target achieved	RIS countries include:  • EU Member States: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.  • Horizon Europe Associated Countries: Montenegro, Republic of North Macedonia, Serbia, Turkey, Ukraine.  • Outermost Regions: Guadeloupe, French Guiana, Réunion, Martinique, Mayotte and Saint- Martin (France), the Azores and Madeira (Portugal), and the Canary Islands (Spain).  No supporting evidence is required.
Number of countries where technolo gy, product or service is commercialized or implemented	KICO6	Number of countries where technology, product or service is commercialized or implemented.  Structured data:  • Year of reporting • Name of the innovation • Country of the company • Country where the product/service/process was introduced on the market • Website for the product/service/process (if applicable)	No supporting evidence is required.





Start-ups created having a financial transacti on of at least 10 000 EUR for a service/p roduct (result of the KIC KAVA) sold to custome rs	EITHEO 4.4	Number of start-ups established in year N as a result / based on the output(s) of KAVA(s), or start-ups created for the purpose of an innovation project to organise and support the development of an asset (but not later than three years after the completion of KAVA) having financial transactions of at least 10 000 EUR for services/products (result of the KIC KAVA) sold to customers.  Structured data:  • Year of reporting • Company name • Company registration number • Country of the company registration • Gender of the company CEO • Link to the specific KAVA • Was the company created through the HEI CB Initiative? • Was the company created through a cross-KIC project?	Registration certificate of a start-up established in year N     Description of the start-up and its core business     Document such as an invoice or an online sales record certifying financial transactions of at least 10 000 EUR for services/products (result of the KIC KAVA) sold to a customer.
Start-ups created of/for innovatio n	EITHEO 4.1	Number of start-ups established in year N as a result / based on the output(s) of KAVA(s), or start-ups created for the purpose of an innovation project to organise and support the development of an asset (but not later than three years after the completion of KAVA).  Structured data:  • Year of reporting • Company name • Company registration number • Country of the company registration	Only EITHE04.4 Start-ups created having a financial transaction of at least 10 000 EUR for a service/product (result of the KIC KAVA) should be used in projects and project proposals and counts for SA achievement targets. EITHE04.1 Start-ups created of/for innovation represent the encompassing KPI, used for statistical purposes (counts starts-ups with or without sales of 10k).  No supporting evidence is required.





		<ul> <li>Gender of the company CEO</li> <li>Link to the specific KAVA</li> <li>Was the company created through the HEI CB Initiative?</li> <li>Was the company created through a cross-KIC project?</li> </ul>	
		Number of Start-ups registered in EIT RIS country in year N and established as a result/ based on the output(s) of Innovation/ Research related KAVA(s), or created for the purpose of an innovation project to organise and support the development of an asset	EU Member States: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.
EIT RIS Start-ups created	EITHEO 4.2- EITRIS	Structured data:  • Year of reporting • Target achieved	<ul> <li>Horizon Europe Associated Countries: Montenegro, Republic of North Macedonia, Serbia, Turkey, Ukraine.</li> <li>Outermost Regions: Guadeloupe, French Guiana, Réunion, Martinique, Mayotte and Saint- Martin (France), the Azores and Madeira (Portugal), and the Canary Islands (Spain).</li> </ul> No supporting evidence is required.





Start-ups and scale-ups supporte d by KICs	EITHEO3 .1	Number of start-ups and scale-ups supported by KICs for at least 2 months in year N, provided the KIC's services contribute to the company's growth (including potential growth).  Structured data:  • Year of reporting • Company name • Company registration number • Country of registration • Gender of the CEO • Reference to a specific KIC KAVA • Was the company supported through the HEI CBI? • Was the company supported through the a cross-KIC project?	KICs should justify that the provided services contribute to the company's growth (including potential growth). Examples of such services are mentoring, consultancy on access to finance and markets, product / service marketing, legal advice, internationalisation, match-making, etc. The services should be  provided for a total period of at least two months. Start-ups and scale-ups will be reported by country of registration of the venture.  No supporting evidence is required.
EIT RIS Start- ups/scale -ups Supporte d	EITHEO 3.2- EITRIS	Number of start-ups and scale-ups registered in EIT RIS country supported by KICs for at least 2 months in year N.  Structured data:  • Year of reporting • Target achieved	RIS countries include:  • EU Member States: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.  • Horizon Europe Associated Countries: Montenegro, Republic of North Macedonia, Serbia, Turkey, Ukraine.  • Outermost Regions: Guadeloupe, French Guiana, Réunion, Martinique, Mayotte and Saint- Martin (France), the Azores and Madeira (Portugal), and the Canary Islands (Spain).



				No supporting evidence is required.
	start-ups		Number of start-ups established in year N by students enrolled and graduates from EIT labelled MSc and PhD programmes or by learners / participants in other EIT labelled activities.	To be eligible, a start-up should be created during EIT labelled programme (by students, participants) or within 3 years from the graduation (by graduates) or within 1 year in case of other EIT Label activities.
brist ei al grand	created by students enrolled and graduate of from EIT-abelled program mes	EITHEO 5.1	<ul> <li>Year of reporting</li> <li>Company name</li> <li>Company website</li> <li>Company registration number</li> <li>Country of the company registration</li> <li>Name of the student who created the company</li> <li>Gender of the student who created the company</li> <li>Was the labelled programme delivered through the HEI CBI?</li> </ul>	Registration certificate of a start-up established in year N     Description of the start-up and its core business     Document such as an invoice or an online sales record certifying the first financial transaction for a service/product sold to a customer     Reference to a specific KIC KAVA.
st cr or la pr	eIT RIS start-ups created of EIT abelled program mes	EITHEO 5.2- EITRIS	Number of start-ups established in EIT RIS countries in year N by EIT-labelled programs students or graduates.  Structured data:  • Year of reporting • Target achieved	RIS countries include:  • EU Member States: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.  • Horizon Europe Associated Countries: Montenegro, Republic of



			North Macedonia, Serbia, Turkey, Ukraine.  • Outermost Regions: Guadeloupe, French Guiana, Réunion, Martinique, Mayotte and Saint-Martin (France), the Azores and Madeira (Portugal), and the Canary Islands (Spain).
		Number of students (per country) who joined start-ups during their EIT Label studies.	JOIN means join as a (co-)owner of an existing start-up or be employed by a start-up.
		Sum of EIT MSc and PhD Label graduates who joined start-ups up to 3 years after graduation.	No supporting evidence is required.
Students and graduate s from EIT labelled program mes who	EITHEO 9.1	Number of learners who joined start-ups as result of their participation in other EIT labelled activity up to 1 year after the activity ended.	
joined start-ups		Year of reporting     Name of the start-ups     Company website     Company registration number     Country of the company registration     Gender of the graduate/student joining the	



		Name of the student joining the company	
EIT RI EIT labell stude and gradu s who joined start-	led ents EITHEO 9.2- uate EITRIS o d	Number of students with EIT RIS country citizenship (also per country) who joined start-ups during their EIT Label MSc and PhD studies.  Sum of EIT MSc and PhD Label graduates with EIT RIS country citizenship who joined start-ups up to 3 years after graduation.  Number of learners with EIT RIS country citizenship who joined start-ups as result of their participation in other EIT labelled activity up to 1 year after the activity ended.  Structured data:  • Year of reporting • Target achieved	<ul> <li>EU Member States: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.</li> <li>Horizon Europe Associated Countries: Montenegro, Republic of North Macedonia, Serbia, Turkey, Ukraine.</li> <li>Outermost Regions: Guadeloupe, French Guiana, Réunion, Martinique, Mayotte and Saint- Martin (France), the Azores and Madeira (Portugal), and the Canary Islands (Spain).</li> <li>No supporting evidence is required.</li> </ul>
Numbor of state ups created by partice nts in Healt (noncee) educate the state of t	cipa n EIT th degr	Number of start-ups created by participants in EIT Health (non-degree) educational programme.  Structured data:  • Year of reporting • Company name • Company website (if known)	A start-up is an innovative small and medium-sized enterprise (SME) younger than 5-10 years that searches for a repeatable and scalable business model.  Year N is the year when the KPI is achieved and reported to EIT.



	n program mes		<ul> <li>Company registration number</li> <li>Country of company registration</li> <li>Gender of the CEO/owner/student creating the start-up</li> <li>Name of the CEO/Owner/student creating the start-up</li> </ul>	No supporting evidence is required.
			Number of start-ups for which a collaboration has been established.	Collaborations with EIT funded activities can include:  facilitating match-making, mentoring, consulting, providing advice, product/service marketing.
	Number of Start- ups engaged	KICO8	Year of reporting     Company name     Company website (if known)     Company registration number     Country of company registration     Gender of the CEO/owner	This KPI is not relevant to define the number of start-ups participating in Innovation projects.  No supporting evidence is required.
Investm ent attracte d by KIC support ed start- ups/sca le-ups	Investme nt attracted by KIC- supporte d start- ups and scale-ups	EITHEO 6.1	Total EUR amount of private and public capital attracted within year N by supported start-ups / scale-ups (per country) that have received KIC business creation services support of total duration of at least two months, within a maximum of three years following the last received KIC KAVA support activity.  Structured data:	Declaration of the start-up/scale-up proving the amount of the investment, type of investment, source of income by type (public/private). In case the investment was attracted from public source, it should be specified (e.g. from EU Structural Funds). If





		<ul> <li>Year of reporting</li> <li>Investment amount</li> <li>Source of income         (public/private)</li> <li>Company name</li> <li>Company registration         number</li> <li>Country of the company         registration</li> <li>Company Website</li> <li>Gender of the CEO/owner</li> <li>Total amount of KIC support         received (if applicable)</li> <li>Year in which the last support         was received</li> <li>Was the company supported         through the HEI CB Initiative?</li> <li>Was the company created         through a cross-KIC project?</li> </ul>	possible, links to further evidence (e.g. website) should be included.
Investme nt attracted by KIC supporte d EIT RIS start- ups/scale -ups	EITHEO 6.2- EITRIS	Total EUR amount of private and public capital attracted within year N by supported start-ups/scale-ups established in the EIT RIS countries, that have received KIC business creation services support of total duration of at least two months, within a maximum of three years following the last received KIC KAVA support activity.  Structured data:  • Year of reporting • Target achieved	<ul> <li>RIS countries include:</li> <li>EU Member States: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.</li> <li>Horizon Europe Associated Countries: Montenegro, Republic of North Macedonia, Serbia, Turkey, Ukraine.</li> <li>Outermost Regions: Guadeloupe, French Guiana, Réunion, Martinique, Mayotte and Saint- Martin (France), the Azores and Madeira (Portugal), and the Canary Islands (Spain).</li> </ul> No supporting evidence is required.



Number of organisat ions from RIS countries		Number of organisations from RIS countries that attracted funding from ESIF (in line with Smart Specialisation Strategies) with support from KICs.  Structured data:	No supporting evidence is required.
that attracted funding from ESIF with support from KICs, and the amount of funding attracted	EITHE2 2	<ul> <li>Year of reporting</li> <li>Name of the organisation receiving ESIF funding</li> <li>Country of the organisation</li> <li>Reference to website publication of the ESIF funding received</li> <li>Was the funding attracted as part of the HEI CBI?</li> <li>Was the funding attracted as part of a cross-KIC project?</li> <li>Title and reference of the ESIF project if available</li> <li>Funding received</li> <li>Reference to KIC KAVA activity in which the organisation has been involved</li> </ul>	
In- company investme nt triggered during or after project lead time (€) as a result of	KIC16	In-company investment triggered during or after project lead time (€) as a result of your project  Structured data:  • Year of reporting • Investment amount • Source of income (public/private)	No supporting evidence is required.





	your project		<ul> <li>Company name</li> <li>Company registration number</li> <li>Company Website</li> <li>Registration number if available</li> <li>Country of registration of the company</li> <li>Gender of CEO/owner</li> </ul>	
Jobs created	Number of jobs created in new business es as a direct result of your project	KIC01	Number of jobs created in new business organisations as a direct result of your programme.  Structured data:  • Year of reporting • Type of job created¹ • How many are women • Organization Name • Country • Sector²  ¹ ILO coding (for employment) will be used:  Managers; Professionals; Technicians and associate professionals; Clerical support workers; Service and sales workers; Skilled agricultural, forestry and fishery workers; Craft and related trade workers; Plant and machine operators and assemblers; Elementary occupations; Armed forces occupations  ² NACE (for companies) coding will be used:  Agriculture, forestry and fishing; Mining and quarrying; Manufacturing; Electricity, gas, steam and air conditioning supply; Water supply,	No supporting evidence is required.



		sewerage, waste management and remediation activities; Construction; Wholesale and retail trade, repair of motor vehicles and motorcycles; Accommodation and food service activities; Transportation and storage; Information and communication; Financial and insurance activities; Real estate activities; Professional, scientific and technical activities; Administrative and support service activities; Public administration and defense, compulsory social security; Education; Human health and social work activities; Arts, entertainment and recreation; Other service activities; Activities of households as employers, undifferentiated goods- and services producing activities of households for own use; Activities of extraterritorial organizations and bodies.	
Number and type		Number and type of jobs and/or employment in existing businesses as a direct result of your programme.  Structured data:  • Year of reporting	No supporting evidence is required.
of jobs and/or employm ent in existing business es	KICO2	<ul> <li>Type of job created¹</li> <li>How many are women</li> <li>Organization Name</li> <li>Country</li> <li>Sector²</li> </ul>	
		<sup>1</sup> ILO coding (for employment) will be used:  Managers; Professionals; Technicians and associate professionals; Clerical support workers; Service and sales workers; Skilled agricultural, forestry and fishery workers; Craft and related	





trade workers; Plant and machine operators and assemblers; Elementary occupations; Armed forces occupations

<sup>2</sup> NACE (for companies) coding will be used:

Agriculture, forestry and fishing; Mining and quarrying; Manufacturing; Electricity, gas, steam and air conditioning supply; Water supply, sewerage, waste management and remediation activities; Construction; Wholesale and retail trade, repair of motor vehicles and motorcycles; Accommodation and food service activities; Transportation and storage; Information and communication; Financial and insurance activities; Real estate activities; Professional, scientific and technical activities; Administrative and support service activities; Public administration and defense, compulsory social security; Education; Human health and social work activities; Arts, entertainment and recreation; Other service activities; Activities of households as employers, undifferentiated goods- and services producing activities of households for own use; Activities of extraterritorial organizations and bodies.





People trained	Students enrolled in EIT- labelled program mes	EITHEO 7.5	Sum of students enrolled in EIT labelled master's, EIT labelled PhD programmes, participants in EIT labelled Fellowship schemes and other education activities awarded EIT Label (in year N).  Structured data:	If a student graduated in year N, the student should be reported as "Graduates from EIT labelled programmes" only. Double reporting of the same student/graduate as "student enrolled" and "graduate" for the same year is not allowed.  [EITHEO7.5] and [EITHEO7.1] should sum up to the total number of participants (continuing or finalizing) of EIT labelled programmes for year N.  For the question "Did the student join a start-up?": JOIN means join as a (co-)owner of an existing start-up or be employed by a start-up.  No supporting evidence is required.
	Graduate s from EIT labelled program mes	EITHEO 7.1	Sum of graduates from EIT labelled master's, PhD programmes and other education activities awarded EIT Label (in year N).  Structured data:   Year of reporting Name Contact detail/email address Gender Country of origin Country of residence E-mail address Education programme/activity Name of the HEI / education provider	If a student graduated in year N, the student should be reported as "Graduates from EIT labelled programmes" only. Double reporting of the same student/graduate as "student enrolled" and "graduate" for the same year is not allowed.  [EITHE07.5] and [EITHE07.1] should sum up to the total number of participants (continuing or finalizing) of EIT labelled programmes for year N.  For the question "Did the student join a start-up?": JOIN means join as





		<ul> <li>Country where the education is delivered</li> <li>Year of starting the studies under the EIT label</li> <li>Year of completing the studies under the EIT label</li> <li>Education programme type</li> <li>Did the student join a start-up?</li> </ul>	a (co-)owner of an existing start-up or be employed by a start-up.  No supporting evidence is required.
EIT RIS Graduate s from EIT labelled program mes	EITHEO 7.2- EITRIS	Graduates from EIT labelled programmes in year N with citizenship in EIT RIS countries.  Structured data:  • Year of reporting • Target achieved	RIS countries include:  • EU Member States: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.  • Horizon Europe Associated Countries: Montenegro, Republic of North Macedonia, Serbia, Turkey, Ukraine.  • Outermost Regions: Guadeloupe, French Guiana, Réunion, Martinique, Mayotte and Saint- Martin (France), the Azores and Madeira (Portugal), and the Canary Islands (Spain).
Participa nts in non- labelled educatio n and training	EITHEO 8.1	Number of successful participants in EIT professional development courses, online training courses and other education/training activities delivered or in a process of delivery (by country and type of programme), including data on country of citizenship and gender.	Only participants, who successfully finished the programme, shall be counted. For this KPI, only those education and training activities which have clearly defined learning outcomes, and which carry out competency assessment method are applicable.



		Structured data:	No supporting evidence is required.
		<ul> <li>Year of reporting</li> <li>Title of         course/training/education         activity delivered</li> <li>Type of the programme¹</li> <li>Key learning outcomes,         competencies and results of         the programme</li> <li>List of of participants         enrolled in the reporting year         incl. names, gender, country         of origin, country of         residence, country where         education is delivered</li> <li>List of successful participants         incl. names, gender, country         of origin, country of         residence, country where         education is delivered</li> <li>Higher Education Institution         (if applicable)</li> <li>Is the training/education         delivered through the HEI         CBI?</li> </ul>	
		<sup>1</sup> Type of the programme:  Professional development course; Online training courses; Other education/training products	
EIT RIS Participa nts with (non- degree) educatio n and	EITHEO 8.2- EITRIS	Number of successful participants in EIT professional development courses, online training courses and other education/training activity delivered or in a process of delivery with citizenship in EIT RIS countries.	RIS countries include:  • EU Member States: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.
training		Structured data:	Horizon Europe Associated Countries: Montenegro, Republic of



		<ul><li>Year of reporting</li><li>Target achieved</li></ul>	North Macedonia, Serbia, Turkey, Ukraine.
			Outermost Regions: Guadeloupe, French Guiana, Réunion, Martinique, Mayotte and Saint- Martin (France), the Azores and Madeira (Portugal), and the Canary Islands (Spain).
			No supporting evidence is required.
Number of students trained by EIT Health educatio n program mes	KICO3	Number of students trained in EIT professional development programmes, online training programmes and other education/training programmes delivered or in a process of delivery (by country and type of programme), including data on country of citizenship and gender. Only students who successfully finished the programme can be counted. For this KPI, only those education and training programmes that have clearly defined learning outcomes and carry out competency assessment method (pre and post test) are applicable.	Students are individuals enrolled in a University/ Academic Institution.  Training happens when people's performance/ knowledge/skills/behaviour change from pre-training to post-training.  Only students who successfully finished the programme can be counted.
		Year of reporting     Country of citizenship of the learner(s)     How many are women?     ECTS or Accreditation (Yes/No)     List the organizations delivering the education/training,(incl. country)	No supporting evidence is required.





		Number of professionals trained in programmes belonging to a funded activity. Training programmes may include: webinars, seminars, workshops, capacity building, cocreation sessions, online courses etc. Professionals may also include EIT Health employees, partners, trainers and activity line coordinators.	Training programmes may include: webinars, seminars, workshops, capacity building, co-creation sessions, online courses etc. Professionals may also include EIT Health employees, partners, trainers and activity line coordinators.
Number of professio nals trained	KICO4	Year of reporting     Country of citizenship of the learner(s)     How many are women?     ECTS or Accreditation (Yes/No)     List the organisations delivering the education/training,(incl. country)	No supporting evidence is required.
Number of healthcar e professio nals trained by EIT Health (nondegree) educatio n program mes	KICO4.1	Number of healthcare professionals trained in EIT professional development programme, online training programme and other education/training programme delivered or in a process of delivery (by country and type of programme), including data on country of citizenship and gender. Only healthcare professionals who successfully finished the programme can be counted. For this KPI, only those education and training programmes that have clearly defined learning outcomes and carry out competency assessment method (pre and post test) are applicable.	Healthcare professionals are individuals who deliver healthcare interventions to patients such as medical doctors, nurses, medical specialists, medical technicians, radiologists, etc.  Training happens when people's performance/ knowledge/skills/behaviour change from pre-training to post-training.
		Structured data:	
		<ul> <li>Year of reporting</li> </ul>	



		<ul> <li>Country of citizenship of the learner(s)</li> <li>How many are women?</li> <li>ECTS or Accreditation (Yes/No)</li> <li>List the organisations delivering the education/training,(incl. country)</li> </ul>	
Number of executiv es trained by EIT Health (non-degree) educatio	KICO4.2	Number of executives trained in EIT professional development programmes, online training programmes and other education/training programmes delivered or in a process of delivery (by country and type of programme), including data on country of citizenship and gender. Only executives who successfully finished the programme can be counted. For this KPI, only those education and training programmes that have clearly defined learning outcomes and carry out competency assessment method (pre and post test) are applicable.  Structured data:	Executives are professionals working in the healthcare sector for example in hospitals, Industry (Pharma, Devices, and Diagnostics), regional/national health agencies, etc.  Training happens when people's performance/ knowledge/skills/behaviour change from pre-training to post-training.  No supporting evidence is required.
n program mes		<ul> <li>Year of reporting</li> <li>Country of citizenship of the learner(s)</li> <li>How many are women?</li> <li>ECTS or Accreditation (Yes/No)</li> <li>List the organisations delivering the education/training,(incl. country)</li> </ul>	



Employm ent Success	KICO5	The percentage (%) of participants who have changed jobs within six months after completing an EIT Health education programme as a result/based on the output(s) of the related KAVA(s).  Structured data:  • Year of reporting • Target • Methodology used for the assessment	A job change is considered any change in employment, including moving companies or changing positions within a company.  No supporting evidence is required.
Program me Attractiv eness and Demand	KICO9	Number of applicants in EIT Health programmes (number requested) vs available places (number requested) expressed as a percentage.  Structured data:  • Year of reporting • Target	No supporting evidence is required.
Number of Participa nts Registere d to the Alumni Network	KIC20	The number of participants in EIT Health funded activities/ events/programmes that have registered to be EIT Health Alumni. During or after an event, participants are invited to sign up to EIT Health Alumni. Activity Leaders can reach out to alumni@eithealth.eu for information and support on the Alumni Network.  Structured data:  • Year of reporting	To track the number of your participants that have signed up to the Alumni Network, please create a user account on the Alumni Platform.  Once logged in, you should navigate to the 'members' tab in the platform menu (https://alumni.eithealth.eu/people) . Now you can filter the full list of members to find those connected



		<ul> <li>Target</li> </ul>	with your programme by following these steps:
			1 Click on 'More filters' button.
			2 Scroll down to the 'EIT Health Connection' section.
			3 In the first box, select which 'Pillar' your activity is under (Education, Accelerator, Innovation).
			4 Once you have selected your pillar, a new box will appear to the right, where you can select your specific programme from a list.
			5 To filter by sign-ups for a specific year, enter the start date (1 month before your activity took place), and end date (e.g. end of year).
			6 The blue box in the bottom right corner will now show the total number of registrations from your programme. – Click on the box to show the filtered list. "
			No supporting evidence is required.
Number		Number of students trained, with a view to innovation and entrepreneurship. Subset of EIT Core KPI EITHE 8.1	This KPI is specific for HEI Initiative only.
of students	HEI01		No supporting evidence is required.
trained		Structured data:	
		<ul><li>Year of reporting</li><li>Target</li></ul>	



Number		Number of students mentored, with a view to innovation and entrepreneurship. Subset of EIT Core KPI EITHE 8.1	This KPI is specific for HEI Initiative only.
of students mentore d	HEI02	Structured data:	No supporting evidence is required.
		<ul><li>Year of reporting</li><li>Target</li></ul>	
Number of		Number of academic staff trained, with a view to innovation and entrepreneurship. Subset of EIT Core KPI EITHE 8.1.	This KPI is specific for HEI Initiative only.
academi c staff trained	HEIO3	Structured data:	No supporting evidence is required.
		<ul><li>Year of reporting</li><li>Target</li></ul>	
Number of		Number of academic staff mentored, with a view to innovation and entrepreneurship. Subset of EIT Core KPI EITHE 8.1	This KPI is specific for HEI Initiative only.
academi c staff mentore	HEI04	Conventioned debay	No supporting evidence is required.
d		Year of reporting     Target	
Number of non-		Number of non-academic staff (e.g. professional staff, support staff) trained, with a view to innovation and entrepreneurship. Subset of EIT Core KPI EIT HE 8.1	This KPI is specific for HEI Initiative only.
academi c staff trained	HEI05		No supporting evidence is required.
		Structured data:	
		Year of reporting	



			• Target	
	Number of non- academi c staff mentore d	HEI06	Number of non-academic staff (e.g. professional staff, support staff) mentored, with a view to innovation and entrepreneurship. Subset of EIT Core KPI EIT HE 8.1.  Structured data:  • Year of reporting • Target	This KPI is specific for HEI Initiative only.  No supporting evidence is required.
Creation and Design /Citizen sand Patients /	Number of citizens/ patients involved	KIC11	Number of individual citizens and/or patients involved in the EIT Health supported programme.  Structured data:  Year of reporting Country of origin How many are women? Description of activity/results Disease areas¹ Range of application² Name of the innovation, product or service (if applicable) Typology of initiative³  Disease areas¹	Stage of Innovation: Identification & Prioritisation, Ideation/Creation, Design & Planning, Development. A citizen is a person who is taking part in a programme as a member of the public and not because of a preexisting health condition. A patient is a person who is taking part in a programme because of a preexisting health condition and who is receiving or registered to receive medical treatment for the same condition. Involvement happens when people share their views and experiences, and these are taken up to guide and inform how programmes are designed (codesign), carried out (co-creation), etc. programmes are done 'with' or 'by' people. Participation of citizens & patients as subjects of research & innovation that is done 'to', 'about' or 'for' them (e.g. clinical trials, usability studies) does not qualify as involvement. Examples (non-



		CVD; Neurology; Ear, Nose and Throat; Occupational Disease; Frailty; Oncology; Gastroenterology; Ophthalmology; Genetic; Pain Management; Infectious Diseases; Respiratory; Immuno- inflammatory; Sleeping Disorders; Metabolic disorder; Vaccine & Virology; Mental Health; Women's Health; Musculoskeletal, Rheumatology & Osteology; Other	exhaustive): membership of advisory groups/boards, membership of focus groups and discussion forums, responses to surveys.  No supporting evidence is required.
		Range of application <sup>2</sup> Prevention; Diagnosis; Treatment	
		Typology of initiative <sup>3</sup> Ideation; Co-creation; Business created; Involvement of civil society stakeholders; Other	
Number		Number of individual citizens and/or patients who have reported a variation in performance, skills, knowledge and/or behaviour further to having attended an EIT Health educational/training programme.  Structured data:	A citizen is a person who is taking part in a programme as a member of the public and not because of a pre-existing health condition. A patient is a person who is taking part in a programme because of a pre-existing health condition and who is receiving or registered to receive medical treatment for the same condition.
of citizens/ patients trained	KIC12	<ul> <li>Year of reporting</li> <li>Number of citizens/patients</li> <li>Country of origin</li> <li>How many are women</li> <li>Description of activity/results</li> </ul>	Training happens when people's performance/knowledge/skills/behaviour change from pre-training to post-training.
			No supporting evidence is required.





Number of citizens/patients reporting a positive impact on their life as a consequence of using (direct impact) or being touched (indirect impact) by the solution developed and implemented in the EIT Health activities.

Stage of innovation: Commercialization, Adoption, System Adoption. A citizen is a person who is taking part in a programme as a member of the public and not because of a preexisting health condition. A patient is a person who is taking part in a programme because of a preexisting health condition and who is receiving or registered to receive

medical treatment for the same

condition.

#### Structured data:

Number of citizens/ patients that benefitte d from solutions develope d or impleme nted in KAVAs

KIC13

Year of reporting

- Country of origin
- How many are women?
- Description of activity/results
- Disease areas<sup>1</sup>
- Range of application<sup>2</sup>
- Name of the innovation, product or service (if applicable)

No supporting evidence is required.

Disease areas<sup>1</sup>

CVD; Neurology; Ear, Nose and Throat; Occupational Disease; Frailty; Oncology; Gastroenterology; Ophthalmology; Genetic; Pain Management; Infectious Diseases; Respiratory; Immunoinflammatory; Sleeping Disorders; Metabolic disorder; Vaccine & Virology; Mental Health; Women's Health; Musculoskeletal, Rheumatology & Osteology; Other

Range of application<sup>2</sup>

Prevention; Diagnosis; Treatment





		Number of subjects in clinical trials.	No supporting evidence is required.
Number		<ul> <li>Year of reporting</li> <li>Country of origin</li> <li>How many are women?</li> <li>Description of activity/results</li> <li>Disease areas¹</li> <li>Range of application²</li> <li>Name of the innovation, product or service (if applicable)</li> </ul>	
of subjects in clinical trials	KIC21	Disease areas¹  CVD; Neurology; Ear, Nose and Throat; Occupational Disease; Frailty; Oncology; Gastroenterology;  Ophthalmology; Genetic; Pain Management; Infectious Diseases; Respiratory; Immuno-inflammatory; Sleeping Disorders; Metabolic disorder; Vaccine & Virology; Mental Health; Women's Health; Musculoskeletal, Rheumatology & Osteology; Other  Range of application²  Prevention; Diagnosis; Treatment	





Comms and dissemi nation	Number of citizens/ patients reached	KIC10	Number of individual citizens and/or patients provided with information about EIT Health or an EIT Health supported activity.  Structured data:  • Year of reporting • Target • Description and links (description of the communication/disseminatio n activity/links to the publication)	Stage of Innovation: Dissemination, Communication. A citizen is a person who is taking part in a programme as a member of the public and not because of a preexisting health condition. A patient is a person who is taking part in a programme because of a preexisting health condition and who is receiving or registered to receive medical treatment for the same condition. Outreach happens when people are provided with information. The primary purpose of outreach is sharing information and/or gaining visibility, not educating and/or training. Examples (non-exhaustive): festivals, open days, conferences and seminars, public events and demonstrations, screenings, social media (number of likes/shares for a post), media coverage.
	Number of non- EIT Heath events/f airs/conf erences where EIT Health partners are presenting	KIC14	Number of events events/fairs/conferences where EIT Health partners are present with the purpose to present the activities/goals of EIT Health.  Structured data:  • Year of reporting • Target • Description and links (text) (description of the communication/disseminatio n activity/links to the publication)	No supporting evidence is required.  No supporting evidence is required.



	Number of publicati ons or articles accepted for publicati on or publishe d	KIC15	The number of publications or articles that were accepted for publication or published in connection with the activity (print and online) counted per publication or acceptance instance.  Articles must have been published/accepted for publication within the reporting year.  Structured data:  • Year of reporting • Target • Description and links (text) (description of the communication/disseminatio n activity/links to the publication)	No supporting evidence is required.
Validati on and adoptio n	Intellect ual property rights	EITHEO 1.1	Number of innovative products, processes and methods & Intellectual Property Rights (IPR) applications resulting from KIC activities  Structured data:  • Year of reporting • Type of intellectual property right: patent; trademark; registered design; utility model; other • Application title • Application reference • Application date • IPR owner • Country of the IPR owner • Does the IPR owner take part in the HEI Capacity Building Initiative (HEI CBI) • IPR status: has the IPR protection been awarded • IPR Award reference if any • Technology Readiness Level	No supporting evidence is required.



		Reference to KAVA/portfolio	
EIT RIS Intellect ual property rights	EITHEO 1.3- EITRIS	Number of innovative products, processes and methods & Intellectual Property Rights (IPR) applications owned by organisations from the EIT RIS countries.  Structured data:  • Year of reporting • Target achieved	RIS countries include:  • EU Member States: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.  • Horizon Europe Associated Countries: Montenegro, Republic of North Macedonia, Serbia, Turkey, Ukraine.  • Outermost Regions: Guadeloupe, French Guiana, Réunion, Martinique, Mayotte and Saint- Martin (France), the Azores and Madeira (Portugal), and the Canary Islands (Spain).  No supporting evidence is required.
Number of new and/or improve d support structure s and mechani sms	EITHE2 1	Number of new and/or improved structures and mechanisms established in or mobilized by HEIs participating in the HEI Capacity Building Initiative with an objective to support innovation and / or entrepreneurship. For example, the following structures and mechanisms will be considered: innovation testbeds, units, programmes, spaces, infrastructures, etc. KICs will need to gather the lists of structures and mechanisms from the participating institutions and provide them to EIT together with explanations as to how the HEI Capacity Building Initiative has	No supporting evidence is required.



establish		contributed to establishing, improving	
ed within		and/or mobilizing these structures.	
or			
mobilize			
d by		Structured data:	
the HEIs		<ul> <li>Year of reporting</li> </ul>	
		Higher education institutions	
participa		involved	
ting in		<ul> <li>Countries where these</li> </ul>	
		structures were established	
the HEI			
Capacity			
Building			
Initiative			
		Number of new partnerships	No supporting evidence is required.
		established by participating HEIs and	
		businesses, research organisations,	
		other actors.	
		Number and % of HEIs which	
		participate in other activities of the KIC.	
Number			
of new			
partners		Structured data:	
hips			
establish	EITHE2	<ul> <li>Year of reporting</li> </ul>	
ed as a	0	<ul> <li>Organisations involved in</li> </ul>	
result of		these partnerships	
the HEI		<ul> <li>Nature of the new</li> </ul>	
		partnership (contract,	
Initiative		agreement, informal	
		cooperation, etc.), including	
		roles of different partners	
		Countries of the	
		organisations involved. Of	
		them: RIS countries.	
		Number of organisations  from BIC countries	
		from RIS countries	
		If the organisation  Participates in other KICs  Participates in other KICs	
		participates in other KICs activities: yes/no.	
		activities. yes/110.	



	Number of pilot projects in InnoStars /RIS regions	KIC17	Number of demonstrators in EIT Health projects in the InnoStars region, where a demonstrator is a product, service process at high maturity level. The demonstration shall take place in a setting where the product, service or process may be applied later (e.g. a hospital or care facility).  Structured data:  • Year of reporting • Target achieved • Description of the pilot/prototype • Main results	No supporting evidence is required.
-	Number of prototyp es develope d and installed in a preclinic al/clinical environ ment	KIC18	The number of prototypes created during the solution development life cycle and implemented in preclinical/clinical settings.  Structured data:  Year of reporting Target achieved Description of the pilot/prototype Main results	No supporting evidence is required.





		Number of pre-prototype ideas/concepts validated. Progress in validation: individuals (potentially under the wings of a project or start-up)	No supporting evidence is required.
Number of pre- prototyp		speaking to assigned mentors or business stakeholders, conducting interviews, interacting with feedback groups, using Living Labs and Test Beds etc.	
e ideas/co ncepts validated	KIC19	Structured data:	
		<ul> <li>Year of reporting</li> <li>Target achieved</li> <li>Description of the pilot/prototype</li> <li>Main results</li> </ul>	





# Annex 16 - EIT Health Recognition Scheme

#### Overview and expected impact

The EIT Health Recognition Scheme is designed to enable the recognition of high-quality activities within the EIT Health portfolio and to further support EIT Health fellows, in order to strengthen the EIT Health network.

The EIT Health Recognition Scheme will target two different types of activity:

A. High quality activities that demonstrated their capacities by reaching a high score in the evaluation process but did not receive EIT Health funding.

or

B. High quality activities that demonstrated successful results during their EIT Health funding period, which has ended.

The EIT Health Recognition Scheme will consist of:

A quality label for activities of type A: Selected activities of type A will be granted the EIT Health Quality Label as an EIT Health project or programme and can gain further visibility within their ecosystem.

A set of services for activities of type B: The set of services made available for activities of type B includes the free continuation use of EIT Health branding in any communication, the promotion of the activity through the EIT Health communication and marketing channels, at the regional and European level, and beyond, premium access to EIT Health platforms. Finally, selected activities of type B will remain in EIT Health portfolio.

Guidelines for the EIT Health Recognition Scheme		
Definition	The EIT Heath Recognition Scheme allows high quality activities, that have not been selected for a grant, or that have demonstrated success during grant support, to benefit from the EIT Health network's reputation and further support.	
Goals	Recognition or portfolio integration of high-quality activities among EIT Health projects/programmes and further support for EIT Health fellows, to strengthen the EIT Health network	
Duration	One year from receipt of Quality Label for Type A	





	Open for Type B in line with project performance		
Co-funding	Not required for type A		
	Partners can provide co-funding in case they have been selected for type		
Indicative	No EIT Health funding involved		
grantamount			
Selection criteria	<ul> <li>Activities that manage to demonstrate their quality through a final high rank during the evaluation process, and/or activities that obtained positive monitoring throughout their period of EIT Health financial support, will be put forward, based on the respective pillar director's proposal.</li> <li>Final approval will be taken by the EIT Health Executive Management Team</li> </ul>		
Financial Contribution back to EIT Health	Not required		
Rules of participation	<ul> <li>Each activity must have applied and undergone a full evaluation procedure (type A) or must have been funded and monitored positively in previous years (type B).</li> <li>For both types of activities, activity leaders or consortia agree to adhere to the EIT Health branding guidelines and, if applicable, ensure that any further direct beneficiaries adhere to the branding guidelines as well.</li> <li>Each activity is required to <ul> <li>Enable data collection via EIT Health tools</li> <li>Go through dedicated monitoring process during the year the Recognition Scheme is implemented (only for type B)</li> </ul> </li> <li>Report annually to EIT about the activity implementation supported by the EIT Health Recognition Scheme (KPIs, DELs, OUTs will be defined at the end of the selection process) (only for type B)</li> <li>Ensure a designated contact person to communicate with EIT Health on topics related to marketing, monitoring, reporting, and overall information linked to the activity</li> </ul>		
Benefits for selected activities	<ul> <li>For type A activity:</li> <li>A unique Quality label</li> <li>For type B activity:</li> <li>Marketing and communication channels (e.g., Newsletters, social media, e-mailing etc.), targeted support</li> <li>Access to EIT Health service platforms (e.g., Alumni network platform)</li> </ul>		





## Annex 17 - Glossary

Activity: EIT Health project

**Activity Leader:** Activity Leaders are the proposal and project coordinators who are the main contact points for EIT Health projects, and represent the consortium

AI: Artificial Intelligence

**AIC**: Artificial Intelligence Community

**Backflow model**: One of two alternative financial sustainability models applicable for EIT Health Innovation projects in the flagship call

**BP**: Business Plan

**Catalyser:** A pre-selected accelerator, incubator and/or cluster from EIT Health network with a proven track record in building, accelerating and scaling-up healthcare companies, that provides support to start-ups with soft-landing services to facilitate new market access and reimbursement activities

**CE mark**: "Conformité Européenne" (French for "European conformity") mark, which affirms a product's conformity with European health, safety, and environmental protection standards, and indicates the product can be traded freely in the European Economic Area

**CO**: Central Office; formerly known as headquarters (HQ), this is the EIT Health office in Munich, Germany that coordinates all EIT Health activities and guides the work of Regional Innovation Hubs

**Co-funding (consortium partners' own resource)**: Activities supported by EIT Health require specific levels of co-funding from consortium partners, defined as a percentage of EIT Funded Activity (EFA, below) costs

**Connections**: EIT Health Community platform

**Cut-off**: Three defined timestamps after which selection processes are triggered for short proposals submitted for the flagship call





**DEL**: Deliverable; a tangible document describing the quantifiable outputs created by a project. Deliverables are outputs produced at a given moment during an activity.

**DiGinnovation**: An EIT Health Programme that links start-ups/scale-ups with an international consortium to accelerate the reimbursement of digital health apps in Europe

**DMD**: Digital Medical Device; EIT Health uses the denomination of Digital Medical Devices (DMD) for its flagship as this terminology is broad in scope.

**ECTS**: The European Credit Transfer and Accumulation System; a tool of the European Higher Education Area that allows credits taken at one higher education institution to be counted towards a qualification studied for at another

EFAs: EIT Funded Activities; activities (projects) implemented with EIT funding

**EIT**: European Institute of Innovation & Technology

**EHDS**: European Health Data Space

**EIT Health Hubs**: The network of EIT Health Hubs includes leading regional incubators, accelerators, prominent medical universities, research centres and institutes. These Hubs are located in 13 countries in Southern, Central and Eastern Europe

**EIT RIS**: EIT Regional Innovation Scheme; introduced in 2014 to advance the innovation performance of more countries and their regions across Europe, especially countries with moderate or modest innovation scores as defined by the European Innovation Scoreboard

**ELSI**: Ethical, Legal and Social Issues

**FAIR**: Principles for the Findability, Accessibility, Interoperability and Reuse of data, outlined in the Communication "<u>European Data Strategy (2020)</u>" by the European Commission as a way to implement interoperability of digital assets

Flagship: EIT Health's flagship concept presents a problem focused approach around defined societal needs and clear business cases, aligned with EU policy priorities across the healthcare landscape. EIT Health defined four flagships: 1) New models to deliver healthcare; 2) Facilitating the uptake of Digital Medical Devices & Diagnostics; 3) Harnessing the full potential of health data for Innovation; 4) Supporting the deployment of Important Projects of Common European Interest in Health (IPCEI) to address market failures.

**FS**: Financial Sustainability





**Grant Agreement (GA)**: Agreement between the EIT and EIT Health signed for 3 years (the duration of the Business Plan)

**Grant for option model**: One of two alternative financial sustainability models for EIT Health Innovation projects in the flagship call. The model is only applicable for Start-up driven Innovation and Fast Track Start-up driven Innovation (DiGinnovation) projects. EIT Health shall participate in the economic success of the start-up by way of receiving options to assume shares in the start-up upon the occurrence of pre-defined Exit Events. In such Exit Events, EIT Health has the right to subscribe to shares in the start-up and subsequently be treated as a shareholder of the company.

**GDP**: Gross Domestic Product

**GDPR**: General Data Protection Regulation

**HC**: Healthcare

**HERA**: The Health Emergency Preparedness and Response department is a key pillar of the European Health Union with the mission to prevent, detect, and rapidly respond to health emergencies

**Horizon Europe**: The European Union's main instrument for supporting innovation and research. Horizon Europe replaces the previous Horizon 2020 Programme and funds the EIT.

**HVC (High Value Care)**: EIT Health's terminology for value-based healthcare concepts and implementation in Europe. High Value Care is the overarching goal of achieving better value for patients. In past calls, HVC was used to refer to a specific type of innovation projects that were targeting healthcare system change based on value. Those innovation projects type are now found under the flagship New Models to Deliver Healthcare and referred to as "Service Quality Assessment innovation projects".

**Innovators Community:** Formerly the EIT Health Alumni Network. In 2022, the EIT Health Alumni Network was rebranded as the EIT Health Innovators Community. This name change reflects a change in the strategic direction of the community, as well as the expanded target audience. Current participants, activity leaders, mentors, and partners are welcome to join this community, alongside the alumni of all EIT Health programmes. The Innovators Community platform also provides programme leaders with a tool to engage with their participants.

**IPCEI**: Important Projects of Common European Interest





IP: Intellectual Property (i.e., patents, trademarks, registered designs, copyrights)

**I&E**: Innovation and Entrepreneurship

KAVA: KIC Added Value Activities; activities (projects or programmes) funded through EIT Grant

KIC: Knowledge and Innovation Communities of the EIT. EIT Health is one of several EIT KICs.

**KPI**: Key Performance Indicator

**Living Labs**: open innovation ecosystems in real-life environments using iterative feedback processes throughout a lifecycle approach of an innovation to create sustainable impact

MCN: Mentoring and Coaching Network

Member(s): used synonymously to Core and Associate Partners of EIT Health

**MS**: A Milestone is a significant stage/event that indicates the completion of a major project achievement/development and shapes the future progress of the project

**NEFAs**: NEFAs are activities that are fully implemented without any EIT funding – they may be completely self-funded by the KIC, or funded by other EU programmes, regional funds etc. NEFAs must comply with the same operational principles as EIT Funded Activities (EFAS).

**OCT:** Overseas Countries and Territories

**OUT**: Outputs; a specific technology, product, service, method, design, concept, methodology, approach, etc., created by a project. Outputs are intangible results of the project.

**Partner**: EIT Health has a world-leading community of approximately 280 <u>leading organisations</u>, exceptional in the worlds of business, education, research and health service delivery

**Partner-driven projects**: Collaborative Innovation projects driven by an industry entity, academic institution or healthcare provider that develop products and/or services that will generate revenues and costs savings when introduced in the market

**PGA**: Project Grant Agreement; lays down the contractual arrangements between the Parties regarding the Project in which the Project Participants are involved





**Regional Innovation Hub (RIH)**: Formerly known as Co-Location Centres (CLCs), these are EIT Health offices around Europe. EIT Health has seven regional Innovation Hubs plus InnoStars. These Hubs operate as strong clusters of partners and activity to drive our thriving ecosystem.

Repositorium: Collection

SA: Strategic Agenda of EIT Health

SB: EIT Health Supervisory Board

**Short proposal**: Proposal document to be submitted by applicants to EIT Health for evaluation by the cutoff date of the call track

**SME**: Small and medium sized enterprises

**Start-up driven Innovation projects**: These are Innovation projects in which the start-up is the center of the project that develops products and/or services that will generate revenues and costs savings when introduced in the market.

**Start-up Amplifier instrument**: A grant-for-option instrument offered to Start-up-driven projects during the proposal submission, focused on elevating the role of top start-ups in Innovation projects by increasing their involvement and available funding in return for option.

**Support programme**: A service offered by EIT Health to all pre-selected applicants from the shortlisting phase to enhance the quality of their proposals, define their strategy in terms of the 1/3 principle implementation and refine synergies with other activities (also part of the support programme or already in the portfolio). The support programme applies to all types of proposals and activities across the flagships.

**Test bed:** Environment for testing and validating ideas, products and services in collaboration with the relevant stakeholders

**UEMS-EACCME**: The European Union of Medical Specialists (UEMS) set up the European Accreditation Council for Continuing Medical Education (EACCME®) for the implementation of continuing professional development (CPD) for specialist doctors in Europe

VBHC: Value-Based Health Care









# Annex 18 – EIT Health Academy

The EIT Health Academy has been built in response to our partners needs to provide a frictionless learning solution. We provide a platform that will be with your learners at each step of their educational journey and be a one-stop shop from their registration through to certification.

The EIT Health Academy is a learning ecosystem consisting of 3 best in class tools that will accommodate the pedagogical needs of your learners and subject matter experts.

- Your learners will access course content through a learner management system, Canvas. Canvas supports all modern learning standards for assessment and content provision and can integrate with most tools. It also allows us to streamline and centralise communication with learners in one location with audit trails.
- Eduframe is our learner administration system that allow you to register and onboard your learners. It also has ecommerce functionality.
- Panopto is our video content management system. Where before your content would have been on multiple sites, Panopto will allow you to record, edit, share and track learner engagement with your content in one secure location.

### The EIT Health Academy is focused on:

- Development and implementation of an innovative and sustainable digital learning platform for European learners – innovators, entrepreneurs, professionals, students, citizens, and patients, with access to EIT Health online educational offerings in the domain of health.
- Bringing learner experience to the forefront by tailoring learner pathways, which
  focus on individual educational needs based as well as on the individual interests and
  educational experience.
- **Supporting the life-long learning** of European learners in the domain of health.
- Facilitating the Community of Practice (CoP), to build and maintain the EIT Health community.

In line with the ambition to improve the visibility and accessibility of the educational content and resources from EIT Health, Academy aims to directly support EIT Health partners in 3 main ways:





- Scaling their educational activities to reach the target audience and open the content to the entire spectrum of European learners.
- **Sustainability** by providing a visible and accessible home and ensuring that the content has the highest possible impact on European learners.
- Applying a pedagogical approach that will improve the impact of the educational content on targeted learners.

Selected consortia will be introduced to our Education team including digital educational and instructional design experts, who will guide you through the process of onboarding and getting the most from the EIT Health Academy for your needs. Based on these needs, training with the EIT Health team can include programme blueprints, instructional design workshops, programme development, and support for your business model. All of this with the aim to have impactful and specific education outcomes for your learners.









# Annex 19 – The European Accreditation Council for Continuing Medical Education

The Union Européenne des Médecins Spécialistes (UEMS) is a non-governmental voluntary organisation representing the interests of specialist doctors at an international level. Its members are the national medical organisations that represent medical specialists in the European Union and in associated countries. In January 2000 the UEMS established the European Accreditation Council for Continuing Medical Education (EACCME®) with the aim of encouraging the highest standards in the development, delivery and harmonisation of continuing medical education (CME) and, later, of continuing professional development (CPD).

The purpose of the EACCME® is to provide accreditation of international CME in Europe and to facilitate the recognition of credits between the various countries in Europe. In order to reach this goal, the UEMS-EACCME® signed agreements of cooperation with countries in Europe, and also outside of Europe. In order to support this recognition process the UEMS-EACCME® introduced a common "CME currency": the European CME Credit (ECMEC®). In 2009, the EACCME® implemented criteria for the accreditation of e-learning materials. In 2016, the EACCME® implemented EACCME® 2.0 including new forms of CME/CPD activities.

The EACCME® supports accreditation for other healthcare professionals (other than medical specialists) in collaboration with their relevant professional bodies. Certificates can be distributed to other healthcare professions.

Details and criteria for application can be found here

Criteria for E-learning

Criteria for live educational events