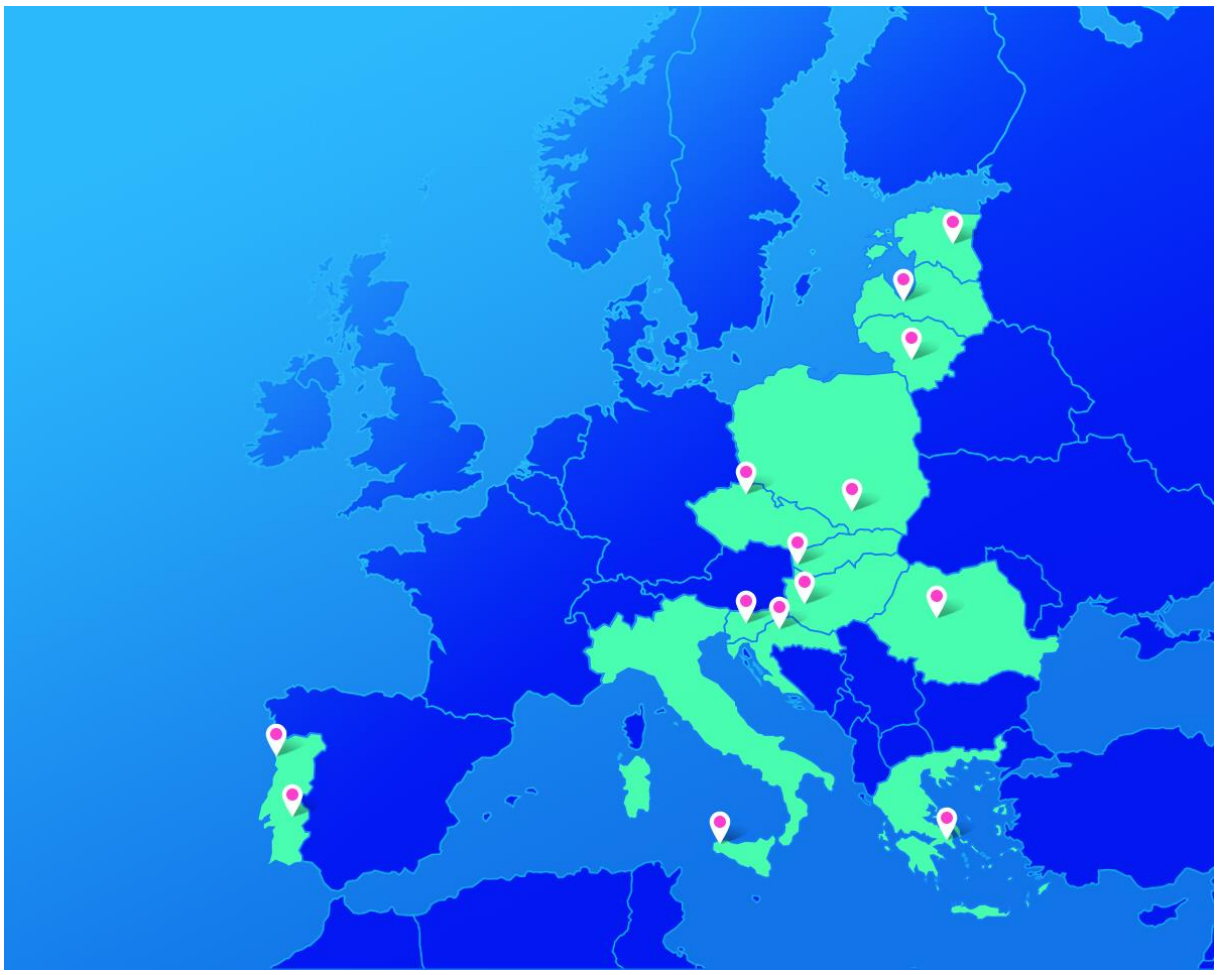
2023 Call for Applications
EIT Health RIS Innovation Call



Co-funded by the European Union

Contents

Applications open 12 August 2022
Deadline: 12 October 2022

Contact: **innostars.ris@eithealth.eu**

Apply under the following link:

https://eithealth.optimytool.com/en/

EIT Health InnoStars seeks partners with early-stage healthcare projects. Its purpose is to fund the proof-of-concept phase of high-quality, strong, balanced projects, targeting EIT Health's four Focus Areas to be developed by local actors, including both business and academic/research/health care institutions.

Take part and gain the following support:

- funding for up to 75.000 EUR
- individual mentoring from the EIT Health Mentor and Coaching Network (MCN)
- online bootcamps
- visibility for successful innovation projects
- opportunity during the later stages of matchmaking events

Is it for me? Eligibility criteria

The EIT Health RIS Innovation Call is open to all legal entities. However, at least two legal entities' collaboration is expected from the same RIS country, where both business AND academic OR research OR health care institutions as partners are represented. Partnerships consist of only affiliated entities that are not eligible.

Eligible RIS countries are Croatia, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, and Slovenia.

Eligible applications must contain a Letter of Support from an EIT Health Hub or Partner and a declaration of non-conflict of interest:

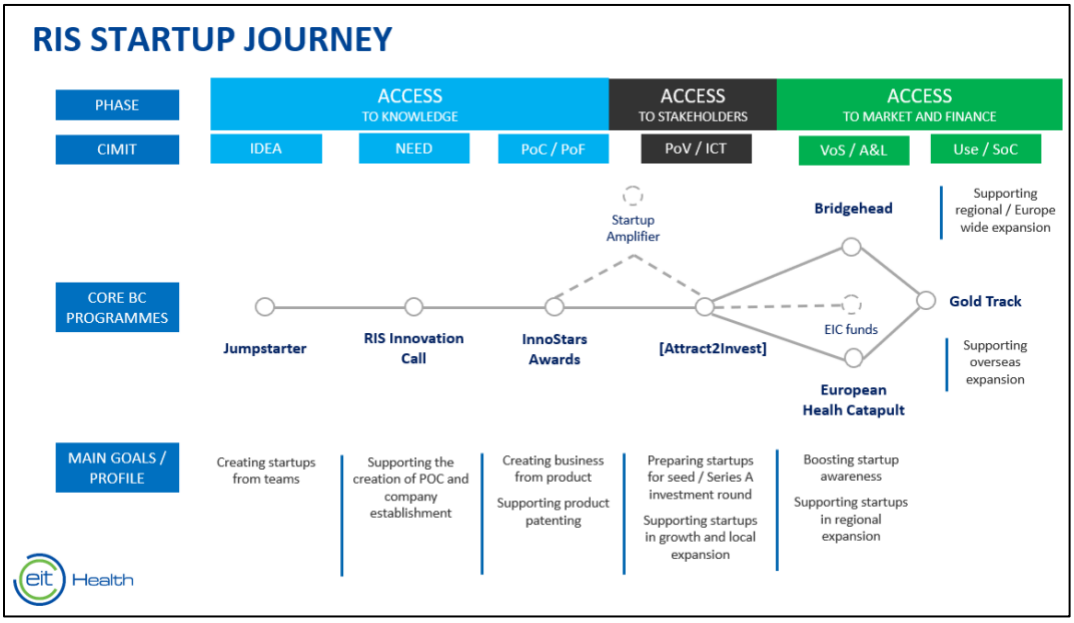
- The EIT RIS Hub *Letter of Support* can be downloaded from here
- The InnoStars partner's *Letter of Support* can be downloaded from here
- *Declaration of non-conflict of interest* can be downloaded from here

1. Background and overview

The European Institute of Innovation and Technology (EIT) Regional Innovation Scheme (EIT RIS) was introduced by the European Parliament and the Council as part of the EIT's Strategic Innovation Agenda (SIA) 2014-2020, and it is an integral part of the Strategic Innovation Agenda of the EIT 2022-2027[1].
In line with the SIA, the EIT RIS is designed to close the gap between regions that are leaders in innovation and those regions which are progressing, as well as to widen participation in KIC[2] activities. The EIT Health RIS program aims to promote healthcare innovation in countries with modest and moderate innovation capacity by developing and introducing new healthcare products and services. Additionally, it aims to match healthcare innovators from the EIT Health network with the talent pool and innovative organizations across these regions.

1.1 EIT Health RIS Innovation Projects

The EIT Health RIS Innovation Call is designed as one step in the EIT Health RIS Start-up journey. The below figure demonstrates the EIT Health Start-up journey for RIS projects and how EIT Health RIS Innovation Call fits into that journey.



POC: Proof of Concept

EIT Health RIS Innovation Call 2023 aims at funding the proof of concept phase of high-quality, strong,

[1] ANNEX to the Proposal for a Decision of the European Parliament and of Council on the Strategic Innovation Agenda of the European Institute of Innovation and Technology (EIT) 2022-2027: Boosting the Innovation Talent and Capacity of Europe, COM(2019) 330 final.

[2] Knowledge and Innovation Communities

balanced projects, targeting EIT Health's four focus areas to be developed by local actors, including both business and academic/research/health care institutions. Local KTI[3] actors in EIT Health RIS countries will apply on this innovation call, participating in original innovation projects.

We ultimately aim at:

1- Development of the local innovation ecosystem in InnoStars and RIS regions.
2- Facilitate and foster cooperation among local KTI actors.
3- Bridge the funding gap between EIT Health InnoStars and RIS regions by operating a proof of concept fund.
4- Support innovation teams through grants, training, mentoring, and matchmaking to further develop and commercialize their scientific output.
5- Provide teams in EIT Health InnoStars and RIS regions with appropriate tools/technics/skills to be matched with EIT Health partners to collaborate and further develop the project and apply for other funding programs.
6- Provide EIT Health InnoStars and RIS regions with internationalization tools.

1.2 Focus Areas

Focus Areas are identified as four of the most urgent healthcare challenges facing society, and we are dedicated to finding solutions that will strengthen healthcare systems, promote better health for citizens, and contribute to a sustainable health economy in Europe.

The four Focus Areas shape this call by directing EIT Health funding decisions and securing long-term sustainability. They ensure that concrete activities and expected outcomes are integral to call proposals. They offer guidance for anyone preparing a proposal, as all proposals should address one (or more) Focus Area(s). **The four EIT Health focus areas are:**

1. **Brain and Mental Health:** Brain health is broader than the absence of disease. It includes improving overall cognitive functioning, resilience, and the state of well-being in which an individual realizes his or her abilities can cope with the everyday stresses of life, work productively, and contribute to his or her community. Brain conditions account for a large portion of the global disease burden, a challenge substantially worsened by the COVID-19 crisis, especially since the mental health of many employees was at risk. Across the globe, four HR leaders report that mental health and well-being are top priorities for their organization. Many employers focus on individual-level interventions that remediate symptoms rather than resolve the causes of employee burnout. Employees frequently cite the feeling of always being on call, unfair treatment, unreasonable workload, low autonomy, and lack of social support. Thus, addressing brain health challenges and focusing on mental health in the workplace is mainly essential. We aim to help people worldwide achieve the best possible

[3] Knowledge Triangle Integration actors are leading entities from higher education, research and business areas.

brain health and improve their mental health at the workplace.

2. **Infectious Diseases:** The COVID-19 pandemic has disrupted lives and livelihoods on a global scale more than any other event in the 21st century and reminds the world about the consistent threat of newly emerging and evolving infectious diseases. Apart from pandemics, infectious diseases remain the main driver of death and suffering across the globe. Many of them, like malaria or dengue, have a clear yet expanding geographical footprint. Others, like common pneumonia, HIV, influenza, or tuberculosis, are prevalent in almost every country. Humanity has made enormous progress in fighting infectious diseases over the last century by improving hygiene and developing highly successful vaccines and therapeutics. At the same time, effective prevention and treatment of infectious diseases remain a major challenge across geographies. Equitably and consistently applying proven strategies, novel approaches, and collaborations across countries, populations, and systems to reduce suffering and death from infectious diseases. Thus, we need to consider how to reduce the threat of infectious diseases more broadly over the next decade.

3. **Fostering Healthier Lives:** The global disease burden is strongly related to behavioural factors, including dietary choices, sedentary lifestyles, smoking, alcohol, and poor medication adherence. Creating awareness about and changing these behaviours also represents a major opportunity to improve health and well-being. A balanced and healthy diet, sufficient and regular sleep, and moderate physical activity are just a few elements enabling healthier living. Patients and citizens in Europe are at the centre of what we do. We want to change lifestyle behaviours by creating the tools and incentives for patients that help protect their health, prevent early ageing, reducing disease and disability.

4. **Harnessing Real-World Data*:*** Healthcare data provides rich insight into diseases and, when used efficiently, will open new possibilities. It will deliver prediction models for early diagnosis, enhance treatment, and inform how we can lead healthier lives. We want to exhaust the wealth of healthcare data available across Europe to improve the lives of patients and citizens.

2. Preparation – Call Introduction

A webinar will be held on **Wednesday 14st September 2022 at 11:00 am (Budapest Time)** and will address the following subjects:

- Introduction of EIT Health and EIT Health RIS Programme
- Introduction of the EIT Health RIS Innovation Call 2023
- Introduction of the Application form in detail
- Tips on how to submit a successful proposal

This webinar is aimed at EIT Health InnoStars and RIS regions' local actors and hubs.

3. Eligibility criteria

A proposal will only be considered eligible if:

(a) Submitted in the English language.

(b) Submitted through EIT Health registration platform, Optimy. Incomplete submissions, late submissions, or submissions via other routes (e.g., email) will not be accepted.

(c) Its content corresponds, wholly or in part, to at least one of the four EIT Health Focus areas (see point 1.2).

(d) It is targeting the completion of the "Proof of Concept" phase as defined by CIMIT (see Annex2). Projects selected will have completed IML 2 (Idea) and have started IML 3 (Proof of Concept) at least in 2 of the four domains. Funded projects' end-point will depend on the: Sector (BioTech, MedTech, Digital Health) and project complexity.

(e) Participation in training (bootcamps) and mentoring sessions are obligatory for a stable team (same team members should be involved in the bootcamps and mentoring sessions).

(f) Applicants who received a grant for the same project/service/product in 2017, 2018, 2019, 2020, 2021, or 2022 from RIS Innovation Call, InnoStars Awards, Attract2Invest, European Health Catapult, EIT Health Headstart, Start-ups Meet Pharma, Start-ups Meet Healthcare Providers, Bridgehead funding, is not eligible to apply for RIS Innovation Call 2023.

(g) Applicants who receive funding from RIS Innovation Call 2023 are excluded from applying with the same project/service/product for InnoStars Awards, Attract2Invest, European Health Catapult, EIT Health Headstart, Start-ups Meet Pharma, Start-ups Meet Healthcare Providers, and Bridgehead funding in 2023.

(h) The eligible applicants should get a letter of support from the local EIT Health Hub or the InnoStars partner in your region before applying and submitting the application to be uploaded as a part of the application

- The Hub *Letter of Support* can be downloaded from here
- The InnoStars partner's *Letter of Support* can be downloaded from here

(i) The eligible applicants should sign and submit the **Declaration of non-conflict of interest** document as part of the proposal. It can be downloaded from here

(j) It complies with the eligibility conditions for participation in the table below.

Eligibility conditions for participation:

- **Mobile applications are not eligible as a standalone solution**. They can be part of the product/service/project only in case they are integrated into a more complex solution.
- At least two legal entities' collaboration is expected, where both business AND academic or research or healthcare institutions as partners are represented.
- Natural persons are not eligible.

  - A **business organization** engages in commercial or industrial activities by providing goods or services to meet customers' needs (SMEs, startups).
  - **An academic institution** is an educational institution dedicated to education and grants academic degree(s) on its own.
  - **The research Institute** is dedicated to doing research and experimentation for innovation in scientific and social fields.
  - **A Healthcare institution** is a public or private organization that provides healthcare and related services, including but not limited to the provision of inpatient and outpatient care, diagnostic or therapeutic services, laboratory services, nursing care, assisted living, and elderly care.

- Each partner must be established in the same country. **Eligible RIS countries are** Croatia, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, and Slovenia.
- The leader legal entity of the partnership must have an established and registered representation/branch in the NUTS2 regions where one of EIT Health Hubs or the listed EIT Health partners is located in the corresponding RIS country.

	Eligible NUTS2 regions	EIT Health Hubs	EIT Health Hubs Emails
1	Grad Zagreb Region (City of Zagreb)	University of Zagreb http://cirtt.unizg.hr/en/about-us/projekti/eit-health/	EITHealthHub@unizg.hr
2	North East Region, Czech Republic	DEX Innovation Centre http://dex-ic.com/	eithealth@dex-ic.com
3	Estonia	Tartu Biotechnologia Park http://biopark.ee/	eithealth@biopark.ee
4	Attica, Greece	National Documentation Centre http://www.ekt.gr/en	eithealth@ekt.gr
5	South Transdanubia Region, Hungary	Institute of Transdisciplinary Discoveries ITD official webpage (itdweb.hu)	itd.eithealth@pte.hu
6	Sicily, Italy	Consortium ARCA http://www.consorzioarca.it/index.php/en/	eithealth@consorzioarca.it
7	Latvia	Rīga Stradiņš University https://www.rsu.lv/starptautiska-sadarbiba/eit-health-ris-centrs	eithealth@rsu.lv
8	North East Region, Lithuania	Kaunas University of Technology https://en.ktu.edu/ **or** Lithuanian University of Health Sciences http://www.lsmuni.lt/en/	eithealth@lsmu.lt
9	Malopolska Region, Poland	Life Science Cluster Krakow www.lifescience.pl	eithealth@lifescience.pl
10	Alentejo, Portugal	University of Évora www.uevora.pt/	eit@uevora.pt
11	North Portugal Region, Portugal	University of Porto https://upin.up.pt/en/content/projects	eithealthporto@reit.up.pt
12	North West Region, Romania	Associatia INIT & Freshblood HealthTech freshblood.ro	eithealthhub@freshblood.ro
13	Western Slovenia Region, Slovenia	Ljubljana University Incubator https://lui.si/	eithealth@lui.uni-lj.si
14	Bratislava Region, Slovakia	Civitta Slovakia	eithealth@civitta.com

	Eligible InnoStars Regions	InnoStars Representative Partner	Main Contact (Name/Email)
1	Hungary- HU11- Budapest	General Electric (GE)	Zsolt Bubori zsolt.bubori@eithealth.eu
		E-Group ICT	
		Semmelweis University	
		Syreon Clinical Research	
2	Hungary-HU32- Northern Great Plain	University of Debrecen	
3	Italy- ITC1 – Piemonte region	University of Torino	Chiara Maiorino chiara.maiorino@eithealth.eu
4	Italy- ITC3 – Liguria region	IIT	
5	Italy- ITC4 – Lombardia	Synlab Italia srl	
6	Italy- ITH2 – Trentino region	FBK	
7	Italy- ITH5 – Emilia Romagna region	ART-ER	
8	Italy- ITF3 – Campania region	UniNA, Synlab SDN, Biocheckup srl	
9	Portugal - Center	University of Coimbra	Marta Passadouro marta.passadouro@eithealth.eu
		Instituto Pedro Nunes	
		Coimbra Hospital and University Centre (CHUC)	
10	Portugal - Metropolitan Region of Lisbon	University of Lisbon	
		University NOVA Lisbon	
		North Lisbon University Hospital Center (CHULN)	
		Glintt	
11	Poland- Łódzkie Region	The Medical University of Łódź	Manal Al-Hammadi manal.al-hammadi@eithealth.eu
		Politechnika Łódzka	
12	Poland- Warsaw Region (Warszawski Stoleczny)	The University of Warsaw	
13	Poland - Dolnośląskie Region	Lukasiewicz Port	
14	Poland – Pomorskie Region	Medical University of Gdańsk	

4. Programme elements and Project funding

EIT Health RIS Innovation Call 2023 contains two types of support.

A. Financial support for the further development of the project/service/product

- Project partnerships will be funded to a maximum of EUR 75.000 (including EUR 3.000 to be spent on mentoring and another EUR 1.500 to be spent on travelling per partner. The requested funding per partner may not exceed EUR 25.000.
- One partnership (i.e., a consortium with the same partners) can apply to multiple projects, but only the highest-ranked can be funded.
- The eligible costs of non-profit organizations and micro and small enterprises are funded up to 100%. Medium-sized enterprises will only be funded up to 70%. Large enterprises cannot receive funding but can be part of a partnership and benefit from the networking opportunities.

Legal entity category	**Staff headcount**	**Turnover**	**or**	**Balance sheet total**	**Maximum Funding €**
Large enterprise	> 250	> € 50 m		> € 43 m	0
Medium-sized enterprise	< 250	≤ € 50 m		≤ € 43 m	17.500
Small Enterprise	< 50	≤ € 10 m		≤ € 10 m	25.000
Microenterprise	< 10	≤ € 2 m		≤ € 2 m	25.000
Non-profit organization	N/A	N/A		N/A	25.000
Academic Institution	N/A	N/A		N/A	25.000
Research Institute	N/A	N/A		N/A	25.000
Healthcare Institution	N/A	N/A		N/A	25.000

- Affiliated Entities can be part of the same or different partnerships; however, if the same beneficiary (including its affiliated entities) is included in more than one winning project's partnerships in any EIT Health Programme, the sum of all grants received by the beneficiary and its affiliates cannot exceed EUR 50,000 in the same year (2023).
- Although the local EIT Health Hub has to be an integral part of the partnership alongside the local KTI actors, they cannot benefit from the project budget due to budget restraints imposed by their contract with EIT Health.
- Affiliates of the local EIT Health Hub and EIT Health partners can be part of partnerships but cannot receive funding from the EIT Health RIS Innovation Call.

B. Mandatory Trainings and Mentoring

- Participants have to participate in training (training modules include: Innovations canvas, Prototyping, IPR, GDPR, Business Development Plan, Pitch training, Start-up financing, Investment strategy, Funding opportunities).

- Partnerships have to dedicate at least EUR 3.000 to be spent on mentoring. The mentors should be chosen from the Mentoring and Coaching Network (MCN) of EIT Health. At least 12 hours of mentoring is obligatory, but the total value must be spent.
- One-third of mentoring sessions are to be conducted at the beginning of the project implementation, one-third halfway through, and one-third at the closure of the project implementation.
- Dedicate EUR 1.500 per partner for travelling (in case the covid situation does not allow on-site training, the partners can shift this cost to other tasks)

The final number of projects funded remains conditional on the approved budget of EIT Health RIS 2023. InnoStars keeps the right to cancel the call based on EIT's decision on the EIT Health RIS 2023 budget.

5. Expected KPIs, deliverables, outputs

- The implementation of the work plan submitted in the proposal is to be proved in the final report and verified by an expert opinion from the mentor.
- Beneficiaries are requested to compile a project development plan with the support of mentor(s) summarizing the actions to be taken for the innovative solution to reach the market. After the mentoring sessions timesheet and performance certificate must be signed to prove the completion of the tasks.
- Providing EIT Health with success stories with a visible result of the project development and setting up at least two promising negotiations per project with EIT Health partners in matchmaking events or other meetings. The KPIs must be supported by evidence (e.g., minutes, letter of support).
- A sharable, clear, and concise value proposition of the project (one-pager) that can help the project partnerships in the negotiation phase and during matchmaking events.
- Sound, specific KPIs should be defined. Projects must ensure that the chosen KPIs, deliverables, and outputs fit the objectives of the listed activities.

6. Eligible costs

Only the cost of those activities can be reimbursed that contribute to the project's development.
The budget breakdown needs to be presented by project partners, not individuals.
Only actual costs are eligible; lump sum, flat rate, and indirect costs are ineligible in connection with the implementation of the activities.

Actual cost means:

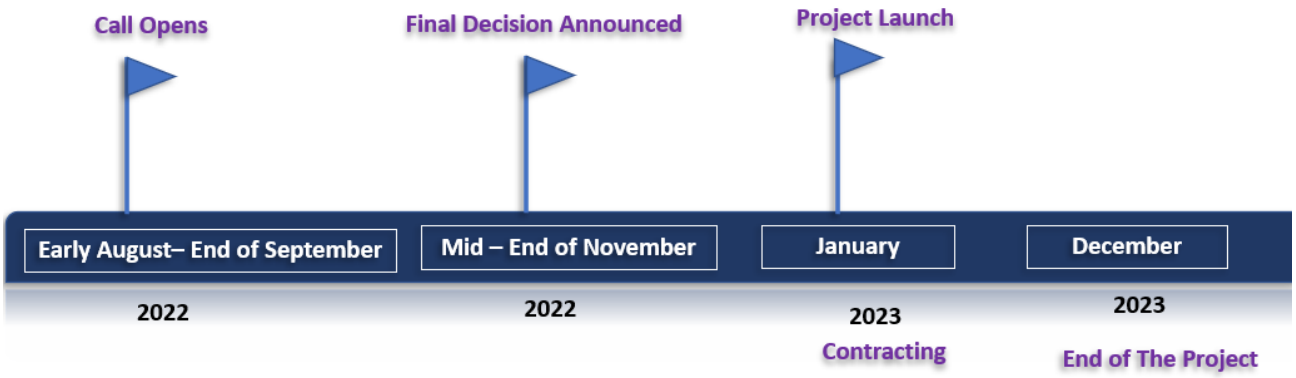
- Incurred in connection with the implementation of the project.
- Incurred during the project implementation period (from the date when the last party signed the sub-granting agreement till 31.12.2023).
- All EIT Health RIS-financed project activities must be completed by the end of December 2023.
- Cost that is identifiable and verifiable must be recorded in the beneficiary's general ledger and supported by documentation.
- Cost that complies with applicable national laws.
- Cost that is reasonable, justified, and complies with sound financial management principles (economy and efficiency).

Eligible cost categories

- Direct personnel costs
    - costs for employees (salary including all social contributions, taxes, etc.)
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
    - costs for SME owners without salary
    - costs for beneficiaries that are natural persons without salary
    - personnel costs for providing trans-national access to research infrastructure
- Direct costs of subcontracting
- Other direct costs
    - travel costs and related subsistence allowances
    - equipment costs
    - costs of other goods and services

7. Evaluation and selection process

Timeline of EIT Health RIS Innovation Call **2023**



All eligible proposals will be evaluated. The call has a single-stage submission and single-step evaluation procedure. Independent experts will conduct the evaluation. These experts may work remotely and, if necessary, meet as an evaluation panel to apply the evaluation criteria.

Remote expert evaluation

Three independent external evaluators will evaluate each eligible proposal based on the criteria indicated below. The evaluators are contracted by EIT Health InnoStars e.V. and receive training on the EIT Health strategy, rules, and procedures. If necessary, they will be instructed to check for conflict of interest and inform the EIT Health headquarters before evaluating the proposals' proceeds.

Each evaluator will award a maximum of 100 points during the remote evaluation. The final remote evaluation score will be the average of all remote evaluators' scores.

Project selection

Projects will be awarded according to the following criteria:

- Project excellence, Novelty of innovation, and Impact (40%)
- Solution readiness, Feasibility, and Project plan (20%)
- Implementation (Commercialization; Adoption) strategy (20%)
- Strength and commitment of team (20%)

Their specific evaluation criteria and relative value are annexed to this call (Annex 1).

Suppose there is Intellectual Property Rights (IPR) involved. In that case, the project should demonstrate that the team has secured the support and approval of the institution that controls the IPR (company, university, hospital, etc.) to participate in the project.

8. Submission

Final proposal submission: all full proposals must be submitted no later than **12 October 2022, 17:00 CET (Budapest time)** on the **Optimy Platform**

EIT Health: Application Interface - EIT Health e.V. (optimytool.com)

Any submission done by any other means and/or after the deadline will not be considered eligible.

We encourage you to complete your application sufficiently before the deadline to avoid late submissions. Problems due to last-minute submissions will be at your risk.

9. Confidentiality and conflict of interest

All proposals submitted will be accessible only to the EIT Health InnoStars team and HQ staff for the processing of the application. Proposals are shared with the assigned external evaluators, bound to confidentiality by contract. Furthermore, EIT Health InnoStars may give access to the submitted data to sub-contractors assigned to maintaining the internal system. These third parties are also bound by confidentiality provisions.

10. Grounds for Appeal and Appeal Procedure

Applicants may appeal against the selection process regarding their proposal(s).

The grounds for appeal are:

- Process errors.
- Technical problems beyond applicants' control (e.g., the technical failure of the electronic submission system).
- Obvious human/mechanical errors made by EIT Health staff.

What is NOT ground for appeal:

Scores are awarded in the course of the evaluation process based on various evaluation criteria. Minding that the technical part is only one aspect of a good project, the EIT team must assess the business prospects and the innovation potential as well.

Appeal process:

- Applicants should write their appeals to the managing director of EIT Health InnoStars as soon as they identify an error, but no later than ten calendar days after the error occurred.
- EIT Health InnoStars staff assesses the claim and delivers a first response.
- If there are grounds for appeal, the staff will attempt to remedy the consequences (e.g., if a technical error of EIT Health InnoStars prevented the submission of a proposal).
- The Supervisory Board is notified about the matter if:
  - the applicant does not accept that EIT Health InnoStars rejects the appeal, or
  - there are grounds for appeal, but the problem cannot be remedied anymore without disrupting the process.

11. Where to get help?

Please ensure you have read all the related documents, **including the FAQ**, and watch the webinar (see section 2) before sending your question(s).

For questions related to the call's content, kindly send your inquiries to innostars.ris@eithealth.eu.

To get the **Support Letter**, We kindly ask you to approach the contact person's email address (pages 9-11).

Annexe 1: Specific evaluation criteria and relative value of these criteria

I. Project Excellence, Novelty of Innovation, and Impact (40%):

- Relevance and fit with EIT Health objectives and focus areas
- Soundness of the concept/idea and credibility of the proposed methodology
- Extent that the proposed work is beyond state of the art and demonstrates innovation potential (e.g., ground-breaking objectives, novel concepts and approaches, new products, services, or business and organizational models)
- Impact (benefits of your solution for society, specific healthcare field, healthcare system, etc.)

II. Solution Readiness and Feasibility (20%)

- Completeness of prior work demonstrating that the proposed solution (product/service/process) has reached the desired maturity level and can be appropriately configured for the relevant domain (including solved IPR issues).
- Completeness of known hurdles (i.e., obvious barriers along the project's path) and potential risks to successful implementation,
- Quality and effectiveness of risk mitigation plans
- Market fit of the innovative solution (i.e., needs-driven innovation, foreseen clients/buyers, etc.)

III. Quality and efficiency of the implementation (20%)

- Quality and effectiveness of the Work Plan, including the extent to which the planned tasks align with the project's objectives, deliverables, and time frame.
- Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role
- Soundness of the foreseen pathway (regulatory, reimbursement, etc.) to reach patient care in the long run.
- Soundness of defined Key Performance Indicators (KPIs)

IV. Strength and Commitment of Team (20%)

- Plan to leverage excellence of involved partners' institutions. Partners having worked together before in similar settings will be considered advantageous.
- Synergies and complementarity of the team and extent to which the partnership as a whole brings together the necessary expertise
- Appropriateness of the management structures and procedures
- Sufficiency of the team coupled with the proposed resources for the planned development and/or implementation.

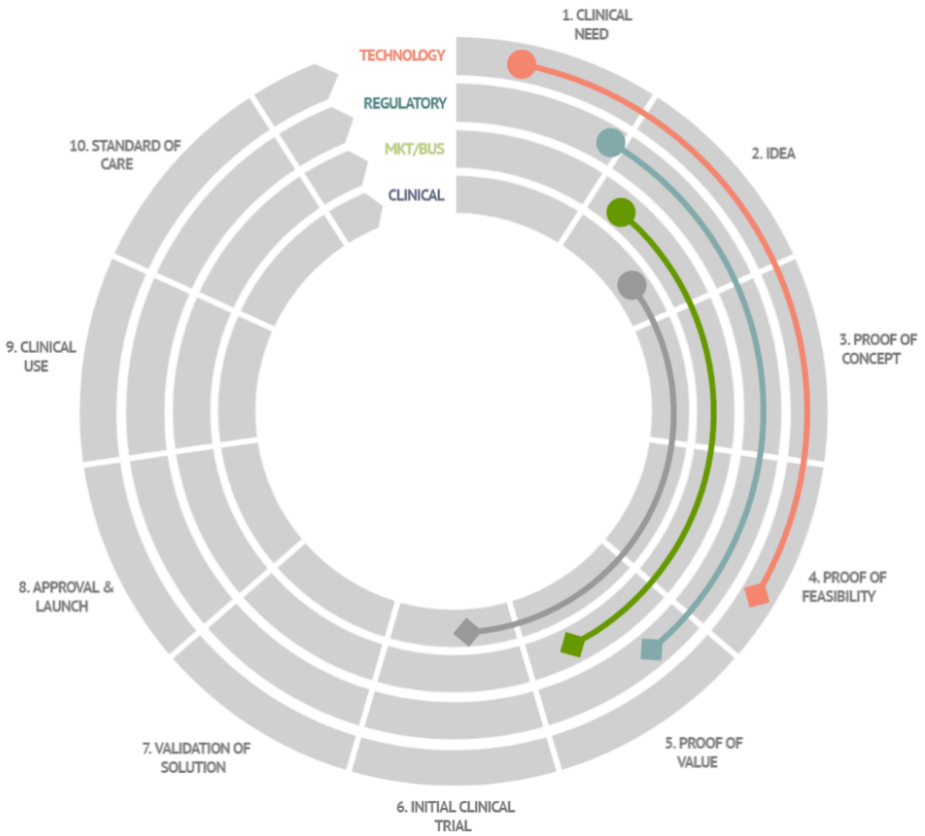
Annexe 2: CIMIT Maturity Innovation Template

The Innovation Maturity Level (IML), defined by CIMIT, will be applied as a matrix system to measure the maturity of four domains: Technology, Regulatory, Marketing/Business, and Clinical.

Projects must start at a minimum of IML 3 (Proof of Concept). Projects' end point will depend on the sector (BioPharma, MedTech, Digital Health).

In the proposal process, the use of the CIMIT Maturity Innovation template will allow understanding of:

- Where projects start (to ensure they are at the right maturity level and thus have a reasonable chance of "success").
- Where they will be at the end of EIT Health intervention (with the support of funds, value-added services, etc.).



IML definition

Milestone Name	Overall Description	Clinical	Market/Business	Regulatory/ Approvals	Technology
1) Need	Insights into unmet clinical needs and available solutions	☐ Unmet needs defined ☐ Disease state characterized	☐ Needs screening & selection ☐ Existing solutions characterized	NA	NA
2) Idea	Potential solutions to unmet need developed and evaluated	☐ Clinical workflow description ☐ Updated need description ☐ Feedback from >5 clinicians	☐ Competitive landscape ☐ Envisioned Value Proposition	☐ Medical device determination ☐ Comparables/ Predicates	☐ Paper Prototype ☐ Hypothesis & experimental design ☐ Idea screening & selection
3) Proof of Concept (PoC)	Key component concepts validated in models and value proposition articulated	☐ Feedback from clinicians in >5 settings ☐ Updated need description and workflow	☐ Competing solutions characterization ☐ Preliminary Value Proposition ☐ Path to Payment plan ☐ Stakeholder Map	☐ Prelim. Sol'n classification ☐ Preliminary indications for/ intended use ☐ Prelim. regl'y pathway	☐ PoC prototypes ☐ Demonstration results ☐ Institutional IP disclosure
4) Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	☐ Feedback from clinicians in >20 settings ☐ Updated need & workflow descriptions	☐ Feedback from >5 economic buyers ☐ Impact Plan ☐ Advisory Board	☐ Draft Essential Req's Table ☐ Draft IFU ☐ IRB Submission(s)	☐ "Works Like" & "Looks Like" prototypes ☐ FTO review ☐ Provisional IP filing ☐ Killer Experiment
5) Proof of Value (PoV)	The potential of the solution to work and create value for all stakeholders is demonstrated (Initial commercial investment)	☐ Feedback from >100 clinicians and KOLs ☐ Animal/First-in-Man experiments ☐ Peer reviewed publication(s) ☐ Scientific Advisory Board	☐ Investor ready business plan ☐ Feedback from >20 economic buyers ☐ Key management team identified ☐ Initial seed investment	☐ Data requirements ☐ IRB Approval(s)	☐ "Works Like/Looks Like" prototypes ☐ BOM, manufacturing plan, and costing ☐ Full IP application ☐ Killer technical experiment
6) Initial Clinical Trials (ICT)	Regulated production of prototypes and collection of clinical and economic data	☐ Conduct Phase 0 and/or 1 clinical trial(s) ☐ Peer reviewed publication(s)	☐ Economic data ☐ Feedback from >50 economic buyers ☐ 1st Institutional Investment	☐ Data requirements confirmation ☐ Pre-submission	☐ Manufacture GMP-compliant pilot lots.
7) Validation of Solution (VoS)	The solution is shown to be effective and its value to all stakeholders is validated	☐ Clinical efficacy trials ☐ Peer reviewed publication(s)	☐ Purchasing intent from >10 buyers ☐ 2nd round of institutional investment	☐ Complete submission package ☐ Regulatory submission	☐ GMP Process Planning
8) Approval & Launch (A&L)	Institutional and regulatory approval received, and sales launched	☐ Training materials & support established ☐ Peer reviewed publication(s)	☐ Initial sales	☐ Registration and Listing ☐ CMS Coverage & CPT Code	☐ Finalized GMP process
9) Clinical Use (Use)	The solution is used successfully in day-day clinical practice	☐ Included in local practice guidelines ☐ Peer reviewed publication(s)	☐ Profitable sales	☐ Monitoring and Inspections	☐ Patents issued ☐ Improvement plan
10) Standard of Care (SoC)	The solution is recognized as the Standard of Care.	☐ Recommended practice by medical specialty	☐ Dominant market share	NA	NA