EIT Health

RIS Innovation Call 2021

General Disclaimer

The present General Disclaimer shall be applied to all documents related to the EIT Health RIS Innovation Call 2021 projects

With the early publication of the RIS Innovation Call 2021 the aim of EIT Health InnoStars is to ensure that the continuity of the RIS Innovation Calls' publication is not interrupted.

Please note that the launch of the new European Union Framework Programme for Research and Innovation, Horizon Europe is expected in January 2021. **New provisions of Horizon Europe Model Grant Agreement will be applied for the execution of the projects, including any documents related to the announcement, implementation and completion of the projects. These changes shall also be applied to the projects already selected.** Consequently, EIT Health InnoStars reserves the right to introduce changes or additional conditions subject to the new provisions of the Horizon Europe and Horizon Europe Model Grant Agreement. Should your project be selected, the proposed budget or accounting requirements might be adjusted according to the provisions of Horizon Europe Model Grant Agreement before the signature of the subgranting or other type of project agreements, if necessary.

EIT Health InnoStars will announce the changes as soon as possible and, at the latest, before the signature of the agreements.

Due to the changes, the present RIS Innovation Call 2021 may also be revoked or invalidated by EIT Health InnoStars, if necessary.

Applicant shall acknowledge and accept that EIT Health InnoStars shall not be responsible to the applicant for any changes, modifications or additions to be applied in accordance with the new provisions of Horizon Europe and Horizon Europe Model Grant Agreement. In particular, if **the changes or the measures related thereto would cause additional costs to the applicant, the applicant may not enforce them and may not bring any claim or action on any basis against EIT Health InnoStars.**

Contents

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 proposed Strategic Innovation Agenda of the EIT 2021-2027[1].

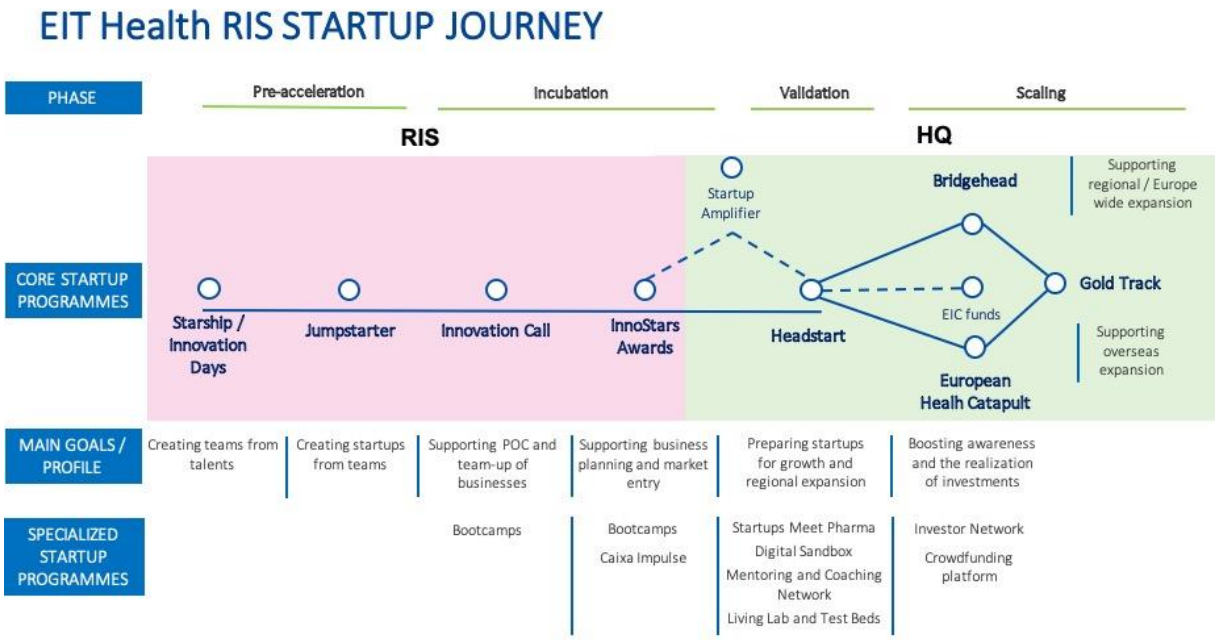
In line with the SIA, the EIT RIS is designed to close the gap between regions that are leaders in innovation and those regions which are progressing, as well as to widen participation in KIC[2] activities. The purpose of the EIT Health RIS programme is to promote healthcare innovation in countries with modest and moderate innovation capacity through the development and introduction of new healthcare products and services. Additionally, its aim is to match healthcare innovators from the EIT Health network with the talent pool and innovative organisations from 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.

[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) 2021-2027: Boosting the Innovation Talent and Capacity of Europe, COM(2019) 330 final.

[2] Knowledge and Innovation Communities



POC: Proof of Concept

EIT Health RIS Innovation Call 2021 aims at funding the proof of concept phase of high-quality, strong, balanced projects, targeting EIT Health's six 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 are to apply on this innovation call, participating with original innovation projects.

We ultimately aim at:

1- Development of the local innovation ecosystem in RIS regions.
2- Facilitate and foster cooperation among local KTI actors.
3- Bridge the funding gap of EIT Health 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 RIS regions with appropriate tools/technics/skills to be matched with EIT Health partners and apply for EIT Health Amplifier programme and/or to get funded from other EU programmes.
6- Provide EIT Health RIS regions with internationalization tools.

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

1.2 Focus Areas

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

The six 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, and they offer guidance for anyone preparing a proposal, as all proposals should address one (or more) Focus Area(s).

The six EIT Health Focus areas are:

1. Reforming Care Pathways

From diagnosis to treatment, care pathways are essential, yet current strategies focus heavily on the treatment phase. We are extending care pathways to provide end-to-end care before the onset of disease through to end-of-life support. And, we are optimising long-term care to enable people with chronic conditions to live as well as possible.

2. Healthcare Transformation

We're uniquely placed to accelerate the modernisation of healthcare systems in Europe. We bring together innovators and pool their talent to overcome fragmentation across healthcare delivery and create a sustainable healthcare system that can support an ageing society.

3. Harnessing Real-world Data

Healthcare data provides rich insight into diseases and, when used efficiently, it will open up 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.

4. Bringing Care Home

We are tackling the health challenges of an ageing population by prioritising innovative solutions that support healthcare delivery in the home and away from the hospital, improving health outcomes. Significantly enhancing the integration of health and social care will be vital in ensuring European citizens receive optimal treatment while releasing pressure on hospital services.

5. Health in the Workplace

In Europe, work-related stress affects one in four employees, leading to significant levels of absence – this is just one of the many work related conditions we need to address. We want to improve workplace health at every level through better education, improved personal awareness and helping to make healthy choices easier.

6. ***Fostering Healthier Lives***

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, preventing early ageing and reducing disease and disability.

2. Preparation – Call Introduction

A webinar on this EIT Health RIS Innovation Call 2021 will be held on **26 October 2020 at 10am** and will address the following subjects:

- Introduction of EIT Health and EIT Health RIS Programme
- Introduction of the EIT Health RIS Innovation Call 2021
- Introduction of the Application form in details
- Tips on how to submit a successful proposal

This webinar is aimed at EIT Health RIS regions' local actors and hubs. Please join us on the following link:
https://us02web.zoom.us/j/82667997061?pwd=ZDcvQW4xdXZ0Sk9KU0xQVDk4MmxuUT09

3. Eligibility criteria

A proposal will only be considered eligible if:

(a) Submitted in English language.

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

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

(d) It is targeting the completion of „Proof of Concept" phase as defined by CIMIT (see Annex2). Projects selected will have completed IML 2 (Idea) AND has started IML 3 (Proof of Concept) at least in 2 of the 4 domains. Funded projects' end-point will depend on the sector (BioTech, MedTech, Digital Health), and complexity of the project.

(e) Participation in trainings (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 grant for the same project/service/product in 2017, 2018, 2019 or 2020 from RIS Innovation Call, InnoStars Awards, European Health Catapult, EIT Health Headstart, Startups Meet Pharma and Bridgehead funding are not eligible to apply for RIS Innovation Call 2021.

(g) Applicants who receive funding from RIS Innovation Call 2021 are excluded applying with the same project/service/product for Innostars Awards, European Health Catapult, EIT Health Headstart, Startups Meet Pharma and Bridgehead funding in 2021.

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

Eligibility conditions for participation

At least two legal entities' collaboration is expected, where both business AND academic or research or healthcare institutions as partners are represented.

<table>
<tr><td colspan="3">At least 2 legal entities' collaboration is expected.</td></tr>
<tr><td rowspan="5">Business</td><td rowspan="5">AND</td><td>Academic Institution</td></tr>
<tr><td>OR</td></tr>
<tr><td>Research Institute</td></tr>
<tr><td>OR</td></tr>
<tr><td>Health care Institution</td></tr>
</table>

Natural persons are not eligible.

A **business organization** is an entity engaged in commercial or industrial activities by providing goods or services, to meet needs of the customers (SMEs, Start-ups).

Academic institution is an educational institution dedicated to education and grants academic degree(s) on its own.

Research institute is an institution dedicated to doing research and experimentation for

innovation in scientific and social fields.

Healthcare institution means 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, elderly care.

Each partner must be established in the same RIS country. Eligible RIS countries are: Croatia, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, Slovenia.

The leader legal entity of the partnership must have an established and registered representation/branch in the NUTS2 region where one of EIT Health Hubs is located in the corresponding RIS country. The local EIT Health Hub has to be a partner in the partnership besides at least two (other) legal entities.

	Eligible NUTS2 regions	**EIT Health Hubs**
1	Grad Zagreb Region (City of Zagreb) and Panonska Hrvatska Region (Panonic Croatia) and Sjeverna Hrvatka Region (North Croatia), Croatia[4]	University of Zagreb http://cirtt.unizg.hr/en/about-us/projekti/eit-health/
2	North East Region, Czech Republic	DEX Innovation Centre http://dex-ic.com/
3	Estonia	Tartu Biotechnoloogia Park http://biopark.ee/
4	Attica, Greece	National Documentation Centre http://www.ekt.gr/en
5	South Transdanubia Region, Hungary	Institute of Transdisciplinary Discoveries http://itdweb.hu/hu/kezdolap/
6	Sicily, Italy	Consortium ARCA http://www.consorzioarca.it/index.php/en/

[4] The NUTS 2021 classification (that will be valid from 1 January 2021) of Croatia discontinues Kontinentalna Hrvatska Region (Continental Croatia Region) and creates three new regions: Grad Zagreb, Panonska Hrvatska and Sjeverna Hrvatka regions. In 2021, as temporary measure, all three new regions of the previous Continental Croatia Region (NUTS 2016 Classification) will be considered as eligible NUTS2 regions of Croatia. Please mark Continental Croatia Region on the Application Form.

7	Latvia	Rīga Stradiņš University https://www.rsu.lv/starptautiska-sadarbiba/eit-health-ris-centrs
8	North East Region, Lithuania	Kaunas University of Technology https://en.ktu.edu/ or Lithuanian University of Health Sciences http://www.lsmuni.lt/en/
9	Pomeranian Region, Poland	Medical University of Gdańsk https://mug.edu.pl
10	Alentejo, Portugal	University of Évora https://www.uevora.pt/
11	North Portugal Region, Portugal	University of Porto https://upin.up.pt/en/content/projects
12	North West Region, Romania	Associatia INIT & Freshblood HealthTech freshblood.ro
13	Eastern Slovakia Region, Slovakia	T-Systems https://myt-systems.sk/en/home/
14	Western Slovenia Region, Slovenia	Ljubljana University Incubator https://lui.si/

4. Programme elements and Project funding

EIT Health RIS Innovation Call 2021 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 per partnership). The requested funding per partner may not exceed EUR 25.000.
- 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 they can 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

Micro enterprise	< 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 (2021).
- 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 can be part of partnerships but cannot receive funding from the EIT Health RIS Innovation Call.

B. Mandatory Training and Mentoring

- Participants have to participate in online trainings (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 choosen 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.

The final number of projects funded remains conditional on the approved budget of EIT Health RIS 2021.

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 visible result of the project development and set up at least 2 promising negotiations per project with EIT Health partners either in Matchmaking events or in 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 need to ensure that the chosen KPIs, deliverables and outputs fit the objectives of the listed activities.

6. Eligible costs

Disclaimer:

Please note that the Horizon Europe Model Grant Agreement is currently under preparation due to the expected launch of the new European Union Framework Programme for Research and Innovation, Horizon Europe in January 2021. **Applicant shall acknowledge and accept the provisions of the General Disclaimer with this regard written in the EIT Health RIS Innovation Call 2021.**

Therefore, the currently applied funding principals from the Annotated Model Grant Agreement of H2020 can be taken as an example only, because the new provisions of Horizon Europe Model Grant Agreement will be applied for the execution of the projects. Should your project be selected, the proposed budget might be adjusted according to the provisions of Horizon Europe Model Grant Agreement before the signature of the subgranting agreement, if necessary.

Only the cost of those activities can be reimbursed that contributes to the development of the project.
The breakdown of the budget needs to be presented by project partners not by 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 project's date of entry into force till 31.12.2021).
- All EIT Health RIS-financed project activities must be completed by the end of December 2021.
- Identifiable and verifiable, so it must be recorded in the beneficiary's accounts and supported by documentation.
- Comply with applicable national laws
- Reasonable, justified and comply with the principles of sound financial management (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 **2021**

All eligible proposals will be evaluated. The Call has a single-stage submission and single-step evaluation procedure. The evaluation will be conducted by independent experts. These experts may work remotely and may, if necessary, meet as an evaluation panel on the application of the evaluation criteria.

Remote expert evaluation

Each eligible proposal will be evaluated by three independent **external evaluators** 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. They will be instructed to check for conflict of interest and to inform the EIT Health headquarters, if necessary, before the evaluation of the proposals' proceeds.

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

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%)

The specific evaluation criteria and relative value of them is annexed to this call (Annex 1).

If there is Intellectual Property Rights (IPR) involved, the project should demonstrate that the team has secured 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 **15 November 2020, 17:00 CET (Budapest time)** in the **Optimy platform:**

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

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

9. Confidentiality and conflict of interest

All proposals submitted will be accessible only to EIT Health InnoStars team and HQ staff for the processing of the application. Proposals are shared with the assigned external evaluators, who are bound to confidentiality by contract. Furthermore, EIT Health InnoStars may give access to the submitted data to sub-contractors that are assigned with 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 in relation to their own proposal(s).

The grounds for appeal are:

- Process errors.
- Technical problems beyond the control of applicants (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 awarded in the course of the evaluation process.

Appeal process:

- Applicants should send their appeals in writing to the managing director of EIT Health InnoStars as soon as they identify an error, but no later than 10 calendar days after the error occurred.
- EIT Health InnoStars staff assess 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 any more without disrupting the process.

11. Where to get help?

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

For questions related to the content of the call, send your enquiries:
InnoStars.ris@eithealth.eu

Annex 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 the 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 health-care field and health-care 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 extent to which the planned tasks are in line 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 on 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 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.

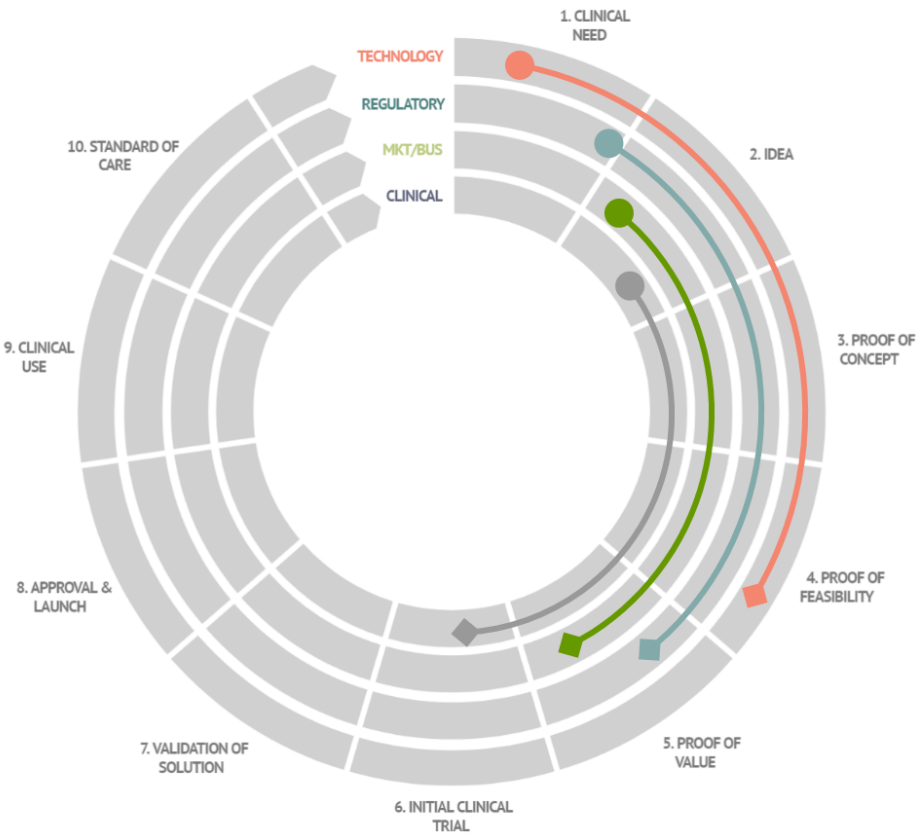
Annex 2: CIMIT Maturity Innovation Template

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 will need to 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 Determination	☐ 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