

*EIT Health InnoStars  
RIS Innovation Call 2020*



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## 1. Background and overview

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. In line with the SIA, the EIT RIS is designed to share good practices and experience emerging from the EIT Community’s activities, as well as to widen participation in KIC activities. The EIT RIS focuses on countries with limited or no participation in the EIT Community’s activities, where innovation capacity is moderate or modest and which otherwise would not be able to benefit from the experience gained by the KICs.

The EIT RIS guidance Note 2018-2020 has designated two action lines of implementation. Under the Action Line I “Engaging local players in ongoing KIC activities” the Guidance Note sets out conditions and gives examples of the innovation activities:

*Innovation and Research: among other things, KICs may involve local start-ups in technology and know-how transfer, engage students benefiting from the EIT RIS (e.g. by specific scholarships) in innovation projects and run pilots and tests of the outcomes of KIC innovation projects, and involve researchers from the EIT RIS countries in KIC innovation projects.*

### 1.1 EIT Health RIS Innovation Projects

EIT Health RIS 2020 innovation call aims at funding high-quality, strong, balanced projects, targeting EIT Health’s six Focus Areas to be developed by local actors including both academic and non-academic partners in collaboration with EIT RIS hubs. The ultimate goal of this activity is to support projects from the RIS regions and provide funding for the preparation phase of their projects to the maturity level that has the potential to join EIT Health partners applying for BP2022 innovation calls.

Local KTI<sup>1</sup> actors (academic and non-academic) in EIT Health RIS regions 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- Provide EIT RIS regions with appropriate tools/technics/skills to participate in EIT Health Business Plan 2022 in consortium with EIT Health partners.

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<sup>1</sup> Knowledge Triangle Integration actors are leading entities from higher education, research and business areas.



4- Provide EIT Health RIS regions with internationalization tools.



## 1.2 Focus Areas

Focus Areas fall within the scope of the themes defined in the EIT Health Strategic Agenda. A Focus Area “zooms in” on a particular aspect, covering related challenges as well as desired impact. 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 Areas. The transition to Focus Areas aligns with our commitment to maintain bottom-up avenues, but acknowledges that, to have true impact, our projects need to be clustered.

The identified and selected Focus Areas are the result of comprehensive analysis of the portfolio for 2018 and 2017, alongside an audit of the European Commission stated priorities and a wider audit of healthcare innovation trends. They also build on the previously expressed interests of our partners.

**The six EIT Health Focus areas are:**

***BRINGING CARE HOME:***

From institutional delivery to health delivered at home – EIT Health will deliver optimal home-based healthcare to older citizens, and consequent financial benefits to society, by designing and demonstrating innovation in home care services and systems.

***HARNESSING THE POWER OF REAL WORLD DATA (RWD):***

From conceptual vision to tangible value – EIT Health will launch RWD initiatives that are robust, inform valid healthcare decisions and demonstrate potential to be scaled up, thereby establishing a framework for EU leadership in access and analysis of RWD.

***CREATING THE ENABLING ENVIRONMENT FOR HEALTHCARE TRANSFORMATION:***

From the current challenge to a sustainable future – EIT Health will deliver an organizational evolution in healthcare management, with value-based benefits for citizens and consequent financial benefits to society, by designing and demonstrating innovation in management models and aligned training.

***TOWARDS HEALTH CONTINUUM CARE PATHWAYS:***

From treatment centric limitations to the health continuum breadth – EIT Health will lead the reform of care pathways, undertaking the design and evidence-based implementation



of innovative care and health delivery solutions.

***EMPLOYER LEADERSHIP IN IMPROVING HEALTH OUTCOMES IN THE WORKPLACE:***

From workplace to health place – EIT Health will deliver improved healthcare to employees, and consequent financial benefits to employers, by going beyond the traditional expectation of employer responsibility for health in the workplace.

***FOSTERING HEALTHY LIVES BY INTRODUCING BEHAVIOURAL CHANGE:***

From dealing with disease and disability to healthy lives – EIT Health will supply the tools and incentives to help citizens modify their way of life to prevent early onset of ageing, disease and disability and to profit from more years in health and wellbeing. EIT Health will focus on providing opportunities, especially to children, and other vulnerable and marginalized groups in society.

## **2. Preparation – Call Introduction**

A webinar on this RIS Innovation Call 2020 will be held on 21 January 2020 at 10am and will address the following subjects:

- Introduction of EIT Health and EIT Health RIS Program
- Introduction of the RIS Innovation Call 2020
- 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://zoom.us/j/351791035?pwd=Z2tZRzUyckRtS3FvQWUrUTZQUUR3dz09>

## **3. Eligibility criteria for all EIT Health RIS regions**

A proposal will only be considered eligible if:

- (a) its content corresponds, wholly or in part, to one of the six EIT Health Focus areas (see point 1.2)
- (b) it complies with the eligibility conditions for participation set in the table below

<b>Eligibility conditions for participation</b>
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At least two legal entities' collaboration is expected, where both academic and non-
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academic partners are represented. Natural persons are not eligible.

Academic institution is an educational institution dedicated to education and research, which grants academic degrees.

Non-academic institutions include local hospitals, SMEs, healthcare industry, start-ups, research institutes, local/regional government and other NGOs.

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 NUT2 region where one of EIT Health Hubs is located in the corresponding RIS country. The local EIT Health RIS Hub has to be a partner in the partnership besides at least one academic and one non-academic partners.

	<b>Eligible NUT2 regions:</b>	<b>EIT Health RIS Hubs</b>
1	Continental Croatia Region, Croatia	University of Zagreb <a href="http://cirtt.unizg.hr/en/about-us/projekti/eit-health/">http://cirtt.unizg.hr/en/about-us/projekti/eit-health/</a>
2	North East Region, Czech Republic	DEX Innovation Centre <a href="http://dex-ic.com/">http://dex-ic.com/</a>
3	Estonia	Tartu Biotehnoloogia Park <a href="http://biopark.ee/">http://biopark.ee/</a>
4	Attica, Greece	National Documentation Centre <a href="http://www.ekt.gr/en">http://www.ekt.gr/en</a>
5	South Transdanubia Region, Hungary	Institute of Transdisciplinary Discoveries <a href="http://itdweb.hu/hu/kezdolap/">http://itdweb.hu/hu/kezdolap/</a>
6	Sicily, Italy	Consortium ARCA <a href="http://www.consortioarca.it/index.php/en/">http://www.consortioarca.it/index.php/en/</a>
7	Latvia	Rīga Stradiņš University <a href="https://www.rsu.lv/starptautiska-sadarbiba/eit-health-ris-centrs">https://www.rsu.lv/starptautiska-sadarbiba/eit-health-ris-centrs</a>
8	North East Region, Lithuania	Kaunas University of Technology <a href="https://en.ktu.edu/">https://en.ktu.edu/</a> or Lithuanian University of Health Sciences <a href="http://www.lsmuni.lt/en/">http://www.lsmuni.lt/en/</a>
9	Pomeranian Region, Poland	Medical University of Gdańsk <a href="https://mug.edu.pl">https://mug.edu.pl</a>
10	Alentejo, Portugal	University of Évora <a href="https://www.uevora.pt/">https://www.uevora.pt/</a>



11	North Portugal Region, Portugal	University of Porto <a href="https://upin.up.pt/en/content/projects">https://upin.up.pt/en/content/projects</a>
12	North West Region, Romania	Asociatia INIT & Freshblood HealthTech <a href="https://freshblood.ro">freshblood.ro</a>
13	Eastern Slovakia Region, Slovakia	T-Systems <a href="https://myt-systems.sk/en/home/">https://myt-systems.sk/en/home/</a>
14	Western Slovenia Region, Slovenia	Ljubljana University Incubator <a href="https://lui.si/">https://lui.si/</a>

## 4. How to apply

- Project proposals must be submitted in English language and only through the web based Optimy system: <https://eithealth.optimytool.com/en/>
- Each project must align with EIT Health Focus areas and should have the potential for internationalization with EIT Health Partners in BP 2022 call.
- Each EIT Health RIS Hub can participate with any number of innovation proposals.
- Although the local EIT Health RIS 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.
- Affiliated Entities can be part of the same or different partnerships, but the sum of all grants received cannot exceed EUR 50,000.
- Proposals which have received funding in the EIT Health InnoStars RIS Innovation Call 2019 are excluded from receiving funding for the same project.

## 5. Maturity level expectations

We are looking for proposals that demonstrate a clear innovation and present potential to apply alongside EIT Health partner consortium in BP2022.

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 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' finish point will depend on the sector (BioTech, MedTech, Digital Health), and complexity of the project.





## 6. Expected KPIs, deliverables, outputs:

- Beneficiaries are requested to complete at least 9 hours mentoring session. After the mentoring sessions timesheet and performance certificate must be signed to prove the completion of the tasks.
- Beneficiaries are requested to compile a project development plan with the support of mentors from EIT Health mentor pool summarizing the actions to be taken for the innovative solution to reach the market.
- 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.
- Providing EIT Health InnoStars 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 with the objectives of the listed activities.

## 7. Project funding

### Amount of the funding

EIT Health RIS innovation project partnerships will be funded to a maximum of EUR 75.000. The requested funding per partner may not exceed EUR 50.000. Large enterprises cannot receive funding but can be part of a partnership applying for funding and they can benefit from the networking opportunities. If the same beneficiary (including its affiliated entities) is included in more than one winning project's partnerships, the sum of all grants received by the beneficiary and its affiliates cannot exceed EUR 50,000.

There will be no need for co-funding from non-profit organizations and from micro and small enterprises, but medium enterprises will only be funded up to 70%.



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	35.000
Small enterprise	< 50	≤ € 10 m		≤ € 10 m	50.000
Micro enterprise	< 10	≤ € 2 m		≤ € 2 m	50.000
Non-profit organizations	N/A	N/A		N/A	50.000
Academic Institution	N/A	N/A		N/A	50.000

The funded project partnerships will have 50% pre-financing while the rest of the amount will be paid upon acceptance of the final report latest by February 10, 2021. The project partners will receive funding directly from EIT Health RIS finance team.

The selected proposals might get other support provided by InnoStars after the end of the implementation.

## Eligible activities

### Compulsory activities

- The partnership will receive a mentor from EIT Health InnoStars mentor pool, who will support the implementation of the project throughout the project lifecycle. At least 9 hours of mentoring is obligatory.
- A project development plan is to be compiled by the end of the project summarizing the actions necessary for the innovative solution to reach the market.
- The beneficiaries shall take part in matchmaking events and organize meetings where the possibilities of taking part in 2022 EIT Health Business Plan proposals can be negotiated.

### Optional activities

- Only the cost of those activities can be reimbursed that contributes to the development of the project to a maturity level that enables the beneficiaries to negotiate with EIT Health partners about the participation in EIT Health BP2022 Innovation calls.



### Eligible costs

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 (project's date of entry into force - 31.12.2020).
- All EIT Health RIS-financed project activities must be completed by the end of December 2020. 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

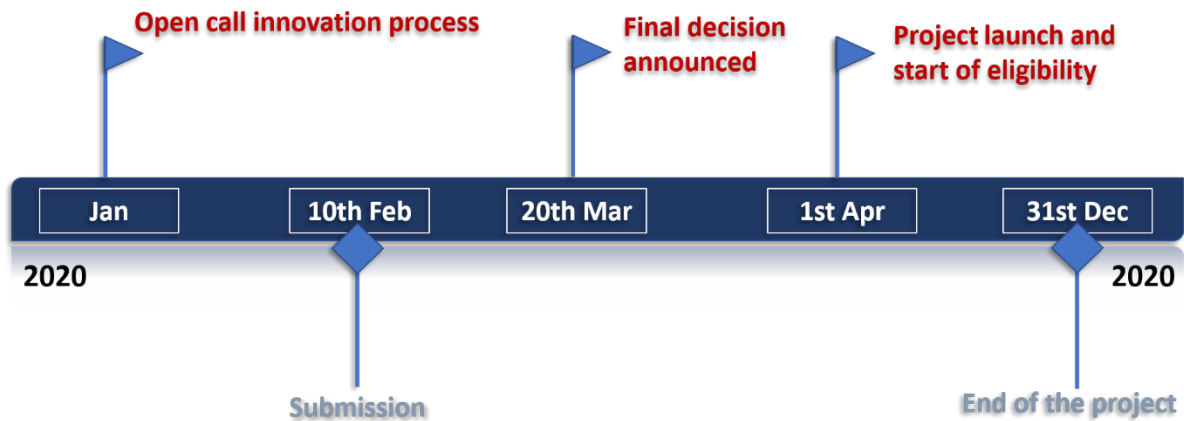
- Direct personnel costs
  - costs for employees (salary including all social contributions, taxes, etc)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that 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

The detailed rules regarding the eligible costs and cost categories can be found in the H2020 [Annotated Model Grant Agreement](#)

## 8. Evaluation and selection process

### Timeline for 2020 Innovation call





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 for selection of proposals for this Call.

#### 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 are instructed to check for conflict of interest and to inform the InnoStars 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 (Annex1)

If there is previous Intellectual Property Rights (IPR) involved, projects should demonstrate that the team has secured support and agreement from the institution that controls the



IPR (company, university, hospital, etc.) to participate in the initiative.

## 9. Submission

Final proposal submission: all full proposals must be submitted no later than **10 February 2020, 12:00 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.

## 10. Confidentiality and conflict of interest

All proposals submitted will be accessible only to RIS 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, 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

## 11. 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. the technical failure of the electronic submission system).
- Obvious human/mechanical errors made by EIT Health staff.

**What is NOT grounds 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 InnoStars as soon as they identify an error but no later than 10 days after the error occurred.



- EIT Health InnoStars staff assess the claim and deliver a first response.
- If there are grounds for appeal, the staff will attempt to remedy the consequences (e.g. if a technical error of EIT Health Innostars prevented the submission of a proposal, a late submission may still be accepted as eligible).
- The Supervisory Board is notified about the matter if:
  - the applicant does not accept that the Management Board rejects the appeal, or
  - there are grounds for appeal, but the problem cannot be remedied any more without disrupting the process.

## **12. Where to get help?**

For questions related to the content of the call, send your enquiries:

[InnoStars.ris@eithealth.eu](mailto:InnoStars.ris@eithealth.eu)

Please make sure, you have read all the related documents, including the FAQ.



## **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: Characteristics of a good EIT Health Innovation Project participating in Business Plan 2021 Calls for Proposals (for information)**

### **Proposal preparation**

- Key Opinion Leaders should be interviewed to gather additional information to the idea.
- The consortium should be able to answer: Why this solution? Why those partners? Why now? Uniqueness of the approach must be clear compared to direct/indirect competition and current gold standard

### **Type of project**

- Project shouldn't be research project. For instance, success cannot only be characterized by publications or education activities.
- For Market-facing innovation projects: they target both 1) better outcomes and 2) cheaper costs (per capita or global basis)
- For System and Organisational innovation projects: they should target sustainable system and Health Economics studies should already be in place

### **Consortium - Partners**

- The right partners should be dedicated to the right activities and expected outcomes
- If the project is intended for healthcare providers, then healthcare providers are expected to be part of the consortium
- The commitment from Partners and/or Users should be ensured. Letters of Intent are better than Letters of Support.

### **Project**

- The elevator pitch should be understandable at the first reading
- Clarity should be made around end results: What should be achieved by the end of the project? How would you know that you have achieved it?



- All necessary steps to de-risk the project both on the technical and business side should be included in the project
- Knowledge Triangle: How educational/training and business creation activities or any existing EIT Health activities related to those pillars are integrated within the project?

### **Workplan**

- The workplan should be clear, with adequate number of WPs. Interdependencies of WPs should be well identified
- The key WP must be identified
- The real risks of the project must be well identified
- The deliverables must be clear

### **Science / Technology**

- The technology should be ready

### **Clinical**

- Clinical validation is well defined

### **Business / Commercialization / Sustainability**

- The commercial opportunity in case of revenue generating project as well as the sustainable opportunity in case of cost saving project should be clearly identified
- Economic buyers as well as users should be clearly identified
- There should be a clear and comprehensive User Story
- After the EIT Health funding is over, only 3 years maximum to market entry or to implementation of a fully sustainable process
- All the potential risks linked to market reach or process implementation from a socio-economic point of view should be clearly identified. A mitigation plan should be provided.
- Key figures should be presented (TAM, sales strategy, societal costs etc.)

### **Funding**

- Co-funding from industry should be clearly identified
- Budget items should be clearly linked to the activities

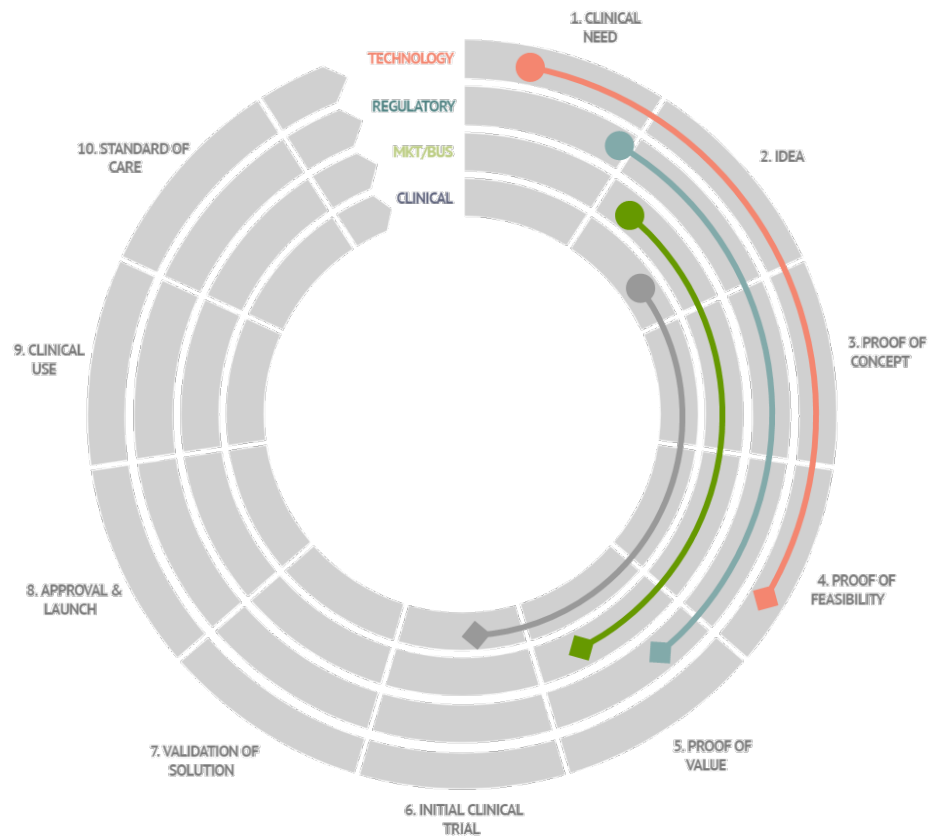


**Typical KPIs**

- EIT N03 – # of products (goods or services) or processes launched on the market
- EIT N04 - # of start-ups created as a result of innovation projects
- OUTKPI6 - # of products brought forward by your project that reach market readiness
- OUTKPI61 - # of jobs created in new business organisations as a direct result of your project



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



## Annex 4. Glossary of terms

### Deliverables

The deliverables are additional outputs produced at a given moment during the action. Core KIC documents (plans and reports that support KIC work) are part of the KIC planning and monitoring process and should not be listed as deliverables of KIC added-value activities.

**DELIVERABLE EXAMPLES:** Workshop proceedings, summaries, comparative studies, market analysis reports, handbook and training tools, workshops, conferences, etc.

### KPIs

Key Performance Indicators (KPIs) are quantitative metrics that measure progress towards reaching a goal or objective over time. KPIs are typically associated with target values. EIT Health will measure its impacts by means of a KIC scoreboard.

### Milestones

A milestone represents a point in time where significant decisions or events can shape the future progress of the project and show an important achievement.

### Outputs

The specific technology, product, service, method, design, concept, methodology, approach, etc., created by a KIC added-value activity. Outputs can also be intangible.

**OUTPUT EXAMPLES:** New products or processes, transformation of existing products, new qualifications, guidance material for new approaches and methodologies, TestBeds and experimental facilities, prototypes, patents.

