EIT Health InnoStars
RIS Innovation Call 2019

Contents

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 2019 innovation call aims at funding high-quality, strong, balanced projects, targeting our 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 throughout they develop their projects to the maturity level that meets the application conditions of the EIT Health BP2021 innovation calls and has the potential to join EIT Health partners applying for BP21 innovation calls.
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 2021 in consortium with EIT Health partners.
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 service 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 and Proposal submission - Training sessions

2.1 Hub Training in innovation activities

A series of training in innovation will be delivered between May 2 – 10 in three EIT Health RIS regions the schedule will be as follows:

- May 2 -3: Sicily; Porto; Evora; Athens
- May 6 – 7: Ljubljana; Zagreb; Pecs; Cluj Napoca; Kosice
- May 9-10: Prague; Liberec; Gdansk; Riga; Kaunas; Tartu

This is an intensive hands-on 2-days training program aimed at EIT Health RIS regions' local actors and hubs. The training will focus on patient-oriented research, Bio design and how to create value from innovative solutions. Attendees will have the chance to consult with experts and EIT Health RIS team about project ideas during these 2-days intensive training.

3. Eligibility criteria for all EIT Health RIS regions

Local KTI actors (academic and non-academic) in EIT Health RIS regions are to apply on this innovation call, participating with original innovation projects and as consortium leaders. EIT Health RIS region (Hub) has to be a partner in the consortium.

- Each project has to align with EIT Health strategic objectives and focus areas and

should have the potential for internationalization with EIT Health Partners in BP 2021 call.

- Each EIT Health RIS region can participate with any number of innovation proposals.
- Although EIT Health RIS region has to be an integral part of the consortium alongside the local KTI actors, they cannot benefit from the project budget due to budget restraints imposed by H2020 financing rules.

Note: We consider academic institutions as an educational institution dedicated to education and research, which grants academic degrees. Non-academic institutions include local hospitals, SMEs, healthcare industry, start-ups, local/regional government and other NGOs.

4. Maturity level expectations

We are looking for proposals that demonstrate a clear innovation and present potential to apply alongside EIT Health partner consortium in BP2021.
Projects selected will be at least Level 3 (Proof of concept) as defined by the CIMIT Maturity Innovation Cycle for Healthcare and Life Sciences (Annex 3), having good chance to be successful in EIT Health matchmaking events and Ideation events.

5. Expected KPIs, deliverables, outputs:

- Beneficiaries are requested to complete at least 9 hours mentoring session (at least 3 in the planning phase, 3 during the implementation, 3 during the assessment of the progress of the implementation) in order to develop their project to meet the goals set above. 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 to prepare the projects for matchmaking and teaming up with EIT Health Partners.
- The implementation of the plan is to be proved in the final report. The successful implementation of the action plan (implementation of the project development plan) must be justified by an expert opinion from the mentor.
- Providing EIT Health InnoStars with success stories with visible result of the project development and at least 2 promising negotiations per project with EIT Health partners either in Ideation and 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 consortiums in the negotiation phase and during Ideation and Matchmaking events.
- Revised project proposal based on the outcomes of the implementation of the project development plan and the recommendations of the mentors.

6. Project funding

Amount of the funding

EIT Health RIS region project consortiums will be funded to a maximum of 75.000 EUR. The requested funding per partner may not exceed 50.000 EUR.

There will be no need for co-funding for non-profit organizations and for micro and small enterprises, but medium and large enterprises will only be funded up to 70%. Medium and large enterprises: having more than 50 employees or having either an annual turnover or annual balance sheet that exceeds €10 million.

The winning consortiums will have 50% pre-financing and the rest of the amount will be paid upon acceptance of the final report latest by January 31, 2020. Consortium partners will receive funding directly from EIT Health RIS finance team.

Eligible activities

Compulsory activities

- The beneficiary shall choose a mentor from EIT Health InnoStars mentor pool, who support the implementation of the project throughout the project lifecycle. At least 9 hours of mentoring is obligatory (at least 3 hours in the inception phase to support the beneficiary to compile a project development plan to be implemented during the project implementation period, at least 3 hours during the implementation and at least 3 hours during the assessment of the progress).
- A project development plan is to be compiled, that serves as a basis of the implementation of the project in 2019.
- The beneficiaries shall take part in matchmaking events and organize meetings where the possibilities of taking part in 2021 EIT Health Business Plan proposals can be

negotiated.

Optional activities

- 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 BP21 Innovation calls.

Eligible costs

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 kick-off date-31.12.2019).
- 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)

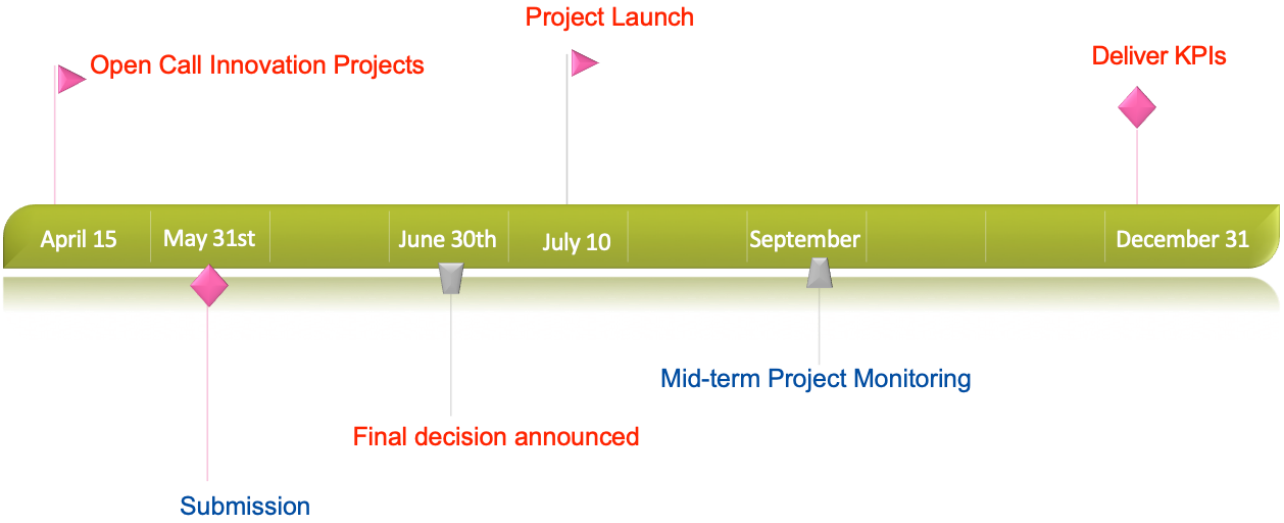
Eligible cost categories

- 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

7. Evaluation and selection process

Timeline for 2019 Innovation call



All eligible proposals will be evaluated. The evaluation process may involve two stages: 1) Remote expert evaluations, and 2) Conference calls whenever questions about the project remains.

STAGE 1: 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.

STAGE 2: Conference calls
Whenever deemed necessary by the Evaluation Board a conference call with experts from InnoStars management may be scheduled to clarify unclear issues regarding the proposals.

Final selection
Projects will be awarded according to the following criteria:

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

The specific evaluation criteria and relative value of them is annexed to this call (Annex1)

8. Submission

Final proposal submission: all full proposals must be submitted no later than **31 May 2019, 16:00 CET (Budapest time)** in the **Optimy platform**, any submission done by any other means and after the deadline will not be considered.

All EIT Health RIS-financed project activities must be completed by the end of December 2019.

9. Progress follow up and Project Monitoring

Progress follow up will be monitored in September 2019. Participation in the interim update **will be mandatory** and will follow the principles below:
Midterm review must be considered a Go/No-Go stage gate. A scorecard will guide the process, and InnoStars management will propose a concerted approach. Three possible outcomes will be then considered:

- Continue the project.
- Continue the project with some necessary amendments.
- Stop the project and the funding.

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.

Annex 1: Specific evaluation criteria, and relative value of these criteria

I. Project Excellence, Novelty of Innovation and Strategic Fit (20%):

- Projects should use innovative and unique approaches wherever possible. For example, applying existing knowledge in a new way or in a different context, or applying 'new' knowledge to solve challenges with a different approach
- Projects should state uniqueness of the proposal compared to the state of the art. In the case of clinical products/services they should be compared to the standard of care, the gold standard. Processes or management innovation should be compared with standard practices, current guidelines, etc.
- Added-value of the proposal should be demonstrated.
- Projects should address the relevance and fit with EIT Health objectives and indicate how they relate to the focus areas, as described in the Call.

II. Solution Readiness, Feasibility and Project Plan (20%)

- The prior work demonstrates that the proposed solution (product/service/process) has reached the desired maturity level and can be appropriately configured for the relevant domain.
- Project plans should be feasible in terms of the timeline, resources allocated and deliverables. Budget distribution between partners and between work packages should be relevant to the tasks to be carried out.
- Project organization should be logical with clear and well-defined work packages.

III. Strategy for Implementation (Commercialization and/or Adoption) (20%)

- Projects should describe a clear implementation strategy – to take the innovation to market or to adopt it – identifying the necessary resources and describing how these will be secured.
- Projects should present a competitive approach with a clearly defined innovation (product, service, process, organization, management, etc.). In addition, project teams should demonstrate a clear awareness of the competitive landscape.
- Known hurdles (i.e. obvious barriers along the project's path) and potential risks to successful implementation/market launch should be identified, and mitigation plans should be clearly defined.

IV. Impact (20%)

- Sound KPIs should be defined. Projects need to ensure that the chosen KPIs, deliverables and outputs fit with the activities' objectives.
- Projects should ensure knowledge transfer. Projects need to explain plans to scale and disseminate within the partnership and beyond, and how to share learnings.
- In the case of products, assuming the technology/science works perfectly, projects have to demonstrate a potential pathway (regulatory, reimbursement, etc.) to reach patient care within the desired timeframe.

V. Strength and Commitment of Team (20%)

- Projects should demonstrate how they will leverage excellence of involved partners' institutions. Partners having worked together before in similar settings will be considered an advantage.
- Projects should show experience of the activity leader and involved team members.
- Projects should demonstrate synergies and complementarity of the team.
- Projects should demonstrate that the team, coupled with the proposed resources is sufficient for its development and/or implementation.
- If there is previous Intellectual Property Rights (IPR) involved, projects should demonstrate that the team has secured support from the institution that controls the IPR (company, university, hospital, etc.) to participate in the initiative.

Annex 2: Characteristics of a good EIT Health Innovation Project

Proposal preparation

- Key opinion leaders should be interviewed to gather additional information for 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.
- Projects developing products and/or services that will generate revenues and thus should be able to reach the market in a rapid manner.

Type of project

- Projects shouldn't be research or education projects. For instance, success cannot only be characterized by publications or education activities.
- Revenue-generating projects should target both better outcomes and cost savings (per capita or global basis).
- Cost-saving projects should try to achieve sustainable systems, and Health Economics studies should already be in place.

Consortium - partners

- The right partners should be dedicated to the right activities and expected outcomes.

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.

Workplan

- The workplan should be clear, with an adequate number of Work Packages. Interdependencies of Work Packages should be well identified.
- The key Work Package 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.

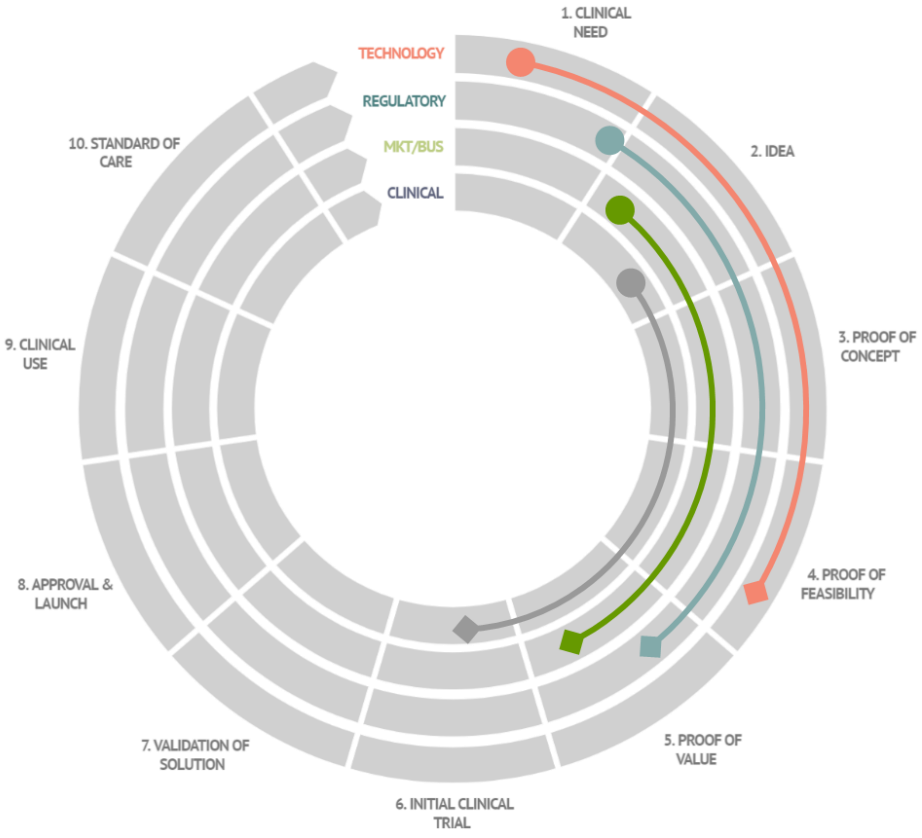
Business/Commercialization/Sustainability

- The commercial opportunity, in the case of a revenue generating project, or sustainable opportunity, in the case of a 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.

Funding

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

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	☐ 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

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.