



EIT Health Accelerator

Headstart Programme and FAQ

EIT Health hereby invites incorporated SMEs to submit Headstart applications

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Table of Contents

The Pitch: Purpose of Programme	2
Timeline	3
Application Support	4
Is it for me? Eligible applicants and projects	4
Eligibility Criteria	5
The Application	5
The Project or product	6
The Funding	6
Specific Requirements	6
Healthy Longevity Grand Challenge	7
EIT Health's Investment (Non-Dilutive) Terms and Conditions	7
Ecosystem-Integration Deliverable	8
Co-Funding funding requirement	8
Regional Funding Schemes	9
EIT Health Terms and Conditions	9
Expectations	9
Funding	9
Promotion and Branding	10
Sustainability vision	10
Selection process and criteria	10
Project Awards	11
Project Reporting	12
EIT Health Regions	12
Specific regional requirements and directions	13
Belgian/Netherlands CLC Applicants	13
German/Swiss CLC Applicants	13
Scandinavian CLC Applicants	14
Spanish CLC Applicants	14
French CLC Applicants	14
UK/Ireland CLC Applicants	14
Innostars regions Applicants	14
Support contacts	15
Frequently Asked Questions, FAQ	15
A. Are the applications treated under confidentiality?	15
B. How many projects will be approved in 2020?	15
C. What is the thematic scope of projects EIT Health supports?	16
D. What are the project categories?	17
E. What are typical project goals?	18
F. What are the target KPIs?	18
G. What are cost categories allowed in the project?	18
H. General cost eligibility criteria for final financial reporting	19
Annex: Understanding TRL	20

EIT Health opens the Headstart Programme 2020 for companies (Start-ups and SMEs) requiring funding for the further development and/or commercialisation of new technologies, products or services.

The Pitch: Purpose of Programme

- Application open: 16 December 2019
- Last possible submission: 16 March 2020. Some regions may offer second cut-off dates.

The EIT Health Headstart Programme provides start-ups support in accelerating their product launch timeline. The EIT Health Headstart Programme provides eligible companies up to €50,000 to support the development of these innovative products and services.

Selected companies will create a project plan with the support of the EIT Health Business Creation Managers (BCMs) to help start-ups harness the local and international network to accelerate their product launch.

In order to create the desired impact, we particularly encourage applicants with projects related to the [EIT Health Focus Areas](#).

The purpose of the EIT Health Headstart Programme is:

- To support the applicants in realising next steps towards market and shorten time-to-market for innovative products and services
- To verify the need/benefit of the product/service for users, customers, payers and partners.
- To increase the possibility of attracting further investment

In addition, the 2020 Headstart Programme (only the first cut-off, the March 16th Deadline) offers an added opportunity for ventures with a focus on physical, mental, and social well-being for people as they age. Through its Headstart Programme, EIT Health will join a global innovation competition founded by the United States National Academy of Medicine (NAM), the [Healthy Longevity Global Grand Challenge](#) to support the next breakthroughs in healthy

longevity. Successful applicants to Headstart will qualify for the first stage of this competition known as the Catalyst Awards.

The NAM's Healthy Longevity Global Grand Challenge seeks bold, new ideas and innovations from any discipline to improve the physical, mental, and social well-being for people as they age. The Challenge includes a three-tiered structure of awards and prizes, beginning with a first phase of Catalyst Awards (to explore new, innovative ideas) leading to Accelerator Awards (to advance a pilot or prototype with the potential for commercialization) and finally to a limited number of Grand Prizes (to reward the achievement of a bold and transformative innovation). Awarded Headstart projects focused on longevity will enter into this Healthy Longevity Global Grand Challenge receiving an additional Catalyst Award certificate and will be eligible to compete in later phases of the competition.

Timeline

- Application period: 16 December 2019 – 16 March 2020, through the [EIT Health Optimy platform](#)
- Some regions may have a second submission deadline depending on the CLC of reference.
- Selection announcement: May – July 2020.
 - U.S NAM Catalyst Award winners will be strongly encouraged to attend the 1st Awardee Innovator Summit in summer 2021 in Washington D.C. organised by NAM. Travel costs will be paid in accordance with institutional travel policies.
- Upon selection:
 - Project grant agreement signatures: Dependent on selection, expected May-September 2020
 - Grant attribution (total budget): Dependent on selection, expected June-October 2020
 - Midterm report: required before 20 December 2020
 - Final report: Required at the end of the project

Projects must start before 31 October 2020, please contact your Business Creation Manager for methods to manage this requirement.

Application Support

Applicants are strongly encouraged to seek advice and contact their regional EIT Health Business Creation Manager (BCM) and/or Business Creation Project Manager (BPM) for guidance before submitting an application. The regional BCMs and/or BPMs can be found in section [Support contacts](#). They may support the applicant in defining the appropriate actions to produce an application which fits the scope and goals of the EIT Health Headstart Funding Programme. All Headstart applications will require a confirmation letter to establish that the company has an existing relationship with the EIT Health network, please see the [Eligibility Criteria](#) for details.

Is it for me? Eligible applicants and projects

A company must be incorporated/registered before the deadline of the Headstart application. Any requests for exceptions must be approved by the regional BCM. [See Specific regional requirements and directions](#).

The EIT Health Headstart Programme is suitable for micro and small enterprises (according to the EU SME [definition](#)) spin-offs, and start-ups that have a well-developed prototype and preparing to launch a product. Please note, drug development projects are not eligible for this programme. Ideal candidates must demonstrate a strong need and ability to create and follow-through with a project plan with meaningful milestones to achieve the next steps in the product launch.

Except in extraordinary circumstances, applicants must submit applications to the region (CLC) that corresponds to the country that the company is registered. If you believe your situation merits individual consideration (for example imminent plans to transfer operations to another region) you must contact the corresponding BCMs in both related regions to explain your rationale **before** proceeding and submitting your application. Decisions will be taken on a case-by-case basis.

In the event that a company is considering applying to multiple programmes in 2020 such as Headstart, Digital Sandbox, European Health Catapult, or Bridgehead, EIT Health strongly suggests choosing only the most suitable for the applicant to apply. Indicatively, EIT Health considers a company more suitable to apply in the Headstart programme if the company's self-estimation for its valuation is less than €1M. If the company's self-estimation is higher

than €1M EHC or Bridgehead are more suitable. Please consult your regional BCM to discuss this point if you don't know which programme fits the best with your needs. Applicants are only able to participate in one of these programmes in 2020.

Companies selected and granted in previous years may not apply to Headstart Programme in 2020 unless the new application relates to a completely different product/solution/project than the one already funded in previous years. In this case, the applicants are strongly advised to contact their regional BCMs and discuss before submitting an application.

Eligibility Criteria

Proposals not meeting the eligibility criteria, as confirmed in the eligibility check, will be excluded.

The Application

- Must be in English.
- Submitted through EIT Health Optimy Registration platform. Incomplete submissions, late submissions, or submissions via any other routes (e.g. email) will not be accepted. All documents requested in the submission platform must be uploaded to the platform before final submission. Register your EIT Health account and apply [here](#).
- Additional information may be attached to the application. This may include graphs or video links (maximum three minutes' duration in English language or with English subtitles). Documents emailed rather than submitted to the platform may be accepted at will. Please be aware that the reviewers may not consider these attachments as a basis for their evaluation.
- An existing relationship between the start-up and EIT Health must be established before the application submission and must therefore be accompanied by a Letter of confirmation. This letter must be provided by an EIT Health partner or the BCM from the region the applicant is applying to. In case of Innostars region and RIS regions, the letter can also be provided by an official RIS Hub or by the local regional manager. The letter serves to confirm a relationship to the EIT Health network and does not constitute endorsement or serve as a certification of validity/eligibility. For applications to the German CLC please look at the section "Specific regional requirements and directions". Please consult your regional BCM to discuss this point if no previous

relationship exists through an EIT Health partner. All EIT Health partners by region can be found [here](#).

The Project or product

- Must be within the scope of the main challenges in EIT Health: Strengthening healthcare systems in Europe, Promoting better health of citizens, Contributing to a sustainable health economy in Europe.
- The applicant(s) or company must own or have rights to the intellectual property that is the basis for the project or product (if applicable).
- The most successful project or product will be at least at TRL 4; however, early-stage innovation projects and ventures will also be considered.

The Funding

- Applicants may not request more than €50 000 in EIT Health funding. An EIT Health funding limit of €50 000 per calendar year, per start-up, applies across all programmes and pillars (Except for Start-up Amplifier). (See the [Frequently Asked Questions](#), ΦΑΘ)
- Projects must show co-funding to be eligible. (Please advise with your regional BCM and see **EIT Health's Investment section**)
- Applicants must agree to the funding terms and conditions outlined in **the EIT Health's investment section**.

Specific Requirements

- Applications should only be submitted once each year and only to one EIT Health region (see [Specific regional requirements and directions](#)).
- Applications should only be submitted to the region the applicant self-identifies with. EIT Health regional distribution information can be found in [Specific regional requirements and directions](#).

Healthy Longevity Grand Challenge

For projects with focus on “Active Ageing and Longevity”

Projects with a focus on active-ageing will enter into the Healthy Longevity Global Grand Challenge, a global innovation competition, founded by the United States National Academy of Medicine (NAM) in collaboration with EIT Health and other leading international institutions.

Through its Headstart Programme (which supports 90+ awards per year), EIT Health will participate in the first, or Catalyst phase, of the Grand Challenge. Awards will be given for projects, products and services (that fit the overall EIT Health objective “Strengthening healthcare systems in Europe, Promoting better health of citizens, Contributing to a sustainable health economy in Europe”). Headstart Programme, the most successful project or product will be laboratory-validated or otherwise validated (test-bed, living lab, etc.); however, early-stage innovation projects and ventures will also be considered. This will constitute EIT Health’s contribution to the NAM Health Longevity Grand Challenge and are eligible to compete for the second tier (Accelerator Awards) of the Grand Challenge.

Starting in 2021, the NAM will convene the global Catalyst Awardees at an annual summit to present their ideas, network with their peers, as well as potential funders. EIT Health will support the participation of select Headstart Programme awardees (whose innovations align with the aims of the Grand Challenge) at the annual summits hosted by EIT Health and the Grand Challenge, whose innovations align with the aims of the Grand Challenge.

EIT Health’s Investment (Non-Dilutive) Terms and Conditions

EIT Health believes it is valuable to invest in promising projects at this development stage. Therefore, the programme offers non-dilutive funds and a maximum EIT Health contribution of €50,000 per year and start-up.

The project must begin before November 2020 and the maximum duration of a project is 12 months from the date that the Subgranting Agreement is signed. In the event of difference between the sign date and the date that the selected companies will receive the awarded funding, the date of signature still counts as the project initiation date and thereafter up to one year.

The funding is non-dilutive and must be spent according to Horizon 2020 guidelines. (See section 14 – FAQ for compliant cost categories). The funding may be used for any activity necessary and relevant to reach the project's objectives, but cannot be used for pure **basic** research activities.

Ecosystem-Integration Deliverable

Successful projects must allocate a small percentage of the funding awarded to an ecosystem-integration deliverable. This deliverable serves to integrate the start-up with and leverage existing EIT Health resources within the network. It may be used to enable co-creation activities, patient involvement and citizen engagement in the product development and validation cycle. A €50 000 grant should anticipate to reserve at least 4%. The BCM will support you in identifying a suitable ecosystem integration deliverable and writing that into the project plan. All deliverables are meant to be directly aligned to your individual project but must also be approved by the regional BCM.

Suitable ecosystem-integration deliverables include:

- [Mentoring and Coaching Network](#), a comprehensive platform with mentors, subject-matter specialists and other experts in the field of healthcare.
- [Living Labs and Test Beds](#), a European platform that supports start-ups in the validation process, for instance co-creation, consume testing as well as feasibility studies.
- Attending meetings or events closely linked to the project objectives (where EIT Health is clearly identified as one of the sponsor).
- Hiring and intern from the Campus programmes. Start-ups are welcome to access the talent pool of EIT Health Campus students and use the funding for internship resources. Contact your regional manager for details.

Co-Funding funding requirement

In order to see commitment from our applicants, we require projects to commit to providing co-funding of at least 50% of the grant amount requested from EIT Health (25% for Innostars region). This requirement is to assure that you will not be solely reliant on EIT Health funds for the period of your project. Please note we are not responsible to ensure your liquidity during the project period.

Co-funding are applicants' own financial resources to cover part of the planned total project costs. These costs are directly linked to the Headstart project and are an integral part of the planned project budget (KAVA). Therefore, co-funding should be reported in the project plan and might be subject to auditing by EIT Health auditors. The cost categories eligible for the start-up's own co-funding are the following: services and subcontracting, personnel, travel and accommodation, consumables and equipment.

Example of Co-funding: The applicant requests €40 000 from EIT Health Headstart. The co-funding should be **at least** €20 000 (€10 000 for Innostars region). The total budget of the project will be €60 000 (€50 000 for Innostars region).

Please contact your local BCM for clarifications.

Regional Funding Schemes

Each CLC/Region receives equal amount of funding from EIT Health, however some regions are able to offer additional funding in state support. Regional funding schemes including awarded amounts, and/or second submission opportunities may be available please see **Specific regional requirements and directions section** for details.

EIT Health Terms and Conditions

Expectations

The Accelerator is open to applications from all entrepreneurs, start-ups, scaleups, and SMEs in Europe. If you have no previous connection to any EIT Health partners or CLCs, introduce yourself: a list of partners can be found [here](#), or contact the Business Creation Managers at regional CLCs. Some applications may encourage Letter of Confirmation from EIT Health partners or regional CLCs as supplements to support the application.

We ask for all entrepreneurs and teams to commit to participating fully in any EIT Health programme. If full participation and commitment cannot be guaranteed an agreement must be made in advance with the activity lead.

Funding

EIT Health can award a **maximum of €50,000** in grants per start-up per year. This maximum refers to grants awarded as part of Headstart, or other funds distributed within an EIT Health Accelerator programme, and reimbursements for travel and accommodation when invited to

participate at an EIT Health event. This maximum does not include the commercial value of an activity. Therefore, applicants are only allowed to participate in one of the following programmes within the same calendar year: Headstart, Bridgehead Europe/Global, Digital Sandbox or European Health Catapult or participate as External Project Partners of EIT Health Projects within the Innovation, Campus or Accelerator Pillar.

Promotion and Branding

Start-ups supported by EIT Health agree to the EIT Health branding. Start-ups participating in Accelerator activities agree to use the “Accelerated by EIT Health” logo as well as the EU flag logo (which includes a sentence about the EIT and display it in their partnership page). Start-ups also agree to mention EIT Health in its press releases as a partner. The branding package will be provided upon selection and must be affixed before June 2020.

Sustainability vision

Since 2016, the EIT Health Accelerator has offered its programmes as complimentary based on structured selection processes to determine company and merit. It has not asked for any contribution in return. In order to continue to support start-ups and the European economy, in the future, EIT Health may ask awarding companies to contribute commitment fees or share in the companies’ economic success. If EIT Health makes amendments to its current complimentary structure, participating companies will be informed in a timely manner and prior to signature.

Selection process and criteria

Upon passing an initial eligibility criteria review, applications to each EIT Health Region will separately be assessed by a team of experts drawn from the EIT Health partners, EIT Health Mentoring and Coaching Network and Investors’ Network, and/or the wider CLC eco-systems as relevant to the call (e.g., local VCs). Confidentiality agreements will be in place and conflicts of interests will be actively managed.

Applications will be judged on a remote evaluation based on the following selection criteria:

Company/product evaluation:

- Innovativeness of Idea
- Market opportunity & Traction
- Development strategy & Business model

Project submitted evaluation:

- Impact of EIT Health Funding on planned work and company development
- Management Capability
- Co-creation and citizen engagement, as well as validation with the end-user

CLCs may elect to invite a shortlist of applicants for an in-person or online interview/pitch in front of the panel of experts and/or the public before a final list of awardees is announced. See [Specific regional requirements and directions](#) section for details.

The Evaluation panel's decision is final and no correspondence or negotiation will be entered into by EIT Health, its CLC offices or any of its partners with respect to results. Raw scores will not be revealed and written feedback from evaluators will only be provided anonymously and upon request.

Project Awards

The selection procedures are carried out regionally by the EIT Health CLCs/Innostars.

The awarding and reporting process upon selection is as follows:

- A project plan will be completed by selected applicants (with the supporting EIT Health partner where applicable) and approved by the regional BCM.
- The recipient must sign electronically a standard project sub-grant agreement centrally with EIT Health CLC/Innostars. The approved project plan will be annexed to this grant agreement.
- The selected companies will be asked to acknowledge the support from EIT Health on media, social networks, papers, presentations, etc. using the 'Accelerated by EIT Health' logo. The logo can be downloaded [here](#).
- A mid-term report will be requested by EIT Health for reporting activities, and is required before 20 December 2020.
- A final report is expected at the end of the project (see also [Project Reporting](#) below).

Project Reporting

Midterm and final reports are mandatory. Templates will be provided through Optimy. The final report will be based on the project plan agreed with the BCM. Reports must contain at least:

- Project description
- Description of results achieved and deliverables of each milestone as outlined in initial project plan
- Financial Statement
- Lessons learned: successes/outcomes
- KPIs achieved (e.g. jobs created thanks to the Headstart grant, investment attracted during the year).

Information requested in intermediate reports will be more concise and required before 20 December, 2020. Final reports are expected after the project has been completed.

EIT Health Regions

Applications may only be submitted to the region the applicant self-identifies with. EIT Health has seven regional offices that represent European states. The seven offices represent:

- Germany / Switzerland / Austria
- France
- Spain
- Belgium / The Netherlands / Luxemburg / Israel
- UK / Ireland (Wales)
- Scandinavia (Sweden, Denmark, Norway, Finland, Estonia)
- EIT Health InnoStars (see below)

Innostars countries include Hungary, Italy, Poland, and Portugal. Innostars also support applicants from the RIS-Region which currently includes: Croatia, Czech Republic, Greece, Lithuania, Slovakia, Malta, Bulgaria, Cyprus and Romania. Each year several new countries will be included into the RIS-Region to allow the ecosystems to develop.

Applicants from other EU Countries (eligible for H2020) that are not listed, are encouraged to contact the Innostars node before applying.

Specific regional requirements and directions

Belgian/Netherlands CLC Applicants

In addition to the submission first cut-off date (16 March 2020) the Belgian/Dutch CLC will offer a second submission cut-off date on 14 September 2020. Start-ups that applied for the first cut-off date cannot apply for the second submission cut-off date.

German/Swiss CLC Applicants

In addition to the submission first cut-off date (16 March 2020) the German / Swiss /Austrian CLC will offer a second submission cut-off date on 14 September 2020. Start-ups that applied for the first cut-off date cannot apply for the second submission cut-off date.

In the application process of both cut-off dates, startups must submit a Letter of Confirmation signed by an EIT Health business partner. Start-ups that do not submit the letter will not be considered eligible for evaluation.

- To identify suitable EIT Health business partners visit the page <https://eithealth.eu/our-network/our-partners>. Select “Business” in the Classification section. In this way only the business partners of EIT Health will be displayed.
- Each partner has a contact whose name and email address are shown on the webpage. Feel free to use this contact to reach out to the business partner. If you already have any contact among the listed EIT Health business partners you can make use of your connection(s).
- A template for the Letter of Confirmation required the the German CLC can be downloaded [here](#). Feel free to use your own template or to modify the existing one.
- The letter can be signed by any relevant person within the EIT Health business partners.

Scandinavian CLC Applicants

In the application process, start-ups must submit a Letter of Confirmation signed by an EIT Health Scandinavian partner (<https://eithealth.eu/our-network/our-partners/#.scandinavia>). Start-ups that do not submit the letter will not be considered eligible for evaluation. Please, ask also the Scandinavian BCM therefore affiliated and third linked parties to these partners who are eligible to sign Letters of Confirmation.

Spanish CLC Applicants

Following the results of online evaluations, highest ranked teams will be invited to a private jury panel. These selected start-ups will receive grants of €40,000 and will then be invited to compete for an additional €10,000 grant at the end of the year.

French CLC Applicants

Following the results of online evaluations, highest ranked teams will be invited to a private jury panel. These selected start-ups will receive grants of €40,000 and will then be invited to compete for an additional €10,000 grant at the end of the year.

UK/Ireland CLC Applicants

In the UK-Ireland companies must be registered before sub-granting begins, if an exception is granted by the BCM and verified centrally. Thus applicants with exceptions must be prepared to be registered absolutely latest by July 2020.

Innostars regions Applicants

Innostars will grant up to €40 000 for their selected start-ups. Winners of the grant will be invited to pitch their project plan in front of a jury panel and compete for an additional €10 000 grant at the end of the year. Start-ups based in Innostars regions and RIS regions are not recommended to simultaneously apply to Headstart and European Health Catapult in 2020. Start-ups should consult their BCM in case they believe they have strong argument to apply to both competitions. It will be the final decision of the BCM about to which competition (s) the start-ups should apply.

Support contacts

A strong international team is prepared to support you on your business creation journey:

Country/Region	Business Creation Manager contact	Email
Germany, Switzerland and Austria	Matteo Consonni	matteo.consonni@eithealth.eu
France	Ipshita Singh	ipshita.singh@eithealth.eu
Belgium and The Netherlands	Nicolas van de Kerkhof	nicolas.vandeKerkhof@eithealth.eu
UK and Ireland	Rosemary Gallagher	rosemary.gallagher@eithealth.eu
Scandinavia	Christos Vaitsis	christos.vaitsis@eithealth.eu
Spain	Javier Vega	javier.vega@eithealth.eu
Innostars region	Inês Matias	ines.matias@eithealth.eu

Frequently Asked Questions, FAQ

A. Are the applications treated under confidentiality?

Applications submitted to the EIT Health Headstart Programme are handled under confidentiality. Everybody that comes in contact with the applications during the review process is bound by confidentiality agreements. Each evaluator involved in the evaluation process will sign the Headstart 2020 code of conduct.

B. How many projects will be approved in 2020?

The total Headstart budget per CLC/Innostars for 2020 is €700 000. A maximum of € 50 000 can be awarded per project. Regional differences exist due to distinct innovation infrastructures, and it is therefore reasonable to expect that approximately 13-18 awards may be granted per region in 2020.

C. What is the thematic scope of projects EIT Health supports?

EIT Health's Mission

EIT Health's mission is to promote entrepreneurship and develop innovations in Strengthening healthcare systems in Europe, promoting better health of citizens and contributing to a sustainable health economy in Europe. EIT Health will enable citizens to lead healthier and more productive lives by delivering products, services and concepts that will improve quality of life and contribute to the sustainability of healthcare across Europe.

The main societal challenges addressed

1. Strengthening healthcare systems in Europe
2. Promoting better health of citizens
3. Contributing to a sustainable health economy in Europe

EIT Health Focus Areas

Companies should be seeking to develop projects that fit the overall EIT Health objective: "Strengthening healthcare systems in Europe, Promoting better health of citizens, Contributing to a sustainable health economy in Europe" Additional more specific focus areas identified by EIT Health for 2020 and 2021 which include:

- Bringing care home
- Harnessing the power of real-world data (RWD)
- Creating the enabling environment for healthcare transformation
- Towards holistic care pathways
- From the workplace to the health place: employer leadership in improving health
- Fostering healthy lives by introducing behavioural change

In order to create the desired impact, we particularly encourage applicants with projects related to the following [Focus Areas](#):

- **BRINGING CARE HOME:** From institutional delivery to health delivered at home – EIT Health aims to tackle the challenges of an aging European population by supporting projects that address 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 aims to tap the potential of RWD such as improved disease

management and early diagnosis and support RWD initiatives that are robust, inform valid healthcare decisions and demonstrate potential to be scaled up.

- **CREATING THE ENABLING ENVIRONMENT FOR HEALTHCARE TRANSFORMATION:** From the current challenge to a sustainable future – EIT Health will foster projects aimed to deliver an organisational evolution in healthcare management solutions, 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 PATHWAYS:** From treatment centric limitations to the health continuum breadth – EIT Health will strengthen projects that address care pathways, undertake the design and evidence-based implementation of innovative care and health delivery solutions.
- **FROM WORKPLACE TO HEALTH PLACE:** From workplace to health place – EIT Health will support innovations that 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 promote projects that offer 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 particularly focus on solutions targeting vulnerable and marginalised groups in society such as children and the elderly population.

D. What are the project categories?

Medtech; Biotech; DigitalHealth

E. What are typical project goals?

The activities supported by EIT Health Headstart Funding should clearly take the project closer to commercialisation. These could be activities for product development, marketing, regulatory and IP related tasks and include:

- Testing in real environments and end-user applicability – e.g. living labs and test beds
- Prototyping
- Production/product cost calculations
- Understanding the regulatory requirements
- Certifications
- IP protection
- 'Purchase' of expertise e.g. legal advice
- Marketing

F. What are the target KPIs?

EIT Health has a number of Key Performance Indicators (KPIs), but the ones that are most relevant for the EIT Health Accelerator and for the Headstart Programme 2020 are:

- Number of new business ideas incubated
- Number of new companies started
- Number of products brought forward by your project that reach market readiness
- New markets accessed
- Number of jobs created
- Investment attracted by start-ups supported by KICs
- Patients Impact and citizen and patient engagement

G. What are cost categories allowed in the project?

These are the allowed cost categories, as defined in the Horizon 2020 Model Grant Agreement, and reflected in the EIT Health Sub-granting agreement:

Personnel: e.g. personnel under employment contract
Travel and subsistence: e.g. travel to an EIT Health event
Equipment/ depreciation: e.g. laptop purchased specifically for the activity
Services and sub-contracting: patent or lawyers fee
Other direct costs: e.g. consumables / catering

H. General cost eligibility criteria for final financial reporting

- Actually incurred, i.e. real and not estimated or budgeted
- Incurred during the action
- The action duration is set to a maximum 12 months from the beginning of the contract
- Entered in the estimated budget of the action, under the relevant budget category
- Incurred in connection with the action and necessary for its implementation
- Identifiable and verifiable i.e. come directly from the beneficiary's accounts and supported by documentation
- Comply with applicable national laws on taxes, labour and social security
- Reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency

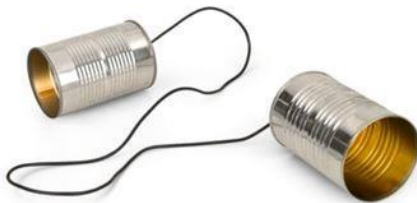
Annex: Understanding TRL

Special thanks to KTH Innovation for providing these images.



The purpose of the TRL

Communication tool



More objective assessment of the development level between stakeholders

Development roadmap




- Minimize risk in the development
- Develop products that are fit for purpose
- Encourage real-world testing and iteration
- Introduce “reality checks” in the development process

TRL according to EU



TRL 9	Actual system proven in operational environment
TRL 8	System complete and qualified
TRL 7	System prototype demonstration in operational environment
TRL 6	Technology demonstrated in relevant environment
TRL 5	Technology validated in relevant environment
TRL 4	Technology validated in lab
TRL 3	Experimental proof of concept
TRL 2	Technology concept formulated
TRL 1	Basic principles observed

TRL 4

	Technology validated in lab
Description	Basic technological components are integrated to establish that they will work together. This is relatively “low fidelity” compared with the eventual system
Example	<u>Separate components</u> – Radio Frequency (RF) communication, sensors, microcontroller, connectors and related components – connected and output signals processed by fall algorithm in computer. <u>Simulated stimuli</u> generates the alarm to be transmitted via wireless communication. (fall alarm system)

“Low-fidelity”

A representative of the component or system that has limited ability to provide anything but initial information about the end product.

Software development



TRL 9	v1.x, v2.x, etc. – continuous development and improvement
TRL 8	v1.0 - Final stable release to the end-users
TRL 7	Open beta testing - open for anyone who signs up ("Black-box")
TRL 6	Beta testing for invited end-users ("Black-box")
TRL 5	"Black-box" alpha testing for selected external end-users or in-house users/testers not associated with the development
TRL 4	Alpha testing of the software by one or a few in-house developers or testers ("White-box")
TRL 1-3	Concept/pre-alpha: script is more of an abstract idea than an actual working program. Through this stage the coding starts and changes to functions are being made until a working draft is created

Alpha: working script, probably lots of bugs, might not have all features, but the core of the program is running and can be tested extensively

Beta: program near completion, all features working, may be some bugs that may not have shown up in alpha testing

White-box: tests internal structures or workings of a program, as opposed to the functionality exposed to the end-user

Black-box: examining functionality without any knowledge of internal implementation. The tester is only aware of what the software is supposed to do, not how it does it.

Medical device development

(Source: US Army Medical Department)



TRL 9	Post marketing studies and surveillance
TRL 8	FDA (CDRH) approves the Premarket Approval (PMA) for medical device or applicable 510(K) for devices
TRL 7	Final product design is validated and final prototypes are produced and tested.
TRL 6	Class III device safety is demonstrated. 510(K) data demonstrates substantial equivalency to predicate device.
TRL 5	MD-CDRH review of Investigational Device Exemption (IDE) results is sufficient to begin investigation
TRL 4	PoC and safety of candidate device or system is demonstrated in a defined laboratory or animal model
TRL 3	Hypothesis testing and initial proof of concept (PoC) is demonstrated in a limited number of <i>in vitro</i> & <i>in vivo</i> models
TRL 2	Research ideas and protocols are developed