



EIT Health Accelerator Digital Sandbox Programme – Biobanks and Quality Registers

EIT Health hereby invites incorporated SMEs to submit Digital Sandbox applications

Publication of call: **22 July 2019**

Online Submission available starting: **01 August 2019**

EIT Health opens the Digital Sandbox (DS) Programme 2019 for companies (startups and SMEs) requiring access and collaboration with Biobanks, Sample Holders and Quality Registers in Europe, for the further development and/or commercialisation of new technologies, products or services.



EIT Health is supported by the EIT,
a body of the European Union

eithealth.eu

1. The Pitch: Purpose of Programme

EIT Health considers that there is still an unused potential for closer collaborations between biobanks, sample holders and registers in the public sector with SMEs in order to develop new solutions for healthcare that will lead to improved (quality for) prevention, prediction-, diagnosis-, treatment- and follow up. Furthermore new solutions that will lead to reduced costs and more efficient working procedures for prevention but also prediction, diagnosis, treatment and follow up. Therefore EIT health is pursuing the strategic activity RABBIT (Biobanks and registers in transition) and as part of this activity but also as part of its Accelerator activities, EIT Health provides funding of up to € 35,000 in the DS programme for SMEs to develop new products and services. These should fit within the overall EIT Health objective: “Healthy Living, Active Ageing, Improved Health Care.”

The main purpose of the EIT Health DS Programme is to enable the leveraging of the “Health Data Business” area, by supporting SMEs in realizing next steps towards the development of relevant products and services through the involvement of, and collaboration with, Biobanks, Sample Holders and Quality Registers, in Europe.

2. Timeline

Application opens: 1 August 2019

Submission deadline: 15 September 2019

Applications may be submitted throughout this period only*

(*however, support for the establishment of a connection to a biobank, sample holder or register reflected by a Letter of Intent (LoI) may be performed after deadline; see Section 3)

Selections: expected 1 October 2019

Project grant agreement signatures: expected latest 1 November 2019

Mid-term and final reports: required during the project

3. Application Support

Applicants are strongly encouraged to seek advice and contact their regional EIT Health Business Creation Manager (BCM) for guidance before submitting an application. They may support the applicant in defining the appropriate actions to produce an application which fits the scope and goals of the EIT Health DS Programme. All DS applications will require a reference contact person confirming that the company has an existing relationship with the EIT Health network. The contact details of the reference person must be submitted within the application.

Support will be also provided within the DS context and specifically regarding to facilitating the contact and connection establishment of applicant SMEs with respective biobanks, sample holders or registers in Scandinavia. However, we can not guarantee that a mutual agreement with a biobank, sample holder or register will be established in Scandinavia. At the same time, applicant SMEs are welcome to bring already established connections with biobanks, sample holders or registers they may have in Europe. In any case of a successful contact, a Letter of

Intent will need to be provided from the biobank, sample holder or register to the applicant SME.

Application support contacts

Country/Region	Business Creation Manager	Email
Germany and Switzerland	Matteo Consonni	matteo.consonni@eithealth.eu
France	Anais Delicourt	anais.delicourt@eithealth.eu
Belgium and The Netherlands	Bart Haex	bart.haex@eithealth.eu
UK and Ireland	Rosemary Gallagher	rosemary.gallagher@eithealth.eu
Scandinavia	Christos Vaitsis	christos.vaitsis@eithealth.eu
Spain	Irene Sánchez	irene.sanchez@eithealth.eu
Innostars region	Nuno Viegas	nuno.viegas@eithealth.eu

Contact for support in biobank, sample holder or register contact and connection facilitation

Role	Name	Email
Digital Sandbox Project Manager	Anna Pedersen	anna.pedersen@lihme.se

Support for questions regarding the overall strategic, procedural, evaluation, technical and granting procedures can be directed to the following individuals:

Role	Name	Email
Business Creation Manager Scandinavia	Christos Vaitsis	christos.vaitsis@eithealth.eu
Business Creation Project Manager, HQ	Salvatore Demelas	salvatore.demelas@eithealth.eu
Business Creation Manager, HQ	Joy Cürten	joy.cuerten@eithealth.eu
Director of Business Creation, HQ	Kurt Höller	kurt.hoeller@eithealth.eu

4. Is it for me? Eligible applicants and projects

A company must be incorporated/registered by the time of the deadline of the application.

Please consult your regional BCM to discuss this point if the company is not incorporated by the deadline of application. In any case the company should be **incorporated/registered** the latest by 15 September 2019.

The EIT Health DS Programme is suitable for micro and small enterprises (according to the EU SME definition).

The applicants must submit their application through 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.

5. Eligibility Criteria

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

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. Register your EIT Health account and apply here: <https://eithealth.optimytool.com/en/>
- It can include graphs or video links (maximum 3 minutes duration in English language or with English subtitles). Please be aware that the reviewers may not consider these attachments as basis for their evaluation.
- Applicants that are currently participating as External Project Partners in EIT Health Innovation Projects or have been selected in Headstart, Bridgehead or for the final stage of European Health Catapult within 2019, **are not eligible to apply**

The Project or product

- Must be within the scope of the main challenges in EIT Health: Healthy Living, Active Ageing, and Improved Healthcare.
- 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). However we will consider also projects where IP protection has not yet developed as long the solution delivers a project of significant value for healthcare.
- Has to be at least at TRL 3 (See section 12)

The Funding

- Applicants may not request more than € 35,000 in EIT Health funding. (An EIT Health funding limit of €50,000 per calendar year, per SME, applies across all programmes and pillars (See section 11– FAQ).
- Applicants must agree to the funding terms and conditions outlined in **next section**.

Specific Requirements

- Applications should only be submitted through one EIT Health region, which should be the same region that the company is registered in. EIT Health regional distribution information can be found in **section 10**.

6. Funding Terms and Conditions

A maximum EIT Health contribution of € 35,000 can be requested by each start-up/SME. The project must begin in 2019 and the maximum duration of a project is 12 months from the date that the Subgranting Agreement is signed.

The funding is non-dilutive and must be spent according to Horizon 2020 guidelines. (See section 11– 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. It is expected that typically a **minimum of 50%** (while no more than 75% required) of the awarded funding, will be spent by the awarded SME to cover the services provided by the collaborating Biobank, Sample Holder or Quality Register, in the duration of the project.

7. Selection process and criteria

Upon passing an initial eligibility review, applications to each EIT Health Region will separately be assessed by a team of experts drawn from the EIT Health partners, and/or the wider Scandinavian CLC eco-system as relevant to the call. 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:

- Need and product/solution
- Team and management capability
- Market and competitive advantage
- Business Model & Development Strategy
- Workplan and feasibility

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.

8. Project Awards

The selection procedure is carried out by the EIT Health Scandinavian CLC. However, the grant will be transferred centrally from EIT Health to the recipient. The awarding and reporting process upon selection is as follows:

- A project plan will be completed by selected applicants (with the support and approval of the regional BCM).
- The recipient must sign a standard project grant agreement centrally with EIT Health. The approved project plan will be annexed to this grant agreement.
- The selected SMEs 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 December 31st
- A final report is expected at the end of the project (see also Section 9 below).
- All selected companies will be invited to attend the "Biobanks & Registers, Your springboard to innovation" event that takes place on 21 October in Stockholm (please **save the date** in case of selection and further details will be communicated to the selected companies).

9. Project Reporting

Final reports are mandatory. Templates will be provided. 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 DS grant, investment attracted during the year).

Information requested in mid-term report will be required before 31 December 2019. Final reports are expected after the project has been completed.

10. EIT Health Regions

Applications may only be submitted to the region the applicant company is registered in. EIT Health has seven regional offices that represent European countries. The seven offices represent:

- Germany / Switzerland
- France
- Spain
- Belgium / The Netherlands
- UK / Ireland
- Scandinavia (Sweden, Denmark, Estonia)
- EIT Health InnoStars (see below)

Innostars: countries include Croatia, Hungary, Italy, Poland, Portugal and Wales. Innostars also support applicants from the RIS-Region which currently includes: 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 Austria, are encouraged to contact the Germany/Switzerland node before applying.

Applicants from Israel, are encouraged to contact the Belgium/Netherlands node before applying.

Applicants from Norway, Finland, Iceland are encouraged to contact the Scandinavian node before applying.

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

11. Frequently Asked Questions, FAQ

Are the applications treated under confidentiality?

Applications submitted to the EIT Health DS 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 DS 2019 code of conduct.

How many projects will be approved in 2019?

In this pilot phase of the DS programme a minimum of five companies are expected to be awarded with the maximum €35,000.

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 healthy living and active ageing, providing Europe with new opportunities and resources. 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. To promote healthy living
2. To support active ageing
3. To improve healthcare

EIT Health Focus Areas

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 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 organisational 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 marginalised groups in society

What are the project categories?

Medtech; Biotech; DigitalHealth

What are typical project goals?

The activities supported by EIT Health DS should clearly leverage the “Health Data Business” area and strongly involve Biobanks, Sample Holders and Quality Registers in order to take the next steps to verify and show proof of concepts, validate hypotheses and transfer into product development and development of collaborations between applicant SMEs and Biobanks, Sample Holders and Quality Registers, as well as expertise access from these entities. These include:

- Data access and data exploitation
- Completion/acquisition of necessary ethical approval(s)
- Development of necessary guidelines (applicable according to needs and context of collaborations)
- Understanding and complying with requirements pertaining to adherence to Biobanks/Registers guidelines
- Proof of concept, validation and development
- Preparation work for subsequent participation to EIT Health programmes such as [Headstart](#) (Commercialization), [European Health Catapult](#) (Business plan competition) and mainly [Innovation Projects](#)

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 DS Programme are:

- Number of new business ideas incubated
- Number of new companies started
- Number of new products / services launched
- New markets accessed
- Jobs created
- Capital attracted to EIT Health SMEs

However, the goal of this Digital Sandbox is to facilitate further collaboration with biobanks, sample holders and registers, in the healthcare sector. Thus, important KPIs here is to increase number of projects within EIT Health who collaborate with healthcare, increase number of projects who are internalized into clinical practice on a broad term and show both improved quality and reduced costs within healthcare. Furthermore new knowledge, improved working

routines within sample holders, biobanks and registers is also within the scope of targeted goals.

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 H 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

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

12. 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



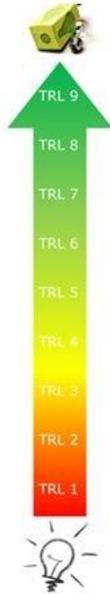
TRL 9	Actual system proven in operational environment
TRL 8	System complete and qualified
TRL 7	System prototype demonstration in operational environment
TRL 6	Technology demonstrated in relevant environment
TRL 5	Technology validated in relevant environment
TRL 4	Technology validated in lab
TRL 3	Experimental 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