**CIMTI Challenge Call 2023**

**Application form**

Please complete the following application form by **23.59 h (+1 GMT) Thursday 17th August 2023.** This form must be completed in English.

All information related to this call can be found on the [terms and conditions of the call](https://cimti.cat/ca/aplica/crida-repte-cimti/).

Those proposals that present a form with one or more evaluable items without information will be discarded.

**Proposal’s name**

A brief name to call the proposal (e.g., 1-3 words) for easy reference.

**Website**

If available, provide the link to the proposal’s website.

**Social Media**

If available, provide the link to social media accounts of your proposal (Twitter, LinkedIn, Instagram, Facebook, etc.).

# **Contact person**

Name and surnames:

Entity/Institution:

e-mail:

Phone number:

**Co-Principal Investigator(s)**

Please add name(s) and institution(s) if applicable

**Abstract**

Write your elevator pitch: Briefly describe your solution, the problem your solution is attempting to solve, the proposed solution and the key benefits of your solution in case it is implemented in the social and/or healthcare system. The abstract should be clear, concise, and understandable.

(1500 chars-limit)

This section will not be scored.

**Support from CIMTI**

The support required by the proposal must be framed within the services offered by CIMTI through its support programs: Please, indicate the support you would like to receive from CIMTI:

Technology: Works-like / looks-like / made-like prototypes

Technology: Access to manufacturing partners

Clinical: obtaining feedback from clinical stakeholders regarding need, clinical workflow, or willingness to adopt

Clinical: contact to Hospitals to test efficacy of the solution

Clinical: advice on scientific advisory board

Regulation: advice on preliminary regulatory classification and pathway

Regulation: advice on instructions for use

Market and business: stakeholder mapping

Market and business: competing solutions characterization

Market and business: value proposition definition

Market and business: advice on preliminary business model definition

Access to health and social Catalan public institutions

Advice on public and private funding

Communication advice

Access to Boston’s CIMIT (only for projects from Proof of feasibility milestone)

This section will not be scored, it will be used to understand your needs to move forward your proposal and to see if you meet the eligibility criteria.

**IDEA**

**1) Unmet need**

|  |
| --- |
| Provide an overview of the clinical need motivating the work and why it is important.  (3000 chars-limit) |

Evaluation criteria: clarity and relevance (based on data and experiences in the field) of the unmet need.

**2) Proposed solution**

**2a) State of the art analysis: alternatives (if any) to the proposed solution**

Provide a description of the existing and/or potential alternatives considered, why you decided not to follow them, and how your proposed solution differs and improves the available ones. Consider the prices of the existing solutions compared to the proposed one.

(3000 chars-limit)

Evaluation criteria: accurate description and analysis of alternatives. Credibility of the proposed solution being a better solution than the existing ones and its viability to be entered into the system.

**2b) Overview of the solution**

Provide a brief description of the proposed solution, the work done to date, why it is innovative, and why it should be pursued. Explain how your solution addresses the selected unmet need on question 1.

(3000 chars-limit)

Evaluation criteria: clarity and a detailed and accurate description of the solution (based on data). Ability of the proposal to solve a problem: the unmet need.

**2c) Solution category**

Select (multiple selection allowed) the category that best describes your proposed solution. More information on the definition of digital health, digital medicine and digital therapeutics [here](https://www.healthxl.com/blog/digital-health-digital-medicine-digital-therapeutics-dtx-whats-the-difference). This section will not be scored.

|  |  |
| --- | --- |
|  | MedTech (electro/mechanical medical devices) |
|  | In vitro diagnostic |
|  | Digital health *(products for data collection, storage, transmission, and visualization of information for health-related purposes)* and digital medicine *(products for measurement and intervention in the service of human health)* |
|  | Others |

**2d) Solution status**

According to the most applicable solution category selected, download the Healthcare Innovation Cycle Matrix and check all the requirements that your project has accomplished and then upload the completed document.

* For MedTech solutions fill in this matrix [here](https://www.gaits.org/documents/3803506/0/MedTech+Innovation+Cycle+Checklist.pdf/7be17494-04ba-ea6a-1fa0-f4072fc0eb1d?t=1623246326590).
* For In Vitro diagnostic solutions fill in this matrix [here.](https://www.gaits.org/documents/11683962/0/IVD+Innovation+Cycle+Checklist+Rev+1+.docx.pdf/a0138450-bcf8-2a96-c2e0-2fc6e3dea232?t=1651078476352)
* For Digital Health and Medicine fill in this matrix [here](https://www.gaits.org/documents/3752413/0/Digital+Med+Innovation+Cycle+Checklist.pdf/b76e437e-e942-f27b-8d76-44ef4f5d1819?t=1614014206067).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **MEDTECH INNOVATION CYCLE MATRIX** | | | | | |
| **Milestone** | **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 | Regulatory Familiarization | State-of-the-Art Summary |
| 1. Idea | Potential solutions to unmet need developed and evaluated | Clinical workflow description  Updated need description  Envisioned benefit statement  Feedback from >5 clinicians | Competitive landscape  Envisioned Value Proposition  Key stakeholders identified  Reimbursement  familiarization | Medical device intended use  Equivalent devices | Idea screening and  selection  Paper Prototype  Hypothesis and experimental design  Institutional IP disclosure |
| 1. 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  Target outcomes | Competing solutions characterization  Preliminary Value Proposition  Path to Payment plan  Stakeholder map  Business protection  model | Preliminary classification  Preliminary intended use  Preliminary regulatory pathway  Preliminary risk and  hazard analysis | PoC prototypes  Demonstration results  Preliminary FTO  Assessment  Institutional IP disclosure (if applicable)  Key in-sourcing  requirements |
| 1. Proof of Feasibility (PoF) | Feasibility of whole solution demonstrated in models and in feedback from stakeholders | Feedback from clinicians in >20 settings  Updated need and workflow descriptions  Updated target outcomes | Feedback from >5 economic buyers  Preliminary business  model  Development Plan  Key relationships  identified  Business advisory Board  Secure Access to Core IP | Draft Essential Requirements Table for directive  Instructions of Use  Submission pathway  defined  Draft product claims  Institutional approval  request(s) | Product Requirement  Document (PRD)  “Works Like” and “Looks Like” prototypes  Essential experiment  results  FTO review  Provisional IP filing  Preliminary BOM and  Manufacturing/QMS plan  Key in-sourcing plans |
| 1. 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  Feedback from 5+ KOLs  Animal/ First-in-Man experiments  Clinical trial endpoints  Scientific/Medical Advisory Board | Key management team  committed  Investor ready business plan  Feedback from >20 economic buyers  Incorporation & Founders  Agreement  Initial seed investment  Key relationships formalized | Application form to national competent authority  Data requirements  Clinical Investigation approval  Electronic protected  health information  (ePHI) plans | “Works /Looks Like, Made Like” prototypes  Essential technical  experiments results  IP search report  Key in-sourcing  requirements committed  cGMP compliant pilot  manufacturing process |
| 1. Initial Clinical Trials (ICT) | Regulated production of prototypes and collection of clinical and economic data | Conduct Phase 0 and/or 1 clinical trial(s)  Demo feedback from 20+ clinical stakeholders  Peer reviewed publication(s)n summited | Economic data  Feedback from >50 economic buyers  1st institutional investment | Data requirements confirmation  Pre-submission  GDPR/HIPAA  compliance  Security and  vulnerability  certifications | Manufacture GMP-compliant pilot lots  Updated specification &  experimental validation  All in-sourcing  requirements achieved  Full IP application |
| 1. 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) accepted | Purchasing intent from >10 buyers  2nd round of institutional investment | Technical File submission to Notified Body (CE Mark) | GMP Process Planning  Updated  specification &  experimental validation |
| 1. Approval & Launch (A&L) | Institutional and regulatory approval received, and sales launched | Training materials and support established  Specialty medical  groups review in place | Initial sales  Update regionalization  plans | Registration and Listing (CE mark obtention)  CMS Coverage and CPT Code Determination | Finalized GMP process  IP for improvements  filed |
| 1. Clinical Use (Use) | The solution is used successfully in day-day clinical practice | Included in local practice guidelines  Peer reviewed publication | Profitable sales  New markets launched | Monitoring and Inspections | Patents issued  Improvement plan |
| 1. Standard of Care (SoC) | The solution is recognized as the Standard of Care | Recommended practice by medical specialty | Dominant market share  Health economics study | Product  Obsolescence Plan | Component Obsolescence Plan |

This section will not be scored, it will only be used to check that the eligibility criteria “The proposal must be at least in Proof of Concept (Healthcare Innovation Cycle milestone ≥ 3" accomplished)”. Those proposals that do not have all the requirements from Milestone 1 (Need) and 2 (Idea) achieved, will be discarded.

**2e) Specific topic of the call**

Select (multiple selection not allowed) the category that best describes the topic of the call related with your solution. This section will not be scored.

**Topic 1.** Solutions to improve women’s sexual health.

**Topic 2**. Tools and technologies to monitor pregnancy.

**Topic 3**. Solutions to early diagnose women’s cancers.

**Topic 4**. Solutions to improve the detection and support of mental health problems in women.

Others

Note that proposals that offer solutions aimed at promoting women's health that fall under any of the four topics mentioned, will have 10 extra points (out of 100) than those proposals that fall under “Others” category.

**2f) References (optional)**

Provide references that objectively support the data mentioned in sections 1) Unmet need and 2) Proposed solution.

(7000 chars-limit)

This section will not be scored.

**IMPACT**

**3) Impact if successful**

Describe the impact that your proposed solution will create if it is successful. Make sure you indicate the number of people who will directly and indirectly benefit from the proposed solution.

(4000 chars-limit)

Evaluation criteria: Capacity of the proposed solution to improve health conditions, patient/citizen safety and autonomy, adherence to treatment, mortality and comorbidity, patient/citizen satisfaction, reduced use of hospital services, economic savings, organizational processes, and the integration of social and health services. Also, capacity of the solution to improve job satisfaction among professionals, the level of stress, the quality of care, the reduction of risks in decision-making, the optimization of time and the ease of use. The proposal must provide associated metrics, such as morbidity, mortality and costs of the problem and explain what would be different if this problem was solved. The proposal must prove to have a high impact either by a large number of beneficiaries or by a large change in the quality of life of a more limited number of beneficiaries.

**4) Potential to be replicable and scalable**

Provide a description of how your proposed solution can be replicated and scaled (from the technological point of view, ease of adoption of the proposed solution, potential for use by the public, universality, possibility of application in any context/territory, etc.).

(1000 chars-limit)

Evaluation criteria: ability of the proposal to improve the ease of adoption of the solution by users and to be replicable in the health and social system, taking also into account technological aspects of implementation. Open access solutions will be positively valued, as well as proposals considering standardization issues in the Catalan healthcare and social system.

**VIABILITY**

**5) Limitations and barriers**

# Describe the most critical limitations and barriers to implement your solution and explain how you would solve them. Take into account the following aspects:

* Product/service limitations and barriers (e.g., technical barriers, usability, etc.)
* Limitations and barriers in the model of adoption (e.g., the solution requires adaptation of the structures and professionals involved)
* Limitations and barriers in the economic sustainability of your solution (e.g., commercialization, revenues, costs, partnership, etc.)
* Limitations and barriers in terms of collaborators needed to move the project forward (e.g., clinicians, engineers, etc.)

(4000 chars-limit)

Evaluation criteria: ability of the team to anticipate, identify, describe and plan how to overcome key limitations.

**6) Implementation**

**6a) Implementation pathway**

Describe the different stages of the proposal, the different agents involved and detail whether the solution is intended to be implemented only in Catalonia or globally.

(2000 chars-limit)

Evaluation criteria: the team's ability to describe the steps to follow for the implementation of the solution within the Catalan and international territory. The feasibility of the implementation will also be assessed.

**6b) Schedule**

Fill in the following table as a Schedule with the main goals to be achieved in each semester and year:

(200 chars-limit/box)

**S1 S2**

**Year 1**

**Year 2**

**Year 3**

**Year 4**

**Year 5**

Evaluation criteria: ability of the team to identify the key stages in the process of implementing its proposal. The clarity and logical planning of the different milestones to be achieved will be positively evaluated.

# **6c) Estimated total budget to develop the project in the next 5 years.**

Upload a document (pdf file) with the estimated budget necessary to implement the project. The estimated budget refers to the total budget that will be needed to develop all activities including internal activities developed by the institution personnel and external activities developed by external experts.

The total budget does not refer to the current available budget but the total budget that will be needed to develop the project in the next 5 years, understanding that this budget will be raised by applying to different calls. The budget should include the costs of personnel, external consultants (market analysis, analysis of competition, Business plan, commercial evaluations, commercial plan, legal support, IP strategy, technology evaluation, valuation of intangible assets, regulatory development, etc.), equipment, R&D, clinical trials, product production, product design, prototyping and indirect costs.

Please note that this document is not binding. The budget will not be evaluated, it will serve to estimate how realistic the development strategy is.

(upload)

Please provide any additional comments related to the budget (optional).

(2000 chars-limit)

# **6d) Envisioned business model**

Describe your business model idea.

(2000 chars-limit)

Evaluation criteria: ability to describe a business model that sounds feasible and sustainable long-term.

**TEAM AND SUPPORT**

**7) Team composition**

Add the information required of each team member, including the relevance and expertise of their profile to carry out specific project tasks, and their level of involvement in all the activities related to Impact Program, as a percentage (so full involvement is 100%). The percentage of dedication does not refer to the dedication that the person has to the project itself, but to the commitment they can achieve with the Impact Program. If the team of the project is formed by more than two people, the person responsible for the project must have a dedication equal to or greater than 50% (2000 chars-limit/box).

Team member 1:

* Name:
* Institution:
* Summary of profile:
* Role in the proposal (relevance of this profile to carry out specific project tasks):
* % of involvement in the Impact Program:

Team member 2:

* Name:
* Institution:
* Summary of profile:
* Role in the proposal (relevance of this profile to carry out specific project tasks):
* % of involvement in the Impact Program:

Team member 3:

* Name:
* Institution:
* Summary of profile:
* Role in the proposal (relevance of this profile to carry out specific project tasks):
* % of involvement in the Impact Program:

(Click the “+” button to add more members to the team, if necessary)

Evaluation criteria: involvement of the promoter team and their experience and knowledge of the health and system. Multidisciplinary teams with internal capacity to address regulatory, clinical, technology, and market and business key aspects.

**8) External support**

**8a) Which collaborators do you currently have?**

Describe whether you have received support from outside your organization (financial, advisory, accreditation, recognition, etc.) and highlight the involvement of end-users (patients, citizens, or professionals) from the beginning in your proposal. Specify third sector entities, if necessary.

(2000 chars-limit)

Evaluation criteria: to have established collaborations with external entities and demonstrate involvement of end-user such as third sector entities (patients associations) will be positively evaluated.

**8b) Which collaborators do you need to develop the proposal? Do you plan to incorporate them in the future?**

(2000 chars-limit)

Evaluation criteria: to be in the process of initiating collaborations with external entities highlighting the involvement of end-users such as third sector entities (patients associations) will be positively evaluated.

**Information on personal data (Privacy policy)**

**Data controller**: FUNDACIÓN LEITAT. Tax number: G-64647654

**Purpose of the processing:** participation of the data subject in the Innovation or Impact Programs.

**Lawfulness**: pre-contractual measures at the request of the data subject (art. 6.1’b´ GDPR).

**Recipients**: FUNDACIÓN LEITAT, as the controller for the personal data of the data subjects, may communicate them to the institutions directly involved in the program, for the sole purpose of managing the selection of candidates and, in the event of being elected, process the corresponding aid. The planned communications are at:

1. The Catalan Agency for Health Quality and Evaluation (AQuAS)
2. CIMIT (Consortia for Improving Medicine with Innovation & Technology).
3. External evaluators, who participate in the project selection process.

The data will also be communicated to processors who provide ICT services on behalf of the controller, such as the OpenWater platform, or when there is a legal obligation.

**International transfers**: participation in this project involves two international transfers of personal data, for the purposes of Article 49 of the GDPR:

1. A first transfer made using the OpenWater platform, domiciled in the United States.

More information here: <https://www.getopenwater.com/privacy-policy/>.

1. A second transfer produced by the management that the CIMIT of Boston makes of the OpenWater platform.

These transfers occur when researchers apply for calls to participate in the IMPACT program and are necessary for the execution of pre-contractual measures and the evaluation of projects, adopted at the request of the data subjects.

**Storage criteria**: Data will be kept for no longer than necessary to maintain the purpose of the processing or as long as there are legal prescriptions that dictate their custody. When it is no longer necessary, data will be deleted with appropriate security measures to ensure the anonymization of personal data or its total destruction.

**Rights of data subjects:** access to, rectification or erasure of data, as well as restriction or object to processing of personal data. Use the forms available on the website:

<https://fundacionleitat.org/Modelo_Ejercicio_Derechos_FL.pdf>

**Additional information**: if you want to expand this information you can consult:

<https://fundacionleitat.org/catala/Politica_de_Privacitat.htm>