CIMTI Call for Innovation 2022

Application form

Please complete the following application form by **23.59 h (+1 GMT) Thursday 20th October 2022.** This form must be completed in English.

All information related to this call can be found on the terms and conditions of the call.

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

Briefly describe the importance of the problem addressed, the proposed solution, the objectives to be achieved, and the possible implementation 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:

- Personalized service and support by the CIMTI team
- Technological advice
- Clinical advice
- Advice on medical device regulation
- Market and business advice
- Access to health and social Catalan public institutions
- Advice on public and private funding
- Communication advice
- Training sessions
- Direct access to Boston's CIMIT

(3000 chars-limit)

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).

2) Proposed solution

2a) 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.

- ○ Medical device
- ○ In vitro diagnostic
- ○ Digital health *(products for data collection, storage, transmission, and visualization of information for health-related purposes)*
- ○ Digital medicine *(products for measurement and intervention in the service of human health)*
- ○ Digital therapeutics *(products for the treatment and management of a medical disorder or disease)*

- ○ Others (specify):

This section will not be scored.

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 supported by objective data. Ability of the proposal to solve a problem addressing the unmet need.

2c) Solution status

Check all the milestones accomplished according to the Healthcare Innovation Cycle Matrix (information about how to fill in this matrix here):

HEALTHCARE INNOVATION CYCLE MATRIX					
Milestone	**Overall Description**	**Clinical**	**Market / Business**	**Regulatory / Approvals**	**Technology**
1) Need	Insights into unmet clinical needs and available solutions	☐Unmet need statement ☐Disease state characterized	☐Needs screening & selection ☐Existing solutions characterization	☐ Regulatory Familiarization	☐ State-of-the-Art Summary
2) Idea	Potential solutions to unmet need developed and evaluated	☐Workflow scenario ☐ Updated need statement ☐Envisioned benefit statement ☐Feedback from >5 clinical stakeholders	☐Competitive landscape ☐Envisioned Value Proposition ☐Key stakeholders identified ☐ Reimbursement familiarization	☐Medical device determination ☐Comparable identified	☐Idea screening and selection ☐Paper Prototype ☐Hypothesis and experimental design ☐ Institutional IP disclosure
3) Proof of concept (PoC)	Key component concepts validated in models and value proposition articulated	☐Feedback from clinicians in >5 settings ☐Updated need statement and workflow scenario ☐Target outcomes	☐Competing solutions characterization ☐Preliminary value proposition ☐Path-to-Payment plan ☐Stakeholder map ☐Business protection model	☐Preliminary regulatory classification ☐ Preliminary regulatory pathway ☐ Preliminary intended / indications for use ☐ Preliminary risk and hazard analysis	☐Key component PoC prototypes ☐Demonstration results ☐Preliminary FTO Assessment ☐Updated institutional IP disclosure ☐Key in-sourcing
4) Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	☐Feedback from clinical stakeholders in 20+ settings ☐Updated need statement and Use Case scenario/workflow ☐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 checklist ☐ Submission pathway defined ☐ Draft product claims ☐ Draft instructions for use ☐ Institutional approval request(s)	☐Product Requirement Document (PRD) ☐"Works Like" and "Looks Like" prototypes ☐Essential experiment results ☐Provisional IP filing & initial FTO review ☐Preliminary BOM and Manufacturing/QMS plan ☐Key in-sourcing plans
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+ clinical stakeholders ☐ Feedback from 5+ KOLs ☐Animal/ First-in-Man experiments ☐ Medical Advisory Board ☐ Clinical trial endpoints	☐Key management team committed ☐ Investor ready business plan ☐ Feedback from 10+ economic buyers ☐ Initial seed investment ☐ Incorporation & Founders Agreement ☐ Key relationships formalized	☐Essential requirements checklist ☐ Application form to competent authority submitted ☐ Clinical Investigation approval(s) ☐ Electronic protected health information (ePHI) plans	☐"Works Like, Looks Like Made Like" prototypes ☐Essential technical experiments results ☐IP search report ☐Key in-sourcing requirements committed ☐cGMP compliant pilot manufacturing process
6) Initial Clinical Trials (ICT)	Regulated production of prototypes and collection of clinical and economic data	☐Endpoints achieved in pilot clinical trials ☐Demo feedback from 20+ stakeholders ☐Peer reviewed publication(s) submitted	☐Value quantification ☐Feedback from 20+ economic buyers ☐1st Institutional Investment	☒GDPR/HIPAA compliance ☐ Security and vulnerability certifications ☐ Data requirements confirmation ☐ Pre-submission sent	☐ cGMPs compliant manufacturing plan ☐ Updated specification & experimental validation ☐ All in-sourcing requirements achieved ☐ Full IP application
7) Validation of Solution (VoS)	The solution is shown to be effective and its value to all stakeholders is validated	☐Endpoints achieved in pivotal clinical trials ☐Peer reviewed publication(s) accepted	☐Purchasing intent from 10+ buyers ☐Second round of institutional investment	☐Complete Technical File ☐Technical File submission to Notified Body (CE Mark)	☐Quality assured process validation (cGMP)

8)	Approval & Launch (A&L)	Institutional and regulatory approval received, and sales launched	☐Training materials and support established ☐Speciality medical groups review in place	☐Initial sales ☐Updated regionalization plans	☐Registration and Listing (CE mark obtention) ☐CMS Coverage and CPT/DRG code Determination	☐Finalized cGMP manufacturing process ☐IP for improvements filed
9)	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	☐Key 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 ☐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 phase, Healthcare Innovation Cycle milestone ≥ 3" is accomplished.

2d) Healthcare Innovation Cycle milestone

According to the Healthcare Innovation Cycle Matrix you have completed above, state your current milestone and the proposed progress at the end of CIMTI's support program for each of the four main dimensions:

	Current status	Proposed status at the end of CIMTI's support program
Clinical		
Market/business		
Regulatory		
Technical		

To indicate the current and proposed status please use the following numbers:

1) Need
2) Idea
3) Proof of Concept (PoC)
4) Proof of Feasibility (PoF)
5) Proof of Value (PoV)
6) Initial Clinical Trials (ICT)
7) Validation of Solution (VoS)
8) Approvals and Launch (A&L)
9) Clinical Use (Use)
10) Standard of Care (SoC)

This section will not be scored.

2e) 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 in the system.

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: 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 (ease of adoption of the proposed solution, potential for use by the general 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. Open access solutions will be positive 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 in 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. The proposal must demonstrate that it is feasible to reach the market/citizenship in 5 years.

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

Upload a document with the estimated budget necessary to implement the project using the template provided *(download template here*). 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, understanding that this budget will be raised by applying to different calls.

This budget should be an approximate financial plan of the project, but it is non-binding.

The support given by CIMTI is in the form of services and it is quantified approximately to 85.000€, but this amount does not need to be reflected on the estimated budget.

The budget must be signed by an authorized institution.

⇧ (upload)

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

(2000 chars-limit)

Evaluation criteria: the budget provided should be adjusted to the project needs and the institution should have agreed to it.

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, the relevance of their profile to carry out specific project tasks, and their level of involvement (%).

(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 dedication to project:

Team member 2:

- Name:
- Institution:
- Summary of profile:
- Role in the proposal (relevance of this profile to carry out specific project tasks):
- % of dedication to project:

Team member 3:

- Name:
- Institution:

- Summary of profile:
- Role in the proposal (relevance of this profile to carry out specific project tasks):
- % of dedication to project:

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

Evaluation criteria: a multidisciplinary team is a must with a clear project leader dedicating an important % of his or her time to the project.

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:

a. The Catalan Agency for Health Quality and Evaluation (AQuAS)
b. CIMIT (Consortia for Improving Medicine with Innovation & Technology).

c. 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:

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

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

b) 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