**CIMTI Call for Innovation 2021**

**Application form**

Please complete the following application form by **23.59 h (+1 GMT) Friday 15th October 2021.** This form must be completed in English.

In order to be accepted, the proposals must obtain a minimum score of 60% on each of the individual criteria. In this call, a maximum of 5 proposals will be accepted to become part of the CIMTI Innovation or Impact program. The notification period will be between 10th and 24th December 2021.

**Proposal’s name**

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

**Elevator pitch**

2-3 sentences summarising your proposal (400 chars-limit).

**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

**Eligibility criteria**

Consider that the reviewers will check first the following eligibility criteria:

* **Problem/unmet need:** the need is classified in one of the strategic lines of the Health Plan for Catalonia (Government of Catalonia).
* **Type of solution:** solutions proposed must be technology-based solutions.
* **Solution status:** the proposal must be at least at the “Idea” stage (TRL ≥2) (see section **2e**).
* **Time to impact:** the proposal must be able to be implemented in the healthcare and social system in a maximum of 5 years (see section **7b**).
* **Interoperability and integration into the system:** the proposed technologies must be developed considering the viability of integration with the existing information systems in Catalonia and the certification processes.
* **Territoriality:** the proposal must be totally or partially implemented in the Catalan healthcare and social system, and at the same time, it should be thought out for its global scalability (see section **7a**).
* **CIMTI services:** the support required by the proposal must be framed within the services offered by CIMTI through its support programs:
* Support in the conceptualization of the project
* Accompaniment by the CIMTI team
* Training sessions
* Communication advice
* Clinical advice
* Market and business advice
* Advice on Health product regulation
* Technological advice
* Investment advice
* Direct access to Boston’s CIMIT
* **Financing:** the proposal that depends exclusively on obtaining funding to advance in its development, will be excluded given the impossibility of starting to work.

**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.

(1500 chars-limit)

Evaluation criteria: the abstract should be clear, concise, and understandable.

**Video pitch**

Show us your ability to explain in lay terms your idea and its projected impact. Upload a video of maximum 3 minutes. The video is not required to be professional.

(upload)

**Support from CIMTI**

Please, indicate the support you would like to receive from CIMTI.

(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 (supported by data and experiences in the field) of the unmet need.

**2) Proposed solution**

**2a) Solution category**

Select (multiple selection allowed) the category that best describes your proposed solution.

|  |  |
| --- | --- |
|  | Medical device |
|  | In vitro diagnostic |
|  | Digital health *(products for data collection, storage, transmission, and visualization of information)* |
|  | Medical Health *(products for measurement and intervention)* |
|  | Digital therapeutics *(products for the treatment and management of a 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.

(2000 chars-limit)

Evaluation criteria: clarity and a detailed and accurate description supported by objective data. Ability of the proposal to solve a problem.

**2c) Addressing the unmet need**

Explain how your solution addresses the selected unmet need on question 1.

(2000 chars-limit)

**2d) Solution status**

Check all the milestones accomplished according to the Healthcare Innovation Cycle Matrix (info about how to fill in this matrix [here](https://www.gaits.org/)):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **HEALTHCARE 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 | NA | NA |
| 1. Idea | Potential solutions to unmet need developed and evaluated | Clinical workflow description  Updated need description  Feedback from >5 clinicians | Competitive landscape  Envisioned Value Proposition | Medical device intended use  Equivalent devices | Paper Prototype  Hypothesis and experimental design  Idea screening and selection |
| 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 | Competing solutions characterization  Preliminary Value Proposition  Path to Payment plan | Preliminary classification  Preliminary intended use  Preliminary regulatory pathway | PoC prototypes  Demonstration results  Institutional IP disclosure (if applicable) |
| 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 | Feedback from >5 economic buyers  Impact Plan  Advisory Board | Draft Essential Requirements Table for directive  Instructions of Use | “Works Like” and “Looks Like” prototypes  FTO review  Provisional IP filing  Killer Experiment |
| 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 and KOLs  Animal/ First-in-Man experiments  Peer reviewed publication(s)  Scientific Advisory Board | Investor ready business plan  Feedback from >20 economic buyers  Key management team identified  Initial seed investment | Application form to national competent authority  Data requirements  Clinical Investigation approval | “Works /Looks Like” prototypes  Manufacturing plan and costing  Full IP application  Killer technical experiment |
| 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)  Peer reviewed publication(s) | Economic data  Feedback from >50 economic buyers  1st institutional investment | Data requirements confirmation  Pre-submission | Manufacture GMP-compliant pilot lots |
| 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) | Purchasing intent from >10 buyers  2nd round of institutional investment | Complete Technical File  Technical File submission to Notified Body (CE Mark) | GMP Process Planning |
| 1. Approval & Launch (A&L) | Institutional and regulatory approval received, and sales launched | Training materials and support established  Peer reviewed publication(s) | Initial sales | Registration and Listing (CE mark obtention)  CMS Coverage and CPT Code Determination | Finalized GMP process |
| 1. Clinical Use (Use) | The solution is used successfully in day-day clinical practice | Included in local practice guidelines  Peer reviewed publication | Profitable sales | 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 | NA | NA |

This section will not be scored, it will only be used to check that the eligibility criteria “The proposal must be at least in Idea phase, TRL ≥ 2" is accomplished.

**2e) TRL**

According to the Healthcare Innovation Cycle Matrix you have completed above, state your TRL status:

|  |  |
| --- | --- |
|  | 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.

**2f) 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.

**2g) References**

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) Number of people who will directly and indirectly benefit from the proposed solution** (1000 chars-limit).

Evaluation criteria: 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) Impact if successful**

Describe the impact that your proposed solution will create if it is successful.

(3000 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.

**5) 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**

**6) 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.

**7) Implementation**

**7a) 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.

**7b) Schedule**

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

(200 chars-limit/box)

**T1 T2 T3 T4**

**Year 1**

**Year 2**

**Year 3**

**Year 4**

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.

# **7c) Budget justification**

Upload a document with the detailed budget using the template provided *(download template here*). The budget must be signed by an authorized institution.

(upload)

Please provide a description explaining why the attached budget is appropriate for the proposed work. Be sure to include personnel responsibilities and effort commitments.

(2000 chars-limit)

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

# **7d) Envisioned business model**

Describe your business model idea.

(2000 chars-limit)

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

# **7e) Compliance – Human subjects**

# Outline your research compliance plans. Describe (if applicable) the subject population and enrollment plans.

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| a) Human subjects? |  |  |

(1000 chars-limit)

Review criteria: compliance matters should be identified. Clarity of description that leads to understand the value of the chosen subject population and study criteria will be positively evaluated.

**TEAM AND SUPPORT**

**8) 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.

**9) External support**

**9a) 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.

**9b) 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>