**CIMTI Open Call for Innovation - Application form**

Please complete the following application form by **23.59 h (+1 GMT) Friday 16th October 2020**.

This form will be used to evaluate and select the projects that will take part in the CIMTI’s Impact program. The projects must obtain a minimum of 60% on each individual criteria to be accepted, a maximum of 10 projects will be selected in this call.

**Project Name\***

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

**Website**

If available, provide the link to the website of the project.

**Social Media**

If available, provide the link to social media accounts of the project.

# **Principal Investigator**

Principal Investigator:

Primary Institution:

Co-Principal Investigators and Institutions (if any):

**Eligibility criteria**

Take into account that the reviewers will check first the eligibility criteria:

* **Unmet need:** The need is classified in one of the 12 lines of the 2016-2020 Health Plan[[1]](#footnote-1)

Line:

* **Solution Status:** Only projects in at least “Proof of Concept” TRL = 3 (Question **6a**) and with a state of the art analysis performed (Question **2c**) are considered.
* **Time to impact:** The proposed route estimates maximum 5 years to be implemented in the Health System. (Question **6c**)
* **Territoriality:** The project must be totally or partially implemented in the Catalan Healthcare System and at the same time it should be thought out for its global scalability (Question **6c**)
* **CIMTI’s services:** the support required must be framed within the services offered by CIMTI through its Impact program:
* Support in project conceptualization
* Accompaniment by the CIMTI team
* Training activities
* Communication advice
* Clinical advice
* Market and business advice
* Regulatory advice
* Technological advice
* Investment advice
* Direct access to the CIMIT in Boston
* **Financing:** projects that depend exclusively on obtaining financing to be able to advance in its development, will be excluded given the impossibility to start working on them.

**Abstract**

Description and evaluation criteria: A summary of the importance of the problem addressed; an overview of proposed work, overall goals, approach, and objectives; and reasons why the work is likely to be successful and reach patient care. It should be concise and accurate, explain the nature of the work, motivation and solution.

(3000 chars-limit)

# **Video pitch**

Show us your ability to explain in lay terms your idea and its projected impact. Upload a video of maximum 1 minute. (The video is not required to be professional).

(upload)

# **Support from CIMTI**

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

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

(3000 chars-limit)

**IDEA .**

**1) Unmet Need**

Provide an overview of the clinical need motivating the work and why it is important.

(3000 chars-limit)

Review criteria: The clarity and relevance (supported by data) of the unmet need.

**2) Proposed Solution**

# **2a) Solution category** (multiple selection allowed)

Please select the category that best describes your proposed solution. In case your solution combines different categories, select multiple boxes.

This section will not be evaluated.

|  |  |
| --- | --- |
|  | Device |
|  | Diagnostic |
|  | Procedure |
|  | App/eHealth |
|  | New healthcare model |
|  | Other |

**2b) Overview of the solution**

Description of the proposed solution, the work done to date, and why it should be pursued.

(1500-chars limit)

Review criteria: Accurate description and capacity of the proposed solution to address the problem presented.

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

Please provide a description on how your proposed solution differs and improves the available alternatives. Describe its viability to be entered in the system (for example, you can explain here if you are aware of the competition prices, your product price, the area where you can implement the product, etc.).

(3000 chars-limit)

Review 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.

# **2d) Cited References**

Please provide at least one and up to five references that support your premise as to the potential value and feasibility of your proposed solution (section 2) and your unmet need (section 1).

This section will not be evaluated.

|  |  |  |
| --- | --- | --- |
|  | Reference URL | Description |
| Reference 1 |  |  |
| Reference 2 |  |  |
| Reference 3 |  |  |
| Reference 4 |  |  |
| Reference 5 |  |  |

**IMPACT .**

# **3) Improvements in efficiency and efficacy in clinical and professional practice**

# Provide a description on how your solution contributes to improve the efficiency and efficacy of current clinical care standards (e.g. improvements in health conditions, mortality, patient satisfaction, hospital readmission, etc.) and practices of healthcare professionals (e.g. ease of application, comfort of use, reduction of learning curve, etc.).

# Explain *what* is improved, and the relation cost-benefit from the perspective of healthcare providers.

# (1500 chars-limit)

Review criteria: Improvement in clinical results in comparison to the usual clinical practice (aspects to be considered: effectiveness, improvement of the living conditions, mortality, morbidity, quality of life, symptomatology, tolerability, ease of use, patient satisfaction, reduction in the number of readmission, etc.) The increase in effectiveness attributed to an improvement in professional practice will be taken into account: ease of application, ease of use, reduction of the learning curve, etc.

# **4) Improvements in safety of the patient and health personnel**

Provide a description on how does your solution contribute to improve the safety of current clinical practices (e.g. adverse effects, derivative complications, etc.), and reduce the risks or damages suffered by the health personnel, reduce the risk in decision making. Explain *what* is improved.

(1500 chars-limit)

Review criteria: Improvement in patient safety compared to the usual clinical practice is evaluated (aspects to be considered: adverse effects, complications derived from the interventions and the concomitant procedures). Risk reduction for the health staff is evaluated in comparison to the usual clinical practice (aspects to be considered: damages suffered by health personnel or risk reduction in decision making).

# **5) Amplification/scalability of social impact**

Describe how your solution contributes to address other health or social challenges beyond the main one identified and tackled by your solution, including future challenges in healthcare, as well as how your solution could be integrated and replicated in a broader healthcare context.

(1500 chars-limit)

Review criteria: The potential of the proposed solution to address future and / or broader challenges in the area of interest of the project is evaluated.

# **VIABILITY .**

# **6) Solution status**

**6a) Solution status**

Please, check all the milestones accomplished according to the Healthcare Innovation Cycle Matrix. This section will be used to classify your project status and verify you accomplish the eligibility criteria of the present call.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 |

Review criteria: Project must be at least at the “Proof-of-concept” (TRL ≥ 3) stage.

**6b) Implementation pathway**

Describe the pathway the solution will take after the proposed work to reach patients. An outline of the steps you anticipate upon the successful completion of the proposed work planned to get the solution to patients.

(3000 chars-limit)

Review criteria: The solution must demonstrate a clear value for the agents to whom it is directed. Feasibility of proposed project progress and consistency of the implementation pathway.

# **7) Limitations and barriers**

# Describe the most critical aspects of your solution and highlight 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)

Review criteria: Proof that the team is aware of their barriers by providing an accurate identification and description of them. Evaluators will take into account the degree of flexibility of the barriers: possibility of overcoming the barriers with small modifications of i) the design of the product / serves, ii) the adoption model or iii) the value system. It will be also taken into account if these modifications require great internal efforts or can be achieved by using elements already available in the ecosystem.

**8) Challenges, Work Plan, and Aims**

# **8a) Managing Challenges**

An outline of the anticipated challenges and problems envisioned and ways that the team will be able to address them.

|  |  |  |
| --- | --- | --- |
|  | Challenge | Overview of Plans to Address (200 chars-limit) |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |

# Review criteria: Potential challenges or roadblocks are identified and a reasonable plan to overcome them is provided; shown flexibility in solving challenges or problems as they arise.

# **8b) Aims**

# A description of up to three specific aims. For each aim, define one or more milestones and associated target dates. (Include Go / No Go decision points).

# **Aim 1**

|  |  |
| --- | --- |
| Aim Title (10 chars-limit) |  |
| Brief description of work to be performed, hypothesis to be tested and/or outcomes (100 chars-limit) |  |
| Primary Health Innovation Cycle Dimension | |  |  | | --- | --- | |  | Clinical | |  | Market/Business | |  | Regulatory/Approvals | |  | Technical | |
| #1 Milestone: Outcome or impact expected (100 chars-limit) |  |
| #1 Date (MM/YYYY) |  |
| #2 Milestone: Outcome or impact expected and date (Optional - 100 chars-limit)) |  |
| #2 Date (MM/YYYY) |  |
| #3 Milestone: Outcome or impact expected (Optional - 100 chars-limit) |  |
| #3 Date (MM/YYYY) |  |

# **Aim 2 (Optional)**

|  |  |
| --- | --- |
| Aim Title (10 chars-limit) |  |
| Brief description of work to be performed, hypothesis to be tested and/or outcomes (100 chars-limit) |  |
| Primary Health Innovation Cycle Dimension | |  |  | | --- | --- | |  | Clinical | |  | Market/Business | |  | Regulatory/Approvals | |  | Technical | |
| #1 Milestone: Outcome or impact expected (100 chars-limit) |  |
| #1 Date (MM/ YYYY) |  |
| #2 Milestone: Outcome or impact expected and date (Optional - 100 chars-limit)) |  |
| #2 Date (MM/ YYYY) |  |
| #3 Milestone: Outcome or impact expected (Optional - 100 chars-limit) |  |
| #3 Date (MM/YYYY) |  |

# **Aim 3 (Optional)**

|  |  |
| --- | --- |
| Aim Title (10 chars-limit) |  |
| Brief description of work to be performed, hypothesis to be tested and/or outcomes (100 chars-limit) |  |
| Primary Health Innovation Cycle Dimension | |  |  | | --- | --- | |  | Clinical | |  | Market/Bus. | |  | Regulatory/Approvals | |  | Technical | |
| #1 Milestone: Outcome or impact expected (100 chars-limit) |  |
| #1 Date (MM/YYYY) |  |
| #2 Milestone: Outcome or impact expected and date (Optional - 100 chars-limit) |  |
| #2 Date (MM/YYYY) |  |
| #3 Milestone: Outcome or impact expected (Optional - 100 chars-limit) |  |
| #3 Date (MM/YYYY) |  |

# Review criteria: Main aims and milestones are identified and detailed and follow a logical time-frame.

# **8c) Budget Justification**

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

(upload)

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

(500 chars-limit)

Review criteria: A budget has been calculated and is adjusted to the project needs and the institution has agreed to it.

# **8d) Compliance – Human subjects**

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

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

(1000 chars-limit)

Review criteria: Compliance matters are identified. Clarity of description that leads to understand the value of the chosen subject population and study criteria.

# **TEAM AND SUPPORT .**

# **9) Team Composition**

Provide the name, home institution, and a description of the project role played by all team members. Highlight the relevance of their profile to the specific tasks of the project, and their level of involvement (%).

(2000 char-limit for each)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name | Home institution | Role on proposed project |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| 4 |  |  |  |
| 5 |  |  |  |

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

Review criteria: The involvement of the promoter team and their experience and knowledge of the health system. The capacity of the internal team to address clinical, market and business and technology aspects.

# **10) External support**

Describe whether you have received support from entities external of your main organization and what type of support you received (financial, accreditation, recognition, evaluation, etc.). Specify the entities from the third sector, if any.

(1000 chars-limit)

Review criteria: The support shown by other entities is evaluated as a sign of the value that the solution has (or may have) for the system. Special interest for projects that have actively involved third sector entities.

# **10a) Other support needed**

Describe whether you need support from other entities and/or plan to involve them in the future.

(1000 chars-limit)

Review criteria: Being in the process of initiating collaborations with external entities will be valued.

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

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

**Purpose of the processing:** participation of the data subject in the IMPACT program.

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

**Recipients**: FUNDACIÓ 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. In this sense, the platform is within the framework of Privacy Shield, so it meets the security standards set by the European Union.

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>

1. http://salutweb.gencat.cat/ca/el\_departament/Pla\_salut/pla-de-salut-2016-2020/linies-estrategiques/ [↑](#footnote-ref-1)