CIMTI application form

Please complete the following application form by 13:00h (UTC+01:00) Friday 15th March 2019.
This form will be used to evaluate and select the projects that will take part in the IMPACT program of CIMTI.cat. 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. The notification period will not exceed 25 working days from the 16th March 2019.

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):

Certificate from the Spanish Tax Agency vouching that the applicant entity has fulfilled its obligations with regard to taxation, valid at the moment of presentation of the project (only if applicable) *Upload document.*

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]
  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 **2a**) are considered.
- **Time to impact:** The proposed route estimates maximum 5 years to be implemented in the Health System. (Question **6c**)

[1] http://salutweb.gencat.cat/ca/el_departament/Pla_salut/pla-de-salut-2016-2020/linies-estrategiques/

- **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 scalability globally (Question **6c**)

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). ⇧

IDEA

1) Unmet Need

Provide an overview of the clinical need motivating the work and why it is important (2000-3000 chars).

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

2) Proposed Solution

Please provide an overview of the proposed solution and how it 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.). Include up to three references that support your position.

Review criteria: capacity of the proposed solution to address the problem, 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.

2a) Overview of the Solution

Description of the proposed solution, the work done to date, and why it should be pursued. (1500-chars limit).

2b) 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.

- ○ Device
- ○ Diagnostic
- ○ Procedure

- ○ System
- ○ App/eHealth
- ○ Organisational
- ○ Health practice
- ○ Other

2c) State of the art analysis: alternatives (if any) to the proposed Solution

Provide a description of existing and/or potential alternatives considered, why you chose not to pursue them, and why your proposed solution is better. Take into account the prices of the existing solution compared to your proposed one. (2000-3000 chars).

2d) Cited References

Please provide at least one and up to three references that support your premise as to the potential value and feasibility of your proposed solution.

	Reference URL	Description
Reference 1		
Reference 2		
Reference 3		

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, and the relation cost-benefit from the perspective of healthcare providers. (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

Please describe the current status of the solution and how far you propose to advance it with this work using the Healthcare Innovation Cycle. Describe the pathway the solution will take after the proposed work to reach patients.
This section will be used to classify your application into one of the 3 types of projects CIMTI can give support to and verify you accomplish the eligibility criteria of the present call. More info here.
Review criteria: Project must be at least at the "Proof-of-concept" (TRL ≥ 3) stage. 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.

6a) Solution status

Please, check all the milestones accomplished according to the Healthcare Innovation Cycle Matrix.

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
2) 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

3)	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)
4)	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
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 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
6)	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
7)	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
8)	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
9)	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
10)	Standard of Care (SoC)	The solution is recognized as the Standard of Care	☐Recommended practice by medical specialty	☐ Dominant market share	NA	NA

6b) Implementation pathway

An outline of the steps you anticipate upon the successful completion of the proposed work planned to get the solution to patients. (2000-3000 chars limit)

7) Limitations and barriers

Describe the most critical aspects of your solution.

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.

- Product/service limitations and barriers (e.g. technical barriers, usability, etc.) (100-word limit):

- Limitations and barriers in the model of adoption (e.g. the solution requires adaptation of the structures and professionals involved) (100-word limit):

- Limitations and barriers in the economic sustainability of your solution (e.g. commercialization, revenues, costs, partnership, etc.) (100-word limit):

- Limitations and barriers in terms of collaborators needed to move the project forward (e.g. clinicians, engineers, etc.) (100-word limit):

8) Challenges, Work Plan, and Aims

A description of the challenges to be addressed in the proposed work and up to three specific aims and associated milestones. For each aim, define one or more milestones and associated target dates. (Include Go / No Go decision points). Provide a budget justification and outline your research compliance plans.

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; a budget has been calculated and is adjusted to the project needs and the institution has agreed to it; compliance matters are identified.

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 word limits)
1		
2		

3		

8b. Aim 1

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

8c. Aim 2 (Optional)

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

#2 Date (MM/ YYYY)	
#3 Milestone: Outcome or impact expected (Optional - 100 Word Limit)	
#3 Date (MM/YYYY)	

8d. Aim 3 (Optional)

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

8e. Budget Justification

Each entity/project must submit a separate budget *(download template here*) signed by an authorized institution in section 8f. Here, please provide a description of why the attached budget is appropriate for the proposed work. Be sure to include personnel responsibilities and effort commitments.

8f. Budget upload

Upload a document with the detailed budget using the provided template.

8g. Compliance – Human subjects

Please describe (if applicable) the subject population and enrollment plans.

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

	Yes	No
a) Human subjects?	○	○

TEAM AND SUPPORT

9) Team and support

Provide a description of the project team and other collaborators.

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. 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 project that have actively involved third sector entities.

9a) Team Composition

Provide the name, home institution, and a description of the project role played by up to 5 key team members. A single PDF with all biosketches for all key personnel, collaborators and significant contributors is to be uploaded via the task on the main page.

	Name	Home Institution	Role on Proposed Project
1			
2			
3			
4			
5			

9b) Other support

Describe whether you have received support from entities external of your main organization, what type of support you received (financial, accreditation, recognition, evaluation, etc.) or whether you plan to involve them in the future. Specify the entities from the third sector, if any.

3rd sector entities (100-word limit):

Other entities (100-word limit):

10) Support from CIMTI

Please, check in the table below, that shows the support we can provide, the support you would like from CIMTI (more information here). Please, write any further comments in the text box below the table. (200-word limit)

This section will not be scored but will be used to understand what do you think you need to move forward your project.

- ○ Mentoring in project conceptualization
- ○ Identification of funding instruments and support on proposal presentation
- ○ Diagnose and follow-up of project improvements following CIMIT's methodology
- ○ Facilitation of access to clinical experts
- ○ Facilitation of access to market, public sector and business development experts
- ○ Facilitation of access to experts in regulatory
- ○ Facilitation of access to experts in technology
- ○ Mentoring with an international investment expert
- ○ Investors identification and organization of presentations
- ○ Formation and training activities to maximize the impact

Comments: