

## CIMTI application form

Please complete the following application form by 13:00h (UTC+01:00) Friday 26<sup>th</sup> October 2018.

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 27<sup>th</sup> October 2018.

### 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<sup>1</sup>  
Line:
- **Solution Status:** Only projects in at least "Proof of Concept" TRL3 (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**)


<sup>1</sup> [http://salutweb.gencat.cat/ca/el\\_departament/Pla\\_salut/pla-de-salut-2016-2020/linies-estrategiques/](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 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 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 are your proposed one. (2000-3000 chars).

### 2d) Cited References

Please profile 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	<input type="text"/>	<input type="text"/>
Reference 2	<input type="text"/>	<input type="text"/>
Reference 3	<input type="text"/>	<input type="text"/>

## 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 $\geq$ 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	<input type="checkbox"/> Unmet needs defined <input type="checkbox"/> Disease state characterized	<input type="checkbox"/> Needs screening & selection <input type="checkbox"/> Existing solutions characterized	NA	NA
2) Idea	Potential solutions to unmet need developed and evaluated	<input type="checkbox"/> Clinical workflow description <input type="checkbox"/> Updated need description <input type="checkbox"/> Feedback from >5 clinicians	<input type="checkbox"/> Competitive landscape <input type="checkbox"/> Envisioned Value Proposition	<input type="checkbox"/> Medical device intended use <input type="checkbox"/> Equivalent devices	<input type="checkbox"/> Paper Prototype <input type="checkbox"/> Hypothesis and experimental design <input type="checkbox"/> Idea screening and selection
3) Proof of concept (PoC)	Key component concepts validated in models and value proposition articulated	<input type="checkbox"/> Feedback from clinicians in >5 settings <input type="checkbox"/> Updated need description and workflow	<input type="checkbox"/> Competing solutions characterization <input type="checkbox"/> Preliminary Value Proposition <input type="checkbox"/> Path to Payment plan	<input type="checkbox"/> Preliminary classification <input type="checkbox"/> Preliminary intended use <input type="checkbox"/> Preliminary regulatory pathway	<input type="checkbox"/> PoC prototypes <input type="checkbox"/> Demonstration results <input type="checkbox"/> Institutional IP disclosure (if applicable)
4) Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	<input type="checkbox"/> Feedback from clinicians in >20 settings <input type="checkbox"/> Updated need and workflow descriptions	<input type="checkbox"/> Feedback from >5 economic buyers <input type="checkbox"/> Impact Plan <input type="checkbox"/> Advisory Board	<input type="checkbox"/> Draft Essential Requirements Table for directive <input type="checkbox"/> Instructions of Use	<input type="checkbox"/> "Works Like" and "Looks Like" prototypes <input type="checkbox"/> FTO review <input type="checkbox"/> Provisional IP filing <input type="checkbox"/> 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)	<input type="checkbox"/> Feedback from >100 clinicians and KOLs <input type="checkbox"/> Animal/ First-in-Man experiments <input type="checkbox"/> Peer reviewed publication(s) <input type="checkbox"/> Scientific Advisory Board	<input type="checkbox"/> Investor ready business plan <input type="checkbox"/> Feedback from >20 economic buyers <input type="checkbox"/> Key management team identified <input type="checkbox"/> Initial seed investment	<input type="checkbox"/> Application form to national competent authority <input type="checkbox"/> Data requirements <input type="checkbox"/> Clinical Investigation approval	<input type="checkbox"/> "Works /Looks Like" prototypes <input type="checkbox"/> Manufacturing plan and costing <input type="checkbox"/> Full IP application <input type="checkbox"/> Killer technical experiment
6) Initial Clinical Trials (ICT)	Regulated production of prototypes and collection of clinical and economic data	<input type="checkbox"/> Conduct Phase 0 and/or 1 clinical trial(s) <input type="checkbox"/> Peer reviewed publication(s)	<input type="checkbox"/> Economic data <input type="checkbox"/> Feedback from >50 economic buyers <input type="checkbox"/> 1 <sup>st</sup> institutional investment	<input type="checkbox"/> Data requirements confirmation <input type="checkbox"/> Pre-submission	<input type="checkbox"/> 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	<input type="checkbox"/> Clinical efficacy trials <input type="checkbox"/> Peer reviewed publication(s)	<input type="checkbox"/> Purchasing intent from >10 buyers <input type="checkbox"/> 2 <sup>nd</sup> round of institutional investment	<input type="checkbox"/> Complete Technical File <input type="checkbox"/> Technical File submission to Notified Body (CE Mark)	<input type="checkbox"/> GMP Process Planning
8) Approval & Launch (A&L)	Institutional and regulatory approval received, and sales launched	<input type="checkbox"/> Training materials and support established <input type="checkbox"/> Peer reviewed publication(s)	<input type="checkbox"/> Initial sales	<input type="checkbox"/> Registration and Listing (CE mark obtention) <input type="checkbox"/> CMS Coverage and CPT Code Determination	<input type="checkbox"/> Finalized GMP process
9) Clinical Use (Use)	The solution is used successfully	<input type="checkbox"/> Included in local practice guidelines	<input type="checkbox"/> Profitable sales	<input type="checkbox"/> Monitoring and Inspections	<input type="checkbox"/> Patents issued <input type="checkbox"/> Improvement plan

	in day-day clinical practice	<input type="checkbox"/> Peer reviewed publication			
10) Standard of Care (SoC)	The solution is recognized as the Standard of Care	<input type="checkbox"/> Recommended practice by medical specialty	<input type="checkbox"/> 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...) (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 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	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>

## 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/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)

## 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/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)

#### 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	<input type="text"/>	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>	<input type="text"/>
4	<input type="text"/>	<input type="text"/>	<input type="text"/>

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### 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.

3<sup>rd</sup> 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 CIMTI'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: