CAMPUS CLINIC INNOVA 2025
"IDEES CAP A MERCAT"

Hospital Clínic de Barcelona (hereinafter, HCB), Fundació de Recerca Clínic Barcelona - Institut d'Investigacions Biomèdiques August Pi i Sunyer (hereinafter, FRCB-IDIBAPS), Barcelona Institute for Global Health (hereinafter, ISGlobal), and Fundació Món Clínic (Món Clínic), which together form the Campus Clínic, are launching the **CAMPUS CLÍNIC INNOVA 2025** initiative.

This initiative stems from Campus Clínic's commitment in recent years to place Innovation on its strategic agenda and integrate it into the culture of Campus Clínic professionals. HCB will act as the managing entity for the funds.

The objective of the CAMPUS CLÍNIC INNOVA initiative is to promote and consolidate innovative projects, including both process improvements (healthcare and non-healthcare) and scientific-technological products, with a clear focus on their applicability in the healthcare environment.

This initiative consists of two programs, focused on different types of innovative projects with distinct approaches that accommodate the aforementioned projects:

- The "**MILLOREM EL CLÍNIC**" program is focused on improvement and transformation projects with an impact on the organization and processes of HCB, at any of its locations. The objective of this program is to recognize projects that provide value and have a clear impact on patients, professionals, and/or resources, in line with the priorities set out in the NUCLI 2025 Strategic Plan, to make a more Accessible, Sustainable, and Intelligent hospital based on pioneering solutions. The terms and conditions for the "Millorem el Clínic" program can be found in a separate document.
- The "**IDEES CAP A MERCAT**" program is designed for innovative scientific-technological projects with commercial potential, accommodating both incipient and more mature projects. It will consist of 2 categories, clearly differentiating projects based on their maturity status:
    - "**Incubem**" will focus on projects with Innovation Maturity Levels (IMLs) 1 (defined need) to 3 (proof of concept).
    - "**Accelerem**" will drive projects with IMLs 4 (proof of feasibility) to 6 (initial clinical trials).

See Annexes for a detailed explanation of Innovation Maturity Levels (IMLs).

Deadlines

The calendar for submitting projects to "Idees Cap a Mercat" is as follows:

2 June 2025	Call opens
23 June 2025	Deadline for Expression of Interest (EOI) – only for "Idees cap a Mercat" projects
25 July 2025, a les 19:00	Call closes
22 October 2025	Event – winners announced

"Idees cap a Mercat" Program

1. Description

The "**IDEES CAP A MERCAT**" program is designed for innovative scientific-technological projects with potential for market transfer, accommodating both initial and more mature projects. It will consist of two categories, clearly differentiating projects based on their maturity status:

- "**Incubem**" will focus on projects with IMLs 1 (defined need) to 3 (proof of concept).
- "**Accelerem**" will drive projects with IMLs 4 (proof of feasibility) to 6 (initial clinical trials).

Within each category, projects can be submitted in three different modalities:

- Biotech: compounds with therapeutic activity, antibodies, biomarkers, cell models, drug combinations, or similar.
- Medtech: medical devices, in-vitro diagnostic tests, among others.
- Digital Health: artificial intelligence (AI), mHealth applications, eHealth, digital therapies (DTx), *Electronic Health Records* (EHR), telemedicine, among others.

Selected projects will receive the following benefits:

- Economic aid (see table for amounts).
- Access to the **Support Program**, which aims to accelerate selected projects, accompanying them in the valorisation of their assets for 12 months from the project's kick-off. The goal is for projects to advance in fundamental aspects within the Health Innovation Cycle (see Annex 3), increasing their IMLs. It is not necessary to evolve in all 4 domains simultaneously, but the methodology provides a holistic view that helps advance all aspects of a project as a whole. The support team consists of experts from the Campus Clínic Innovation teams and is supported by external experts from the Catalan innovation ecosystem.

With this program, Campus Clínic seeks to offer new competitive funding channels to innovative projects that help advance the maturation of selected technologies and reduce their risk, with the objective of:

(1) Supporting the definition and development of the project strategy.

(2) Validating the market potential and feasibility of the project for the "Incubem" category.

(3) Bringing them closer to market requirements and enabling their transfer through a license to an existing company or the creation of a spin-off, for the "Accelerem" category.

2. Eligibility Criteria for Beneficiaries and Projects

Requirements for Professionals:

- Must have an indefinite contract or a contract valid for the next 3 years with one of the following institutions that form the Campus Clínic: HCB, FRCB-IDIBAPS, or ISGlobal.
- A single professional can submit a maximum of one proposal in the same call for the "Idees cap a Mercat" program. However, they can be part of the work team of a proposal led by another professional.

Eligible Projects:

- Must be part of one of the three funded modalities.
- Must be focused on the development and/or validation of a technology (to advance its IML and/or reduce project risk) that must necessarily have an innovative focus and potential for market transfer.
- Must be able to justify ownership by Campus Clínic institutions (HCB, FRCB-IDIBAPS, ISGlobal) exceeding 50% individually or jointly. Projects that do not have an ownership distribution agreement at the time of submitting the project must confirm their commitment that this condition will be met at the time of distribution. If this condition is not met and the project has been selected, the prize money must be returned to the initiative's managing entity.

Projects that are not eligible:

- Cannot justify ownership exceeding 50% for Campus Clínic institutions (HCB, FRCB-IDIBAPS, ISGlobal).
- Have been incorporated, via a licensing agreement, into an already constituted company (spin-off) or any other external company at the time of application.
- The ownership of the technology or exploitation rights belongs to an external company or spin-off.
- Have been winners in previous editions, with the exception of winning projects in IML 1-3 that justify their evolution and apply to “Accelerem Projects”.

3. Economic Conditions

Selected projects will receive financial aid based on the category they apply for and the funding needs justified in the work plan. Projects in the “Incubem” category will receive a maximum of €15,000 per project, while projects in the “Accelerem” category can receive up to €30,000.

Program	**IDEES CAP A MERCAT**	
Categories	**Incubem (IML 1-3)**	**Accelerem (IML 4-6)**
Scope	Biotech	
	Medtech	
	Digital Health	
Funding	Max 15.000€ / project	Max 30.000€ / project

The funding granted to beneficiary projects can only be used for project development expenses with the purpose of advancing its viability and valorisation, increasing its IML.

In no case can the aid be justified by salaries of researchers and/or administrative staff. Indirect costs (overheads) cannot be included either.

Details of **eligible expenses**:

- Consumables (for validation experiments, proof of concept).
- Subcontracting Innovation activities (e.g., external services necessary for project development, such as consulting on business aspects, intellectual property, regulatory).
- Technological product development (prototyping, with a clear orientation towards validation/market).
- Maintenance costs of existing intellectual property, up to a maximum of 20% of the total budget.

Details of **non-eligible expenses**:

- Personnel hiring expenses.
- Basic research activities.
- Subcontracting services to companies in which Campus Clínic institutions have a stake.

Compatibility of aid:

If selected projects have previously or concurrently obtained other types of funding, it must be ensured that both funding lines cover different activities, avoiding double funding. In the case of having other funds, beneficiaries commit to signing a document declaring that the received funds do not subsidize the same tasks to be developed in the project, and if applicable, to inform funders of existing aid. Failure to comply with the terms of the call once funding has been granted, the managing entity reserves the right to reclaim it.

4. Application

Step 1: EOI

Projects interested in applying may send an Expression of Interest (EOI) directly by email to innovacio@clinic.cat by **June 23, 2025**. Projects that send an EOI will receive support from the Campus Clínic Innovation team in drafting the final project proposals.

If no EOI is sent, projects may still apply to the "Idees cap a mercat" call, but support in drafting and submitting proposals cannot be guaranteed.

Step 2: Submission of project proposals

To submit the proposals, interested professionals must submit the following documentation through the AcceleratorApp platform, which can be found at the following link:

https://campusclinicinnova.acceleratorapp.co/application/new?program=idees-cap-a-mercat-cci-2025

- Completed application form (found at the application link).
- Project PPT presentation complementing the form: providing preclinical results, images that help understand the problem-solution, problem size estimation, etc., with 5 slides.

5. Evaluation and Selection Process

The selection of winning projects will be governed by the conditions specified below, which include the evaluation criteria and the composition of the evaluation committee. Once the call closes, proposals will be reviewed to determine their validity based on inclusion and exclusion criteria. At this point, the evaluation committee may decide to discard applications that do not meet the mentioned criteria. The committee also reserves the right to change projects between categories (Incubem and Accelerem) if it considers that they have applied to a category that is not appropriate for the maturity level presented by the project.

Evaluation Phase 1: Remote evaluation

From among the candidate proposals, the evaluation committee will select a maximum of 12 finalist projects from all received (6 projects in the "Incubem" category and 6 in "Accelerem"). The evaluation committee is composed of external experts to Campus Clínic, who will contribute their knowledge in the evaluation of innovative projects in the Health sector.

Evaluation Phase 2: Finals

The 12 finalist projects will defend their project before an external expert jury in an oral presentation. This

jury will be responsible for deciding the 6 winners, 3 in "Incubem" and 3 in "Accelerem". The selected projects will be announced during the presentation and awards ceremony that will take place during the CAMPUS CLÍNIC INNOVA 2025 Conference. These selected projects will have to briefly present their project in 1 minute to the public.

Evaluation Criteria:

PROBLEM (30%) • Relevant identified need • Market size and potential • Project impact (social, economic, and sustainability)	**SOLUTION (20%)** • Degree of solution disruption • Value proposition, competitive advantage • lability of the solution (the solution can be easily implemented in other hospitals, reach different geographical areas, etc.)
TRANSFERABILITY AND IMPLEMENTATION CAPACITY (20%) • Viable business model • Viability of IP strategy • and economic justification	**TEAM (30%)** • Motivation and dedication of the work team • Complementarity of team members

It is important to mention that the evaluation committee commits to selecting winning projects in both categories (Accelerem and Incubem) independently. However, there is no guarantee that projects will be selected within all three modalities per category. The organization of the initiative reserves the right to redistribute winning projects across different modalities if it considers that they have not applied to the correct category based on their maturity status (IMLs).

6. Commitment of Selected Projects

- Project leaders of winning projects commit to participating in the support program, which implies:
- A first kick-off meeting with the Campus Clínic Innovation team to design the work plan and the use of economic resources (tentatively, in December 2025).
- Periodic monthly work and project follow-up meetings (to be defined with the support team).
- Mentoring sessions with external experts, to receive active feedback on the project.
- A closing meeting, to assess the support received, the project status, budget execution, and evaluate next actions. A brief summary of the milestones achieved in the project thanks to the received funding must be provided.

Failure to actively participate in the support program, HCB reserves the right to reclaim the unexecuted economic aid from the project team. In case of project inactivity or agreed closure with the project team, any money not used after one year must be returned to the initiative's managing entity (HCB).

7. Confidentiality and Personal Data Protection

All those involved in the organization of the initiative are subject to confidentiality agreements. In

compliance with applicable regulations on the protection of personal data, we inform that the personal data provided within the framework of participation in the Campus Clínic Innova initiative will be incorporated into a file with the exclusive purpose of the correct organization and development of the program. The submitted documentation will be deleted from the archives of the HCB Research and Innovation Directorate upon request of the applicant.

8. Ownership of Results and Intellectual Property

Selected projects must adhere to the internal Intellectual Property Rights (IPR) policies of the Campus Clínic institution to which they belong.

9. Publicity and Dissemination

Selected projects commit to authorizing Campus Clínic institutions to record their oral communication within the framework of the CAMPUS CLÍNIC INNOVA 2025 Conference if applicable, and the subsequent dissemination of their work through any of the institutional communication channels. This authorization implies the commitment of Campus Clínic institutions not to transfer the images to any other company and not to use them for any commercial purpose.

10. Acceptance of the Terms

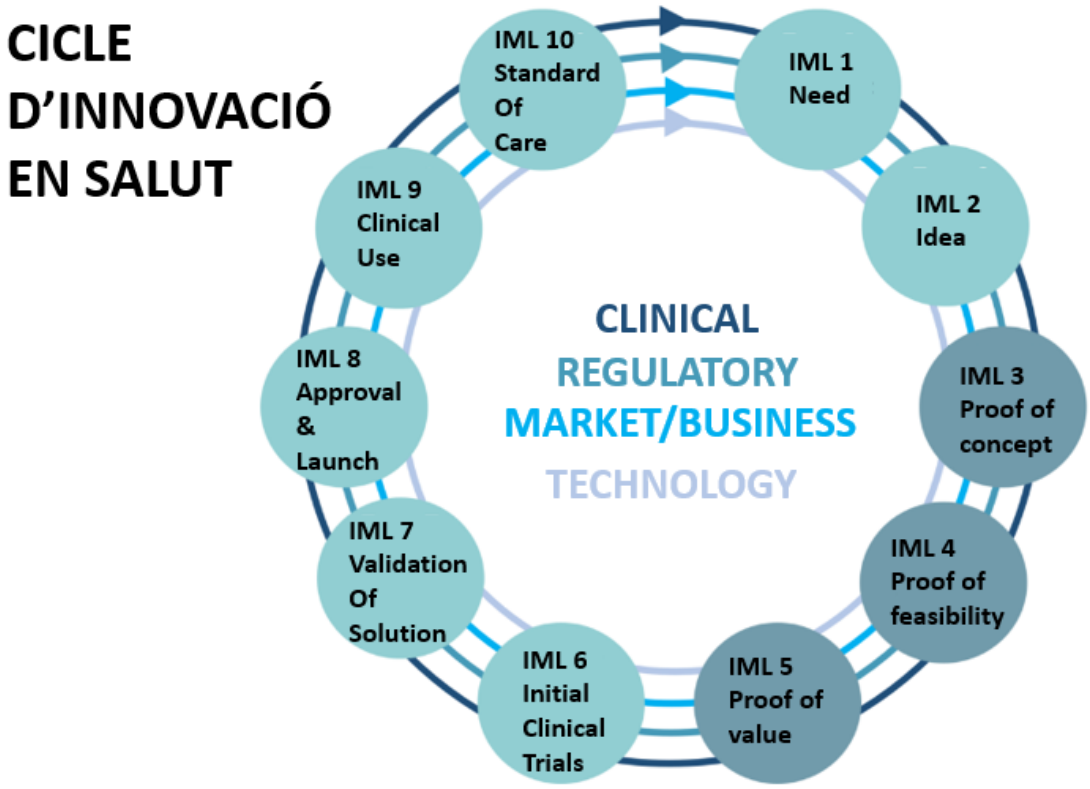
Through the registration process, candidates assume the following commitments:

- They accept and comply with the program's terms.
- Participation in this call implies acceptance of these terms and the decision of the evaluation committee, and the renunciation of any type of claim.
- The information provided is truthful. If not, the submitted proposals will be discarded.
- They are the intellectual authors of the ideas they present and have not used privileged or registered information without the corresponding permissions.
- They commit to delivering additional information that may be required and is not confidential.

Annex 1 – Innovation Maturity Levels (IMLs)

To evaluate the maturity of an innovation project, we use the **Health Innovation Cycle**, which is based on the Innovation Maturity Levels (IML) scale. It is a 10-phase scale (10 IMLs) based on milestones that determine the milestones of the **Health Innovation Cycle**. This methodology is based on a 10-phase scale (10 IMLs), which allows innovative individuals and entities to advance more quickly and effectively in the development of their projects. To maximize the efficiency and probability of project success, it is important to advance in parallel in 4 domains (clinical, market/business, regulatory, and technology) between each of the phases.

It is a methodology developed by CIMIT in Boston (www.cimit.org), specific to Health projects and with a degree of distinction between projects in the Biotech, Medtech, and Digital Health fields.



To know exactly which activities a project must have completed to be considered at one IML or another, there are checklists for different types of projects. These checklists are detailed in the following Annexes.

Annex 2 –MEDTECH projects

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical	Market/Business	Regulatory	Technology
1	Need	Insights into unmet clinical needs and available solutions	❑ Unmet need statement ❑ Disease state characterization	❑ Needs screening & selection ❑ Existing solutions characterization	❑ Regulatory familiarization	❑ State-of-the-Art summary
2	Idea	Potential solution to unmet need described, evaluated and selected	❑ 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 (MDR in EU) ❑ Comparable identified	❑ Idea screening and selection ❑ Paper Prototype ❑ Institutional IP disclosure
3	Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	❑ Feedback from clinical stakeholders 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 Freedom to Operate (FTO) Assessment ❑ Updated institutional IP disclosure ❑ Key in-sourcing requirements
4	Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	❑ Feedback on users 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	❑ Draft essential requirements checklist ❑ Draft product claims ❑ Draft instructions for use ❑ Institutional approval request(s) ❑ Submission pathway defined	❑ Product Requirement Document (PRD) ❑ "Works Like" and "Looks Like" prototypes ❑ Essential experiment results ❑ Provisional IP filing & initial FTO review ❑ Key in-sourcing plans ❑ Manufacturing/QMS plan
5	Proof of Value (PoV)	The potential of the solution to work and create value for all	❑ Feedback from 100+ users ❑ Feedback from 5+ KOLs	❑ Key management team committed ❑ Investor ready business plan	❑ Essential requirements checklist ❑ Application form to competent authority submitted	❑ "Works Like, Looks Like, Made Like" prototypes ❑ Essential technical experiments results

		stakeholders is demonstrated	❑ Use Case/ scenarios testing with 10+ users ❑ **Animal/first in/with man experiments** ❑ Medical advisory board ❑ Clinical trial endpoints	❑ Feedback from 20+ economic buyers ❑ **Initial Seed Investment** ❑ Key relationships formalized ❑ Incorporation & Founders agreement	❑ Clinical Investigation approval(s)	❑ IP search report ❑ GMP compliant pilot manufacturing process ❑ Key in-sourcing requirements committed
6	**Initial Clinical Trials (ICT)**	**Regulated production of prototypes and collection of clinical and economic data**	❑ **Endpoints achieved in Feasibility clinical trials** ❑ Demo feedback from 25+ users ❑ Peer reviewed publication(s) submitted	❑ Value quantification ❑ Feedback from 25+ economic buyers ❑ **1st institutional investment**	❑ GDPR/HIPAA compliance ❑ Security and vulnerability certifications ❑ Data requirements confirmation ❑ Pre-submission filed	❑ cGMPs compliant manufacturing process ❑ Updated specification & experimental validation ❑ All in-sourcing licensing 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 ❑ **2nd round of institutional investment**	❑ Submission of Technical file to regulatory body	❑ Quality assured process validation (cGMP) ❑ Updated specification & experimental validation
8	**Approval & Launch (A&L)**	**Institutional and regulatory approval received and sales launch**	❑ Training materials & support established ❑ Specialty medical groups review in place	❑ **Initial sales** ❑ Regionalization plans	❑ **Registration and listing** ❑ **CMS/Public Coverage and CPT/DRG code determination**	❑ Finalized cGMP production environment ❑ IP for improvements filed
9	**Clinical Use (Use)**	**The solution is used successfully in day-to-day clinical practice**	❑ Included in local practice guidelines ❑ Peer reviewed publications	❑ **Profitable sales** ❑ New markets launched	❑ Monitoring/ inspections	❑ Improvement plan ❑ **Key patents issued**
10	**Standard of Care (SoC)**	**The solution is recognised as the standard of care**	❑ Recommended practice by medical specialty	❑ Dominant market share ❑ Health economics study	❑ Product Obsolescence plan	❑ Component Obsolescence plan

Annex 3 –DIGITAL HEALTH projects

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical	Market/Business	Regulatory	Technology
1	Need	Insights into unmet clinical needs and available solutions	❑ Unmet need statement ❑ Disease state characterization	❑ Needs screening & selection ❑ Existing solutions characterization	❑ Regulatory familiarization	❑ State-of-the-Art summary
2	Idea	Potential solution to unmet need described, evaluated and selected	❑ 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 (MDR in EU) ❑ Comparable identified	❑ Idea screening and selection ❑ System and module requirement specification ❑ Interface mock-ups ❑ Institutional IP disclosure
3	Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	❑ Feedback from clinical stakeholders 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	❑ Preliminary system and software architecture ❑ Key module PoC prototypes ❑ Demonstration results ❑ Updated institutional IP disclosure ❑ Key in-sourcing requirements
4	Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	❑ Feedback on users 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	❑ Draft essential requirements checklist ❑ Draft product claims ❑ Draft instructions for use ❑ Institutional approval request(s) ❑ Cyber security plan ❑ Submission pathway defined	❑ Product Requirement Document (PRD) ❑ Software and hardware architecture ❑ "Works Like" prototype ❑ Essential experiment results ❑ Provisional IP filing & initial FTO review ❑ Key in-sourcing plans ❑ Risk mitigation and interoperability plan
5	Proof of Value	The potential of the solution to work and create value for all	❑ Feedback from 100+ users ❑ Feedback from 5+ KOLs	❑ Key management team committed ❑ **Investor ready business plan**	❑ Essential requirements checklist	❑ "Works Like, Looks Like, prototypes ❑ Essential technical experiments results

	(PoV)	stakeholders is demonstrated	❑ Medical advisory board ❑ Clinical pilot ❑ Clinical trial endpoints	❑ Feedback from 20+ economic buyers ❑ Initial Seed Investment ❑ Key relationships formalized ❑ Incorporation & Founders agreement	❑ Application form to competent authority submitted ❑ Clinical Investigation approval(s) ❑ Protected Health Information (ePHI) plans	❑ Interoperability validation ❑ cGMP medical software and production environments (s) ❑ Key in-sourcing requirements committed
6	Initial Clinical Trials (ICT)	Regulated production of prototypes and collection of clinical and economic data	❑ **Endpoints achieved in Feasibility clinical trials** ❑ Demo feedback from 25+ users ❑ Peer reviewed publication(s) submitted	❑ Value quantification ❑ Feedback from 25+ economic buyers ❑ **1st institutional investment**	❑ GDPR/HIPAA compliance ❑ Security and vulnerability certifications ❑ Data requirements confirmation ❑ Pre-submission filed	❑ Updated specification & experimental validation ❑ All in-sourcing licensing 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 ❑ **2nd round of institutional investment**	❑ Submission of Technical file to regulatory body	❑ Quality assured process validation (cGMP) ❑ Updated specification & experimental validation
8	Approval & Launch (A&L)	Institutional and regulatory approval received and sales launch	❑ Training materials & support established ❑ Specialty medical groups review in place	❑ Initial sales/deployment ❑ Regionalization plans	❑ **Registration and listing** ❑ **CMS/Public Coverage and CPT/DRG code determination**	❑ Finalized cGMP production environment ❑ Regionalization requirements
9	Clinical Use (Use)	The solution is used successfully in day-to-day clinical practice	❑ Included in local practice guidelines ❑ Peer reviewed publications	❑ **Profitable sales** ❑ New markets launched	❑ Monitoring/ inspections	❑ Improvement plan ❑ Regionalization implemented
10	Standard of Care (SoC)	The solution is recognised as the standard of care	❑ Recommended practice by medical specialty	❑ Dominant market share ❑ Health economics study	❑ Product Obsolescence plan	❑ Component Obsolescence plan

Annex 4 –BIOMARKERS projects

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical	Market/Business	Regulatory	Technology
1	Need	Insights into unmet clinical needs and available solutions	❑ Unmet need statement ❑ Disease state characterization	❑ Needs screening & selection ❑ Existing solutions characterization	❑ Regulatory familiarization	❑ State-of-the-Art summary
2	Idea	Potential solution to unmet need described, evaluated and selected	❑ Clinical 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 (MDR in EU) ❑ Comparable identified	❑ Idea screening and selection ❑ Preliminary Target Product Profile ❑ Biological mechanism of action identified ❑ Institutional IP disclosure
3	Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	❑ Feedback from clinical stakeholders 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	❑ Key mechanism of action validated ❑ Updated Target Product Profile (TPP) ❑ Preliminary Freedom to Operate (FTO) Assessment ❑ Updated institutional IP disclosure ❑ Key in-sourcing requirements
4	Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	❑ Feedback on users 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	❑ Draft essential requirements checklist ❑ Draft product claims ❑ Draft instructions for use ❑ Institutional approval request(s) ❑ Submission pathway defined	❑ Updated Target Product Profile (TPP) ❑ "Works Like" and "Looks Like" packaging prototypes ❑ Essential experiment results ❑ Provisional IP filing & initial FTO review ❑ Key in-sourcing plans ❑ Manufacturing/QMS plan
5	Proof of Value (PoV)	The potential of the solution to work and create value for all stakeholders is demonstrated	❑ Feedback from 100+ users ❑ Feedback from 5+ KOLs ❑ Animal/first in/with man experiments ❑ Medical advisory board	❑ Key management team committed ❑ Investor ready business plan ❑ Feedback from 20+ economic buyers ❑ Initial Seed Investment ❑ Key relationships formalized	❑ Essential requirements checklist ❑ Application form to competent authority submitted ❑ Clinical Investigation approval(s)	❑ "Works Like, Looks Like, Made Like", "Made Like" prototypes ❑ Updated TPP & Essential technical experiments results ❑ IP search report

			❑ Clinical trial endpoints	❑ Incorporation & Founders agreement		❑ cGMP compliant pilot manufacturing process ❑ Key in-sourcing requirements committed ❑ Conference/poster session/paper submitted
6	Initial Clinical Trials (ICT)	Regulated production of prototypes and collection of clinical and economic data	❑ **Endpoints achieved in Feasibility clinical trials** ❑ Peer reviewed publication(s) submitted	❑ Value quantification ❑ Feedback from 25+ economic buyers ❑ **1st institutional investment**	❑ Data requirements confirmation ❑ Pre-submission filed	❑ cGMPs compliant manufacturing process ❑ Updated TPP & experimental validation ❑ All in-sourcing licensing 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 ❑ **2nd round of institutional investment**	❑ Submission of Technical file to regulatory body	❑ Quality assured process validation (cGMP) ❑ Updated TPP & experimental validation
8	Approval & Launch (A&L)	Institutional and regulatory approval received and sales launch	❑ Training materials & support established ❑ Specialty medical groups review in place	❑ **Initial sales** ❑ Regionalization plans	❑ **Registration and listing** ❑ **CMS/Public Coverage and CPT/DRG code determination**	❑ Finalized cGMP production environment ❑ IP for improvements filed
9	Clinical Use (Use)	The solution is used successfully in day-to-day clinical practice	❑ Included in local practice guidelines ❑ Peer reviewed publications	❑ **Profitable sales** ❑ New markets launched	❑ Monitoring/ inspections	❑ Improvement plan ❑ Key patents issued
10	Standard of Care (SoC)	The solution is recognised as the standard of care	❑ Recommended practice by medical specialty	❑ Dominant market share ❑ Health economics study	❑ Product Obsolescence plan	❑ Component Obsolescence plan

Annex 5 – BIOTECH projects

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical Validation	Market/Business	Technology	Regulatory
1	Need	Insights into unmet medical needs and available solutions	❑ Unmet needs defined ❑ Disease state characterized ❑ Biological Mechanism of action identified ❑ Cellular disease pathway identified and described	❑ Deficiency in existing solutions identified ❑ Competitive landscape identified (academic, in pre-clinical/clinical development/commercial) ❑ Market Assessment/ Initial description of target population and its biological characteristics	❑ Molecular target/s identified ❑ Approaches for pharmacological targeting searched and identified ❑ Proposed technological modality explored (small molecule, antisense oligo, antibody, gene therapy, cell therapy, repurposed/repositioned product, etc) ❑ Initial patent landscape reviewed and patentability assessment done ❑ Initial institutional "Idea" (IP) disclosed to employer	❑ Clinical trials in the indication identified for reference trial design and timelines (ie. clinicaltrials.gov landscape)
2	Idea	Potential solution to unmet need described, evaluated and selected	❑ Biological pathway studied and intervention/perturbation approaches developed ❑ Biotechnological platform characterized and potential use cases developed ❑ Proposed patient population (SOP) defined including genetic or other bio markers (biochemical, cellular, imaging/digital/electrophysiological) if possible	❑ Envisioned Value Proposition ❑ Target Product Profile – (TPP) first iteration ready ❑ Identified complementary IP ❑ Initial dialogue with potential stakeholders (Pharma, VC, Corporate VC, Incubators) with positive feedback ❑ Investor ready business plan (milestone-based development plan R&D)	❑ Technological modality selected ❑ Mechanism of action of target group elucidated in vitro ❑ Compound starting point, screening and selection scheme planning done ❑ Compound selection assay development initiated ❑ Biological hypothesis and pharmacological hypothesis formulation identified ❑ For repurposed molecules not in the market (ie, shelved big pharma products) explore availability of clinical dossier from originator ❑ In licensing discussions with owners of IP have started (host institute, exclude originators of repurposed products until method of use patent is filed) ❑ Statement of employer issued ❑ Prior art has been assessed (Freedom to Operate analysis) and patentability of the innovation is confirmed by a patent attorney ❑ Translational models (patient sample based or in-vivo) identified	❑ Regulatory Familiarization started ❑ For rare disease, paediatric or cell & gene therapy: Consulted the regulatory roadmap pathways if applicable and familiarized with alternative pathways
3	Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	❑ Mechanistic and therapeutic hypothesis validated in genetic/metabolic models and/or patient derived cells – go/no-go decision ❑ For repurposed products: Proof of concept in relevant in vivo model obtained with repurposed candidate with favourable HED (prospective dose in humans below doses already tested or within safety margins)	❑ Business model defined - Value inflection points identified and preliminary value creation plan defined ❑ **Seed investment secured** ❑ Stakeholder map defined ❑ Scientific Advisory Board recruited ❑ Communication & public dissemination plan established (ie: thesis, papers & communications in relevant scientific forums) ❑ Killer experiment identified	❑ Initial hits/compound candidates synthesized and evaluated ❑ Initial pharmacology analysis – efficacy, safety, PK and bioavailability in rodent/relevant animal model (if applicable) ❑ **IP strategy defined and first IP filing initiated** ❑ For non-generic repurposed products: started negotiations with originators to access IP & clinical development - enabling data (updated IPMD, only if robust IP is filed) ❑ For biological or gene-therapy products: manufacturing roadmap and costing estimates defined ❑ If platform – initial creation and testing of platform modules and building blocks	❑ Preliminary regulatory pathway defined ❑ For advanced therapies or paediatric diseases: scientific advice / pre-IND meeting or equivalent feedback required
4	Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	❑ **Hit/lead compounds efficacy and potency in animal model or patient derived model validated**	❑ Deal and market benchmark cases identified ❑ Collection of economic data compared to SoC initiated (e.g. validating beach-head market)	❑ Feasibility proven in essential experiment – safety, bioavailability, PK-PD. **For gene therapy product: biodistribution data in big animal (monkey, pig) provided** ❑ **Composition of matter IP filed** - IP search report is promising	❑ Drafted essential requirements checklist ❑ Retrospective study performed if data available

			❑ For biologicals or gene-therapy products: efficacy data in animal model obtained with regulatory compliant final candidate. ❑ Updated need description with confirmation of target patient population ❑ Proposed treatment scheme developed (preventive/therapeutic acute/chronic etc.) ❑ Clinical KOLs consulted in adhoc preparatory meetings, positive engagement and commitment to participate in clinical trials ❑ Draft clinical development plan completed (Incl. target population and line of care and target regimen) ❑ CRO screening initiated ❑ Potential biomarkers identified	❑ Pricing estimates validated through third party independent primary research ❑ Target Product Profile – (TPP) refined	❑ In-licensing or round-A discussions are in progress to mutual satisfaction ❑ Manufacturing expertise initial conversations	❑ Submission pathway defined and validated by a regulatory body (scientific advice in EMA or official pre-IND meeting for FDA) ❑ Biomarker validation study approved, if needed
5	**Proof of Value (PoV)**	**The potential of the solution to work and create value for all stakeholders is demonstrated**	❑ **Clinical lead candidate validated in clinically relevant animal model** ❑ Clinical advisory board recruited ❑ **Clinical protocol completed** ❑ Clinical CRO selected ❑ Clinical endpoints defined and validated vs. competition – clinical target efficacy value defined	❑ Peer reviewed publication(s) accepted - preclinical (consider strategic perspective) ❑ Collection of economic data compared to SoC completed ❑ Series A/B financing completed ❑ Advanced stakeholder partnering discussions ongoing ❑	❑ Minimum viable product (MVP) ready – clinical lead optimized ❑ CMC development started in parallel to IND-enabling safety tox preclinical package. ❑ Pharmaceutical development started ❑ **Full IP application – freedom to operate positive opinion.** ❑ In-licensing of essential IP is completed (For Repurposed products: including third party IND-enabling clinical data)	❑ Application form to competent authority submitted ❑ Submission data package defined (essential Requirements checklist) ❑ IND/CTA meeting scheduled/performed ❑ **IND/CTA approved** ❑ Clinical Investigation approval(s) achieved (Ethical committees/IRBs)
6	**Initial Clinical Trials (ICT)**	**Regulated production of prototypes and collection of clinical and economic data**	❑ **Endpoints Successfully achieved in clinical safety/efficacy trials (Phase 1/2 clinical trials)**	❑ Pharmacoeconomics analysis performed ❑ Advanced discussions for next steps with investors and stakeholders (pharma) ❑	❑ Pre-clinical development of additional portfolio products ❑ Long term safety studies if appliable ❑ Potential formulation updates for lead product explored	❑ Additional data submitted ❑ Scientific advise / FDA consultation to validate phase II design
7	**Validation of Solution (VoS)**	**The solution is shown to be effective and its value to all stakeholders is validated**	❑ **Endpoints Successfully achieved in clinical efficacy trials (Phase 2a/2b)** ❑ Preparation of Phase 3 clinical studies ❑ Peer reviewed publication(s) accepted -clinical ❑ Additional indications explored ❑ Biomarker /companion diagnostic validated (if applicable)	❑ **Collaboration in place with Pharma / multiple pharma's** ❑ Gearing up partnerships and development of new pipeline products ❑ Financing efforts in place for next round (private or public)	❑ Pharmaceutical development (final commercial formulation) completed ❑ Carcinogenicity studies if applicable. ❑ For biological products: full specs validated with regulatory bodies ❑ For immunological products: potency test validated with regulatory bodies ❑ Manufacturing of clinical batch for later phase clinical studies ❑ **Development of new products on the pipeline – IP submitted**	❑ Additional data submitted ❑ Proactive scientific advise / FDA consultation to validate phase III strategy
8	**Approval & Launch (A&L)**	**Institutional and regulatory approval received and sales launch**	❑ Specialty medical groups review in place ❑ KOL's and clinical leads recruited and supportive ❑ **Endpoints Successfully achieved in Phase 3 clinical studies** ❑ Post marketing trial initiated	❑ **Initial sales achieved** ❑ Expanding sales activities	❑ Three manufacturing batches validated ❑ Alternative manufacturers identified ❑ Manufacturing capability expansion planned	❑ **Registration approval and listing** ❑ CMS/Public Coverage and CPT/DRG code determination obtained
9	**Clinical Use (Use)**	**The solution is used successfully in day-to-day clinical practice**	❑ Included in practice guidelines ❑ Additional data published in peer reviewed journals	❑ Profitable sales achieved ramp-up ❑ New markets launched	❑ Key patents issued. ❑ Competition monitored ❑ Alternative manufacturing sites validated (it may take over 2 years)	❑ Monitoring/ inspections
10	**Standard of Care (SoC)**	**The solution is recognised as the standard of care**	❑ Recommended practice by medical specialty	❑ Dominant market share status ❑ Operating margin profile achieved	❑ Patents issued - Patent Lifecycle Management	❑ Health economic studies carried