

Terms and conditions

1. Introduction

[Impact1](#) at Stanford Biodesign and [i4KIDS](#) at Sant Joan de Déu Barcelona Children's Hospital are two leading initiatives in the field of pediatric and maternal health innovation. Impact1 at Stanford Biodesign focuses on developing and supporting breakthrough healthcare technologies through a rigorous methodology encompassing identification of unmet needs, development of solutions, and implementation strategy. i4KIDS is a pediatric innovation hub coordinated by SJD Barcelona Children's Hospital, which is dedicated to help advancing innovative projects that can generate an impact and social change in the field of pediatrics and maternal health.

The Impact4kids collaboration aims to leverage the strengths of both Impact1 and i4KIDS to drive significant advancements in pediatric and maternal health. The strategic objectives of Impact4kids program include promoting research and innovation by facilitating the exchange of knowledge, expertise, and resources. By strengthening collaboration between the US and EU; and increasing awareness of the need for innovation in this sector the program seeks to create a robust network of researchers, innovators, and advocates.

To support innovators, Impact4kids will provide comprehensive education and training programs, offer mentorship and support for early-stage projects to streamline the processes of unmet need validation, solution development, clinical validation, regulatory approval and market access. In addition, it will provide an ecosystem immersion to facilitate connections in both the US and EU markets, and enhance networking opportunities, reputation, and visibility will be key components of the program, as well as facilitate access to vital funding sources. This program is a unique opportunity bringing together top experts from both US and EU specifically in the fields of pediatric and maternal health.

2. Impact4kids Program Structure and Services Provided

The Impact4kids program offers a comprehensive, 6-month support structure designed to drive innovation in pediatric and maternal health. Through this structured approach, innovators receive essential guidance, resources, and connections tailored to address the unique challenges of healthcare innovation, including solutions spanning medtech, biopharma, and digital health.

The program provides interactive sessions that deliver insights into the critical steps of development, validation, and implementation strategies across the US

and EU markets. The sessions will cover crucial areas, including key differences and considerations on regulatory pathways, intellectual property, pricing, and reimbursement in the US and EU, enhancing the projects' readiness for market entry and long-term success.

Beyond structured sessions, the program offers ongoing, personalized support through coaching that guides innovators in clearly articulating their project's unmet need and refining their overall development and implementation strategy. Participants also receive expert feedback and gain access to valuable connections that help advance their innovations.

A key component of the program is fostering a collaborative community where entrepreneurs can support each other and share experiences, strengthening their networks as they work toward market access. To broaden their perspective, participants will also benefit from a virtual ecosystem immersion in both the US and EU, providing direct exposure to the dynamics of innovation in these healthcare markets.

3. Eligibility Criteria:

The following conditions are mandatory for participation in the Impact4kids Program. Proposals that do not meet these eligibility criteria will not be admitted to the evaluation phase.

- **Target Population:** The proposal must address needs in the field of fetal, neonatal, pediatrics, and/or maternal health.
- **Type of Solution:** Proposed solutions must be innovative and technology-based, falling within one of the following categories: medical devices, diagnostics, digital health, healthcare services, and biotechnology.
- **Solution Status:** The proposal must be at least in the proof-of-concept stage (Technology Readiness Level; TRL 3) and at most have the technology demonstrated in a relevant environment (TRL 6).
- **Geography:** The competition is open to projects and companies based in the US or EU that comply with the above criteria and are interested in entering the opposite market (US or EU).
- **Team Composition:** The promoting team must have at least one team member with full-time dedication.
- **Team Commitment:** The team applying to the Program must be committed to participate fully in its activities (with a minimum of 80% of the total).
- **Funding:** The project must have less than \$5 million in total funding.

- **Support Services:** The support required by the proposal must align with the services offered by the program. The viability of the project at the time of application must not rely exclusively on obtaining funding. Proposals dependent solely on securing funding to progress will be excluded.

4. Application Process

Applications must be submitted in English and exclusively through this form ([link](#)). Applications submitted in other languages, incomplete applications, or those submitted on paper or through any other channel will be excluded.

The form will be open From December 2, 2024 until **January 26, 2025 at 11:59pm Pacific Time, which corresponds to 9:59am Central European Time.**

5. Evaluation Process

Impact1 and i4KIDS will be responsible for coordinating the evaluation of the submitted applications according to the detailed evaluation criteria below. Proposals that do not meet the eligibility criteria will be directly discarded and not considered for evaluation.

Each proposal will be assessed by three community experts from Impact1 and i4KIDS. Subsequently, the results will be analyzed, and an evaluation report will be prepared based on the average scores obtained from the three individual assessments of each proposal. Based on the score analysis, a maximum of 6 projects will be selected.

All participating proposals will receive a final report summarizing the overall evaluation, indicating whether they have been selected or rejected. Rejected proposals will receive a roadmap for improving their proposal. Selected proposals will receive a proposed date for organizing an initial meeting, signing program conditions, and establishing a work plan.

Once the program has started, Impact1 and i4KIDS reserve the right to revoke a project's participation if it fails to comply with participation regulations and does not demonstrate the required commitment. In such cases, a first warning will be issued. If the project fails to address this issue, other proposals submitted to the program and/or in the Impact1 and i4KIDS portfolio may be considered to fill that position.

6. Evaluation Criteria

Only proposals that meet the eligibility criteria will be evaluated.

The table below details the evaluation criteria. Proposals must obtain a minimum of a 6/10 as an overall score to be selected.

| | |
|--|---------------|
| Idea | 25% |
| Unmet need: clearly identified and validated | 25% of idea |
| Solution: relative to unmet need, and technical/scientific viability | 25% of idea |
| Value proposition for different stakeholders: clear and significant | 25% of idea |
| Competitive analysis: differentiation and competitive advantage | 25% of idea |
| Impact | 25% |
| Incidence and market size | 25% of impact |
| Severity and impact on patients and society | 25% of impact |
| Costs to the healthcare system | 25% of impact |
| Indication: pediatric or maternal as primary | 25% of impact |
| Implementation | 20% |
| Intellectual property strategy | 25% of impl. |
| Validation strategy | 25% of impl. |
| Regulatory pathway | 25% of impl. |
| Business model and reimbursement strategy | 25% of impl. |
| Team | 30% |
| Experience | 25% of team |
| Complementarity of backgrounds and roles | 25% of team |
| Dedication and commitment | 25% of team |
| Availability of funding for key activities | 25% of team |

7. Call and Program Timeline

- Open call for proposals: December 2nd, 2024 to January 26, 2025.
- Announcement of selected proposals: February, 2025.
- Support phase: March to September, 2025.

Please note program sessions will take place at 5-7pm CEST, 8-10am PT.

8. Contact Information

For questions or more information, please contact:

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