Philadelphia Pediatric Medical Device Consortium

Request for Applications for Grant Funding – White Paper Submission

MEMBERSHIP REQUIRED TO APPLY

Applications for the PPDC grant are only accepted from PPDC network members. Membership is free. Visit our website at https://ppdc.research.chop.edu/ to create a member account.

PROGRAM OVERVIEW

The Philadelphia Pediatric Medical Device Consortium (PPDC) is pleased to announce its sixth Request for Applications for funds to support the development of pediatric medical devices. This competitive program gives members of the scientific and business community, including entrepreneurs, clinicians, businesses, academic researchers, and medical, science, and engineering students, funds to develop and commercialize pediatric medical devices.

The PPDC is a consortium based at Children's Hospital of Philadelphia and funded by the United States Food and Drug Administration to foster new medical device technologies for pediatrics. The PPDC provides an international platform to translate pediatric medical device ideas from concept to commercialization. The PPDC mission is to provide funding and business, legal, marketing, clinical, engineering, and scientific resources to inventors in an effort to assist in the translation of innovative ideas into commercial pediatric medical devices. Your response to this Request for Applications is the first step in the competitive process of receiving funding from the PPDC.

The application for funding begins with a written White Paper Application to the PPDC. The White Paper will be evaluated serially by the PPDC Clinical and Scientific Advisory Committee (CSAC) for clinical feasibility and scientific merit, and the PPDC Oversight Committee (OC) for commercial potential. The most competitive White Paper submissions will be invited to submit Full Proposals. Proposals will again be reviewed by the CSAC and OC, phone meetings will be conducted with the finalists and PPDC leadership, and final funding decisions will be made. The Oversight Committee will conduct short phone interviews with the finalists during the Oversight Committee meeting. The White Paper Application should contain only non-confidential information. Evaluation of projects that are invited as Full Proposals will be conducted under Confidentiality Agreements.

Building on our successful partnerships with Drexel University and the University of Pennsylvania, the PPDC is pleased to announce a new partnership with the McGowan Institute for Regenerative Medicine and sciVelo at the University of Pittsburgh. The McGowan Institute is a global Class III medical device development enterprise that has been at the forefront of researching, testing, and translating medical devices that have played a critical role in repairing or replacing damaged tissue and organs for the past twenty-five years. Partnership with the McGowan Institute brings Class III device development capabilities, experience in the adaptation of well-developed adult devices for the pediatric population, and a strong connection to the biomedical landscape of Southwestern Pennsylvania. SciVelo is a first-of-its-kind commercial translation program born from the University of Pittsburgh Health Sciences and School of Engineering. Its pediatric-focused commercial translation program with Children's Hospital of Pittsburgh (sciVelo-CHP) will facilitate and advance the translation of market-oriented pediatric technologies to the clinic. SciVelo-CHP will be a strategic asset to the PPDC by providing extensive translational mentorship resources to clinicians and innovators. The unification of the Pennsylvania biomedical ecosystem will expand the PPDC network of expertise for assisting pediatric devices. As part of this new partnership, the PPDC will re-brand to be known as the Pennsylvania Pediatric Medical Device Consortium. The official re-brand will be announced later this round.

AWARD

The maximum project budget is $50,000. Indirect charges are prohibited. The maximum project duration is 12 months. Up to $250,000 is available for pediatric medical device projects.

The PPDC strongly encourages projects to secure and report leveraged funds in addition to applying for PPDC funding.

SUBMISSION PROGRAM DEADLINES

RFA Issued	September 7, 2018
White Paper Deadline	September 30, 2018
Full Proposal Invitation	November 16, 2018
Deadline for Draft Submissions	November 28, 2018
Full Proposal Deadline	December 14, 2018
Awards Announced	February 4, 2019

GENERAL GUIDELINES

Eligibility

The PPDC seeks proposals for medical device concepts or ideas at any stage along the commercialization pathway for use with pediatric patients. Proposals should address a significant pediatric unmet need with commercially-viable device ideas ready to make progress along the commercialization pathway.

The Proposal should be directed towards development of a commercializable product. This funding mechanism is not designed to support basic or exploratory research or initial feasibility studies. Issues such as prototyping, pre-clinical and clinical trials, manufacturing, marketing, and regulatory clearance will be paramount and should be addressed explicitly.

All submission must be medical devices per the FDA Medical Device Definition outlined below (see Note below) and must address patients from birth to age 21.

White Paper Submissions

Please see the White Paper format outlined below in this document. Please be sure to provide concise information and answer all questions posed in the guidelines. Successful submissions will demonstrate extensive research and due-diligence performed to understand the steps required to produce a commercial product.

REVIEW PROCESS AND SCORING CRITERIA

The Clinical and Scientific Advisory Committee (CSAC) will evaluate White Papers for clinical and technical feasibility. The CSAC is comprised of leading clinicians and scientists across multiple pediatric specialties. Following review from the CSAC, the Oversight Committee (OC) will evaluate and score the White Papers informed by the input from the CSAC. The OC consists of medical device industry leaders and entrepreneurs.

The CSAC and OC will evaluate each project on the basis of some or all of the following factors (these are provided as a guide during evaluations):

1. Demonstration of an unmet need for a pediatric medical device within the scope of a well-defined clinical paradigm
2. Strength of the IP position
3. Clinical and scientific feasibility of proposed pediatric medical device
4. Clinical significance of the proposed pediatric medical device
5. Competitive landscape and likelihood of marketing success
6. Progress of product development to date
7. Feasibility and understanding of proposed regulatory pathway
8. Current leveraged funding
9. Method by which proposed funding will de-risk and/or add value to the technology, and how this could lead to subsequent funding in the future

10. Estimated time to market

Based upon the results of the White Paper evaluation, applicants may be invited to prepare a Full Proposal.

FUNDING PERIOD EXPECTATIONS

Awardees will be required to complete and submit three quarterly report forms (to be provided upon award) and a final report; all should reflect progress toward project milestones. The information will be used in the PPDC reports to the FDA.

POST-AWARD EXPECTATIONS

It is expected that each project will make significant progress toward one or more of the following outcomes:

1. Product commercialization pathways; they may be identified through the PPDC and/or in partnership with industry
2. Licensing of IP; product must include a pediatric application should it go to market
3. Merger or acquisition, IPO
4. Awarding of additional funding, e.g., SBIR grants, support from industry

It is also expected that the project team provide annual project updates for five years post award, including any and all interactions with the FDA.

NOTE

FDA Pediatric Medical Device Definitions

Per the U.S. Food and Drug Administration, a medical device is:

> "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:
>
> - Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
> - Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> - Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Per the U.S. Food and Drug Administration, a pediatric medical device is defined as a device that "treats or diagnoses diseases and conditions from birth through age 21."

SUBMISSIONS AND QUESTIONS

Once the White Paper Application has been completed, please submit along with images/diagrams and supporting documents (up to 5 pages, pdf format) via email to:

ppdc@email.chop.edu

Questions or concerns regarding your application can be addressed to:

Joshua Dienstman, PPDC Project Manager
Office: 215-590-4069
Email: DienstmanJ@email.chop.edu

To learn more about the PPDC and this RFA, including previous recipients of this award, please visit our website at: https://ppdc.research.chop.edu/.