



# MAKE YOUR MEDICAL DEVICE PITCH FOR KIDS!™

## THE PEDIATRIC PANDEMIC NETWORK EDITION

### RFP Background

Under this solicitation, the Pediatric Pandemic Network (PPN) and the Alliance for Pediatric Device Innovation (APDI) have united their efforts to pool resources for the selection and support of a new cohort of device innovators. These innovators will receive grant funding and comprehensive support services provided by PPN and APDI. We are actively inviting proposals from innovators who are concentrating on FDA-regulated pediatric medical devices, diagnostics, and digital health solutions, with a specific emphasis on the development of Medical Countermeasures (MCMs) designed to address preparation for and response to the needs of children for healthcare during pandemics and other disasters.

These MCMs play a pivotal role in bolstering our readiness and response capabilities to disasters arising from a broad spectrum of threats. We are particularly enthusiastic about backing research and development (R&D) initiatives that focus on pioneering early-stage technologies tailored to tackle disasters. Such initiatives have the potential to secure subsequent funding from other federal agencies operating within this domain, such as BARDA.

Proposals should be oriented toward the development of a market-ready product, rather than the exploration of a scientific concept. Key considerations such as prototyping, manufacturing, marketing, and regulatory clearance will be of paramount importance and should be addressed explicitly. Collaboration with the small business community is not required but is encouraged. There should be a focus on health equity and communities, especially rural and low-resource areas.

### Key Dates

Submission deadline	February 15, 2024
Finalists notified	March 1, 2024
Presentation date	March 15, 2024
Awardees notified	April 1, 2024

### Application Details

Applicants are asked to submit their application online and attach a proposal as outlined below. Proposal Page limit: 8 pages total (includes 2 pages for refs and budget)

**Font size: 11 Arial, Margin: 0.5 inches**

#### Application should include:

1. Cover page (1 page) with the following information:
  - a. Title of Project
  - b. Applicant Name(s), Titles, Email Addresses
  - c. Company, Institution, or School and Department
  - d. Notification email address
  - e. Requested Award Amount (please note that indirect costs are not allowed)
  - f. Abstract – A short executive summary

2. Description of proposed project following the outline provided below (5 page maximum).  
The Applications are generally for one year of funding.
  - a. Product: Describe the MCM that will be developed with the grant funding. As applicable, provide detail on the prototype fabrication, materials, specifications, any software requirements, and method of manufacturing.
  - b. Significance: Describe the benefits the project will have on MCMs against disasters to protect or treat healthcare issues in the pediatric population. The focus on health equity and community/rural/low resource areas should be described.
  - c. Approach/Milestones: Identify the current state of development of your MCM (concept, prototype, preclinical, clinical, manufacturing, marketing or commercial use) and describe your approach for moving it through the next few phases with funding from this opportunity. Provide an outlook describing potential sources of funding beyond this opportunity. Describe the current status of your intellectual property.
  - d. Product marketing plans: Describe your market analysis to date. Please include a description of potential competitors and/or competing technologies.
  - e. Project team, resources, and environment: Describe your project team and the resources you will require to complete the work proposed. Briefly describe any relevant prior experience.
3. Budget (use form PHS 398, Revised 1/2018) & Budget Justification (1 page):  
Provide an itemized budget for funds requested. Prototype production, data collection and analysis, clinical and pre-clinical studies, testing, manufacturing costs, cost of consultants, quality systems development, materials, and personnel support are eligible budget categories. Grants are expected for up to \$50,000 for one year.
4. References (no page limit, but 1 page is recommended):  
References and citations may be used in support of the description of the proposed project but should be kept within the page limit.

### **Review Process and Scoring Criteria**

Scoring will be done by a panel of judges and will be based on an assessment of the following factors:

1. Clinical significance of the pediatric device
2. Approach to product development
3. Likelihood of being marketed successfully
4. Project team, environment, and resources
5. Potential for follow-on funding
6. Impact on health equity and rural/low resource communities

This grant funding is intended to promote the market readiness of MCMs for pediatric healthcare in preparation for or response to a disaster. The application should include a description of the long-term funding strategy.

The long-term success of this program will be measured by advancement through the product development progress, generation of intellectual property, clinical trials progress, FDA clearance or approval, follow-on funding, and clinical impact.

Publications arising from this solicitation are required to acknowledge the funders citing the grant numbers.

Awardees will be required to submit semi-annual progress reports and a final report. This information will be used in our updates to HRSA and FDA and must be submitted in a timely fashion. Investigators that do not submit this report will be at risk of losing continued funding support.

Applicants must be up to date with or be able to obtain Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) approval for work proposed, if applicable. Any additional relevant certifications (FWA numbers, CITI certifications, etc.) must be made available upon request.

A second year of grant funding will be granted based on progress made during the initial year of funding. Quarterly reports are required.

## Competitive Renewals

In cases of exceptional products, competitive renewals may be considered based on progress made during the previously funded project. Investigators may request an informal review before submission of a renewal application.

## Submission and Questions

Applications must be submitted directly to this program via the web and do not need institutional sign-off at this phase of the competition.



**Submit a PDF file of the proposal via this link:**

**<https://cri-datacap.org/surveys/?s=R7HCYPC9YHP38N4T>**

**Late submissions will not be accepted.**

**The deadline for receipt of proposals is: February 15, 2024**

**Note:** The objective of the PPN and APDI is to help move products from concepts to working products that have commercial viability. In addition to grant funding, PPN and APDI will provide assistance to innovators in the areas of technical, clinical, trial design, biostatistics, business planning, marketing, regulatory, legal and intellectual property.