Pediatric Medical Device Pre-Consortium
Critical Path Institute
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Tucson, AZ 85718-5893
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July 1, 2020

REQUEST FOR PROPOSAL

Digital Design and Virtual Meeting Services to Support an Effective, High Quality Experience for the Critical Path Institute's Pediatric Medical Device Pre-Consortium Virtual Conference and Workshop

(Workshop dates currently expected to be three days between Nov 10-19)

The Pediatric Medical Device (PMD) Pre-Consortium is seeking a proposal, including timelines and budget, to provide multimedia digital design services that support the educational, streamlined, professional and innovative virtual conference experience planned for a period of 3 days, tentatively between November 10-19, 2020.

The Critical Path Institute's Pediatric Medical Device Pre-Consortium, launched in September, 2019, presents a collaboration between Healthcare Providers, Academics, Regulators, Patient Advocacy Groups, Device Industry Groups, Investors, Private Payors and Government Funders, aimed at innovating the Pediatric Medical Device development ecosystem and process. Further details about working groups and charters are included in the PMD Info deck *(Appendix A).* The November conference is intended to transition and progress the initiative's focus from framework design to strategic course setting by:

- Educating participants about the vision, purpose, function, benefits, etc.
- Allowing participants to contribute their expertise in individual session goals and objectives
- Developing a network of constituents in the adoption and realization of PMD concepts
- Setting strategic course for next steps for each of the key workgroup areas of focus as well as the initiative at large

In the scope of the above-mentioned objectives, the tasks included in the scope for this proposal include:

1. Optimize and facilitate a virtual workshop that will include multiple breakout and plenary sessions with the goal of fostering engagement, dialogue, and feedback around the PMD/System of Hospitals for Innovation in Pediatrics (SHIP) concept
2. Create both in-workshop and offline structured feedback mechanisms (portals, surveys, etc.) that maximize meaningful community response
3. Assist with coordinated graphics/videos for five workstreams and overall PMD/SHIP ecosystem including messaging and presentations
4. Experience managing discussions of complex issues with multiple stakeholders required; medical device and/or pediatric device experience preferred

This Request for Proposal (RFP) describes the intended scope of work and deliverables expected. Also included is a budget template to be completed by your organization to document the direct, pass-through, and any optional task costs associated with completing the defined scope of work and associated deliverables.

Information contained in your proposal will be evaluated by the members of the PMD Pre-Consortium's Executive Committee and will be considered confidential. If selected for consideration, a brief (up to ten minutes) presentation of the proposal to the PMD Coordinating Committee is requested to be delivered via teleconference **on July 17, 2020 at 1PM EDT.**

Clarifying questions must be received no later than **July 10, 2020;** a conference call may be convened if deemed necessary. Proposals must be received by **July 15, 2020**. Both are to be sent to:

Sarah Spieth
Project Coordinator, PMD Pre-Consortium
Critical Path Institute
Sspieth@c-path.org
347-755-2981

Project Overview
The proposal is a firm offer that will be considered valid for 180 calendar days from the submission date. Please provide the contact information of the person responsible for submitting the proposal. C-Path shall not be responsible for any errors or omissions on the part of the Bidder in preparing this proposal. Bidder shall bear all costs associated with preparing this proposal.

Please prepare your proposed strategy to address the objectives and scope of the Digital Design and Virtual Meeting Support Services. You must demonstrate a knowledge base consistent with the objectives and requirements of this RFP and describe your Digital Design and Virtual Meeting strategy and rationale of design concepts as they pertain to various stakeholders. All the required elements should be clearly explained in 10 pages or less.

Expected Statement of Work / List of project deliverables

1. Optimize and facilitate a virtual workshop that will include multiple breakout and plenary sessions with the goal of fostering engagement, dialogue, and feedback around the PMD/SHIP concept
2. Create both in-workshop and offline structured feedback mechanisms (portals, surveys, etc.) that maximize meaningful community response
3. Assist with coordinated graphics/videos for five workstreams and overall PMD/SHIP ecosystem including messaging and presentations
4. Experience managing discussions of complex issues with multiple stakeholders required; medical device and/or pediatric device experience preferred

PMD Pre-Consortium Challenges

1. Multiple workstreams working on complex inter-related topics causing a progress bottleneck
2. Need to display these complex topics in an easy to understand language: for the workstreams as well as for lay public attending the public meeting

Overall Project Management
It is anticipated that the contractor will participate in regularly designated PMD Coordinating Committee Group teleconferences held on the second and fourth Friday of every month from 1:00 pm – 2:00 pm Eastern (US). Contractor will also participate in other individual workstream meetings. There are five workstreams and their meeting frequency varies from one to four times per month. Occasionally there are inter-workstream meetings as well, the frequency of which varies. Contractor will be expected to provide a written monthly project status report throughout the project period.

Previous Experience
Please define your organization's capabilities and describe previous experience with Virtual meeting planning, developing, and hosting. Describe how you would optimize and facilitate a virtual workshop that will include multiple breakout and plenary sessions with the goal of fostering engagement, dialogue, and feedback around the PMD/SHIP concepts. Describe

your experience creating both in-workshop and offline structured feedback mechanisms (portals, surveys, etc.) that maximize meaningful community response. Describe how you might assist with coordinated graphics/videos for five workstreams and overall PMD/SHIP ecosystem including messaging and presentations. And describe experience managing discussions of complex issues with multiple stakeholders required; especially where it may have included medical device and/or pediatric device topics.

Key Personnel
Describe the roles and responsibilities of key personnel on this proposed project. Please include brief descriptions (100 words or less for each) of all key personnel who will be involved in the project.

Bidder Organization
Please provide a brief description (300 words or less) of your overall organization (e.g., size, locations, and primary business units).

Timelines
Bidder needs to be available to start Aug 03, 2020 and continue support through the November, 2020 workshop.

Costs
Costs are to be broken out Please provide your proposed budget using the templates for direct, pass-through, and optional task costs provided below. Also, please provide proposed payment terms.

BUDGET TEMPLATE

Note: *Below entries are required at a minimum; additional details will be appreciated.*

Direct Costs

Task Name	Time to Completion from Kick-off (in weeks)	Total Hours for all Staff	Blended Hourly Rate	Total
Project Management (e.g., including workstream teleconferences work between meetings, prepare and deliver monthly status report)	N/A			$
Additional Tasks (Please specify any additional tasks)				$
If applicable				
			Total Direct Costs	$

Optional Tasks

Task Name	Time to Completion from Kick-off (in weeks)	Total Hours for all Staff	Blended Hourly Rate	Total
Optional Task #1 (Please specify)				$
Optional Task #2 (Please specify)				$
Optional Task #3 (Please specify)				$

PAYMENT TERMS:

Proposed payment terms are to be provided in the proposal submitted to Critical Path Institute/Sarah Spieth.

Appendix A

Pediatric Medical Device Ecosystem

Members, Meetings & More

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Workshop Sessions: Questions to Frame Discussions

Work Sessions		Sample Questions
1	SHIP Boarding, Sailing, Exit *SHIP role, evaluation process, conditions for participation, etc. Benefits, process, time in SHIP, exit*	1. What role should SHIP play vis a vis FDA, innovators, venture capitalists, payers and other stakeholders? 2. How might SHIP evaluate devices that enter SHIP? 3. What should the top 5 conditions that innovators should agree to before entering SHIP? 4. How might SHIP coordinate and facilitate input and mobilize actions across the ecosystem to advance development? 5. How would SHIP determine which devices receive funding from the SHIP investment pool? 6. What are the top 3 organizations that SHIP should plug into help expand expertise / leverage complimentary efforts? 7. What is a reasonable length of time to stay in the SHIP; when should exit occur?
2	Criteria for Qualifying Hospitals *High-level list of criteria*	1. What are the top 10 criteria that hospitals must satisfy to be in the SHIP network? 2. How should these criteria be monitored to ensure on-going performance and quality is maintained? 3. What process should SHIP follow to ensure adequate geographic and subspecialty coverage? 4. How might SHIP tier its approach to subspecialties? (e.g. start with all sub specialties vs. focus on key sub specialties)
3	Reimbursement *Guarantees, Process*	1. How might SHIP work with ecosystem members (e.g. hospitals, innovators) to secure reimbursement for devices? 2. What role would SHIP play in this process? What role do innovators play? hospitals?
4	Finance *Seed Funding, Business Model, Value Prop and Investment Pool*	1. How much seed money will be needed to launch SHIP? 2. What are the 3 most plausible business models SHIP should consider? (revenue sources, revenue mix, operating model) 3. What are the 10 most important considerations for funding and managing the investment pool? 4. What are the key assumptions that underlie 1-3 above?
5	Regulatory *Implications, connection*	1. How should SHIP interact with FDA?

Workstream Summary

What workstreams have you established? Are they basically working groups to tackle specific questions and if so what are those questions?

There are five workstreams that evaluate key aspects of the pediatric device ecosystem, focusing on their relation to SHIP (System of Hospitals for Innovation in Pediatrics): The workstreams and a brief overview of their current focus follows:

1. Experience: This workstream focuses on defining the process through SHIP, including qualification factors for entry and exit and the scope of SHIP vis-à-vis regulators, innovators, funders, payers and other stakeholders.

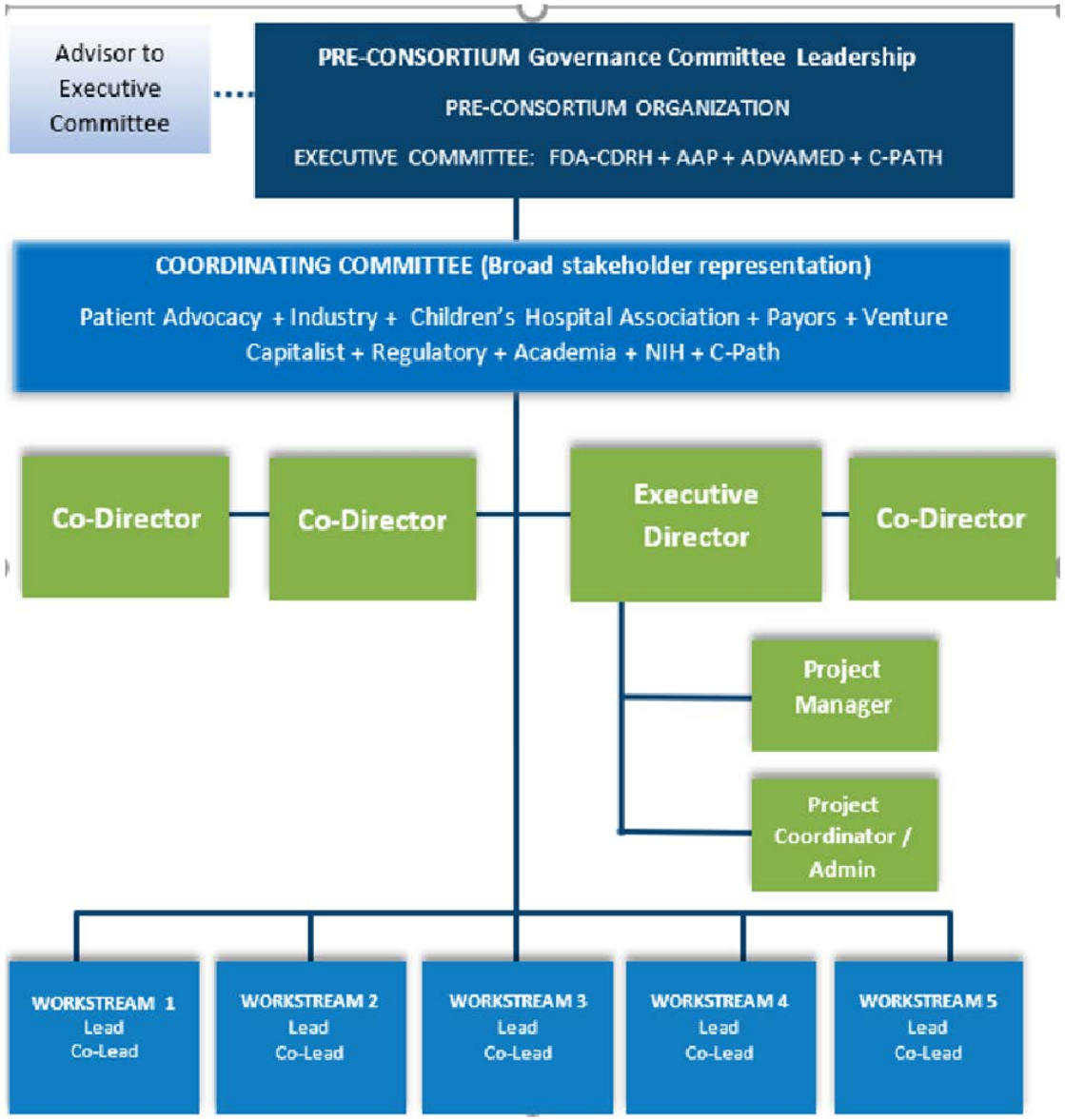
2. Hospitals: Focuses on clarifying the qualifying criteria, which ensures a safe environment with the breadth and depth of infrastructure and expertise, for a hospital to be part of SHIP.

3. Reimbursement: Focuses on addressing the practical aspects of optimizing reimbursement potential for devices qualified to benefit from SHIP.

4. Finance: Focuses on evaluating financing models that meet the needs of SHIP, including early development support and long-term independent financial sustainability. In addition, the team is considering options to engender investment in devices qualified for SHIP, if requested by the sponsor.

5. Regulatory: Focuses on models for facilitating and optimizing interaction of SHIP with current and potential regulatory programs and agents, such as FDA's Center for Devices and Radiological Health (CDRH).

Governance Structure



LEAD	CO-LEAD	START	END	MEETING CADENCE
		4/XX/20	9/30/20	2-3X Month/Thursday PMs

GOAL: Using the SHIP Concept document as a guide, design a 90-minute workshop session to answer the questions noted below.

WORKSHOP OBJECTIVES FOR THIS SESSION:	TEAM MEMBERS (Sarah C-Path Support)	SHIP MEMBER?
Engage attendees in active discussion to refine the roles of the SHIP.		
Engage attendees in active discussion to refine the scope of the SHIP.		
Enable attendees to visualize an end-to-end journey within the SHIP.		

IN SCOPE:	Developing a concept for entry, ongoing support and exiting the SHIP.
OUT OF SCOPE:	Direct financial investment in project

QUESTIONS TO BE ADDRESSED DURING THE WORKSHOP:	
1	What should be the role of the SHIP?
2	What should be the scope of the SHIP?
3	How might SHIP coordinate and facilitate input and mobilize actions across the ecosystem?
4	What doses success look like in the SHIP?

MAJOR MILESTONES:

1	Kick off	4/XX/20
2	Questions approved by EC	4/20/20
3	Design completed	6/20/20
4	Pre-reads completed	8/1/20
5	Workshop	9/1-2/20
6	Summaries for white paper due	9/30/20

One Pager: CHARTER Criteria for Qualifying Hospitals

Draft 1.2, April 14.2020

CO-LEAD	CO-LEAD	START	END	MEETING CADENCE
		4/14/20	9/30/20	Once a month (or often as needed)

GOAL: Using the SHIP Concept document as a guide, design a 90-minute workshop session to answer the questions noted below.

WORKSHOP OBJECTIVES FOR THIS SESSION:	TEAM MEMBERS (Sarah C-Path Support)	SHIP MEMBER?
Engage attendees in active discussion to refine a list of criteria for hospitals in the ecosystem + refine the metrics that will be used to measure progress/success		
Summarize key points for 'report-out' and white paper		

IN SCOPE:	Criteria listing: US pediatric hospitals
OUT OF SCOPE:	Naming specific hospitals

QUESTIONS TO BE ADDRESSED DURING THE WORKSHOP:	
1	What are the top criteria that hospitals must satisfy to be in the SHIP network?
2	Define common criteria for monitoring progress and collecting metrics

MAJOR MILESTONES:		
1	Kick off	4/XX/20
2	Questions approved by EC	4/20/20
3	Design completed	6/20/20
4	Pre-reads completed	8/1/20
5	Workshop	9/1-2/20
6	Summaries for white paper due	9/30/20

CHARTER: Reimbursement

Draft 1.2, May 11.2020

LEAD	CO-LEAD	START	END	MEETING CADENCE
		4/14/20	9/30/20	2X Month/Monday 4:00 pm ET

GOAL: Using the SHIP Concept document as a guide, design a 90-minute workshop session to answer the reimbursement questions noted below.

WORKSHOP OBJECTIVES FOR THIS SESSION:
Engage attendees in active discussion to prioritize reimbursement goals and strategies for pediatric device innovation
Use attendee input to confirm reimbursement deliverables to ecosystem stakeholders
Achieve alignment among reimbursement, regulatory, hospital, finance and other workstreams
Summarize key points for report-out and white paper

TEAM MEMBERS (Laura Butte C-Path Support)	CC Member

IN SCOPE:	Reimbursement constructs and strategies that are “mission-critical” to ped. Dev. innovation
OUT OF SCOPE:	Specific locations or hospitals to start reimbursement pilot programs

QUESTIONS TO BE ADDRESSED DURING THE WORKSHOP:	
1	What are the reimbursement decision-making criteria and process for Medicaid and other priority payers that will advance innovative pediatric devices?
2	What are the links between reimbursement and FDA/regulatory policy?
3	What are the criteria to define a location/state best positioned for a reimbursement pilot program?
4	How can national and local reimbursement policy-making support all classes of innovative pediatric devices?
5	Identifying the role for SHIP in the reimbursement ecosystem

MAJOR MILESTONES:		
1	Kick off	4/20/20
2	Questions approved by EC	4/20/20
3	Design completed	6/20/20
4	Pre-reads completed	8/1/20
5	Workshop	9/1-2/20
6	Summaries for white paper due	9/30/20

One Pager: CHARTER FINANCE

Draft 2.0, April 15.2020

LEAD	CO-LEAD	START	END	MEETING CADENCE
		4/20/20	9/30/20	2x Month/Monday PMs

GOAL: Using the SHIP Concept document as a guide, design a 90-minute workshop session to answer the questions noted below.

WORKSHOP OBJECTIVES FOR THIS SESSION:	TEAM MEMBERS (Laura C-Path Support)	SHIP MEMBER?
Engage attendees in active discussion to refine a list of criteria for hospitals in the ecosystem		
Use attendee input to stress test and refine a plan to fund/finance the initiative		
Summarize rationale for recommended approach explain discarded ideas		
Summarize key points for report out and white paper		

IN SCOPE:	High-level estimates with assumptions
OUT OF SCOPE:	Fundraising activities; applications for grants, etc.

QUESTIONS TO BE ADDRESSED DURING THE WORKSHOP:	
1	How much seed money will be needed to launch SHIP?
2	What are the 3 most plausible business models SHIP should consider?
3	What are the most critical considerations for funding/financing* product development?
4	What are the key assumptions that underlie 1-3 above?

MAJOR MILESTONES:		
1	Kick off	4/20/20
2	Questions approved by EC	4/20/20
3	Design completed	6/20/20
4	Pre-reads completed	8/1/20
5	Workshop	9/1-2/20
6	Summaries for white paper due	9/30/20

**equity, debt or grants*

One Pager: Charter for Work Session 5 – *Regulatory*

LEAD	CO-LEAD	START	END	MEETING CADENCE
		4/10/20	9/30/20	1X Month / 90 minutes

GOAL: Using the SHIP Concept document as a guide, design a 90-minute workshop session to answer the questions noted below.

WORKSHOP OBJECTIVES FOR THIS SESSION:	ADDITIONAL TEAM MEMBERS (Supported by Sarah Spieth – C-path):	SHIP MEMBER?
Engage attendees in active discussion to refine regulatory needs for furthering the development of pediatric medical devices.		
Use attendee input to discuss how the current regulatory framework can be used to accelerate pediatric device development.		
Summarize rationale for recommended regulatory approach.		
Summarize key points for report out and white paper.		

IN SCOPE:	High-level outline of recommendations to C-Path regarding pediatric device development within the SHIP ecosystem.
OUT OF SCOPE:	SHIP assuming any statutory FDA responsibilities, e.g., negotiations, approvals, clearances, QSR, IP, guidance development, etc.

QUESTIONS TO BE ADDRESSED DURING THE WORKSHOP:

1	Definite how the network governance structure interacts w/FDA and how the agency can provide assistance to pediatric device developers? Define the interaction with advisory panels? How can SHIP provide benefit-risk information on device perspectives (i.e., risks to patients) to FDA?
2	Define the criteria for development/use of existing data (i.e. RWE, off label, reverse extrapolation) by the network to facilitate product approval/review?

MAJOR MILESTONES:

1	Kick off	4/10/20
2	Questions approved by Coordinating Com	4/20/20
3	Design completed	6/20/20
4	Pre-reads completed	8/1/20

THANK YOU

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