FNIH
Foundation for the National Institutes of Health

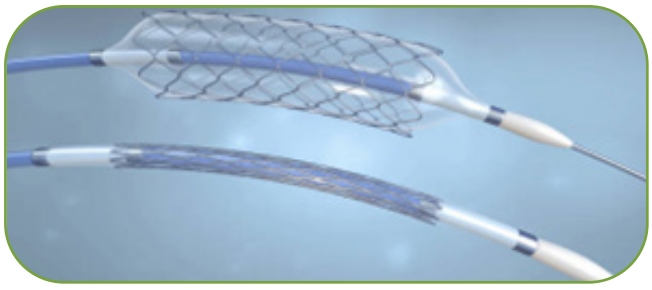
Pediatric Medical Devices

CHALLENGES OF PEDIATRIC MEDICAL DEVICE DESIGN

Despite numerous legislative, regulatory and scientific efforts in the recent past, innovative pediatric medical devices (PMDs) have yet to be made available at the same rate as adult medical devices. In many cases, the cause of this disparity is not a lack of technologies, but rather a lack of incentives for the industry to become involved in PMD research and development. Furthermore, many innovative medical devices approved for adult use have not been approved for pediatric use. When used "off-label" in children, it exposes children to a benefit/risk profile that has not been evaluated by the Food and Drug Administration (FDA), deepening the health inequities between these two populations. Over the past 13 years, the FDA Center for Devices and Radiological Health (CDRH) developed multiple programs for accelerating the innovation of PMDs. Nevertheless, medical device development for pediatrics has remained relatively stagnant, as evidenced by premarket approvals (PMAs) and humanitarian device exemptions (HDEs) with labeling for pediatric usage. During this period, at CDRH, approvals of PMAs and HDEs labeled only for adults increased at about twice the rate of devices labeled for both adult and pediatric use and about 21 times the rate of devices labeled solely for pediatric use. These data point to the persisting lack of availability and subsequent access to medical device options designed and approved for the pediatric population, which is even more dramatic for the youngest patients. This is a long-standing and significant public health problem.

UNIQUE DESIGN CONSIDERATIONS

Challenging issues to address for these products include: 1) Lack of validated endpoints in the very young populations (e.g., difficult to assess benefit); 2) Children may be long-term device users (device longevity, exposure to implanted materials); and 3) Relatively low return on investment (small market/sample size). The underlying challenges impose the need to establish transdisciplinary, multi-stakeholder collaborative platforms to develop reasonable solutions. Coordinating national multi-stakeholder efforts through a Public-Private Partnership (PPP) could be a game-changer for the pediatric medical device arena.



AIMS OF THE PEDIATRIC MEDICAL DEVICES PUBLIC-PRIVATE PARTNERSHIP PROJECT

Aim 1: Consolidate a national ecosystem to accelerate advancements in medical devices designed, evaluated, and approved for pediatric populations.

Aim 2: De-risk and streamline processes enabling translation of medical advances from bench to bedside for medical devices for children.

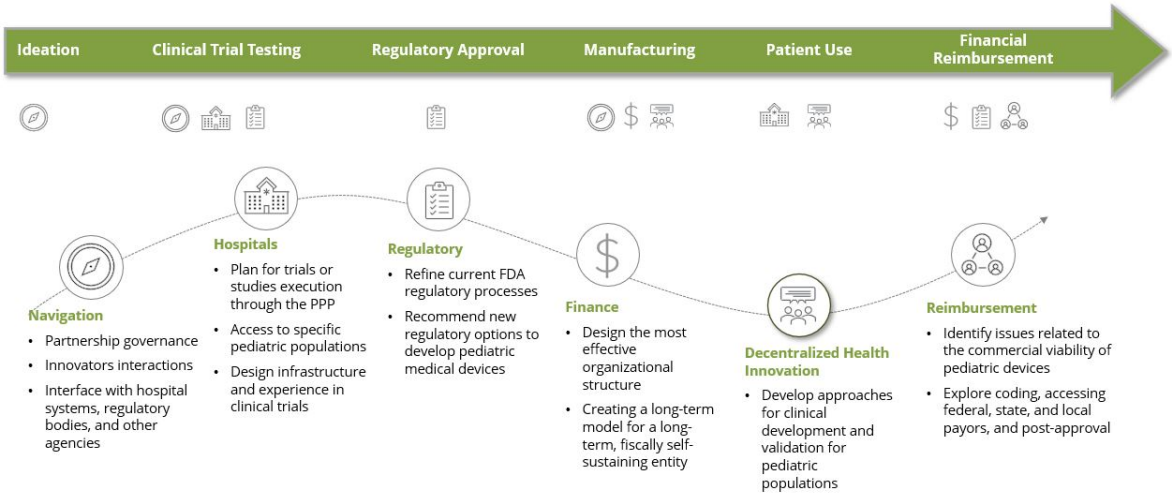
Aim 3: Ultimately address the lack of access to medical device options designed and approved for the pediatric population.

PMD PUBLIC-PRIVATE PARTNERSHIP

To address this inequality in our healthcare system, the Foundation for the National Institutes of Health (FNIH) will lead the design of a full-scale PPP, bringing together the resources of multiple U.S. government agencies and private sector organizations, including industry and non-profits. The Design Phase of the PMD project will assemble a governance structure incorporating and building on foundational elements developed during the System of Hospitals for Innovation in Pediatrics – Medical Devices (SHIP-MD) 2021 pre-consortium workshop and convening a series of meetings for up to six integrated workstreams as shown on the next page.

Additionally, this phase will produce a white paper with a detailed plan to build and launch a multi-year PPP. The focus is on the critical primary processes of creating the national pediatric medical device ecosystem, as proposed in the SHIP-MD framework. This would include a network of hospitals and associated but decentralized elements, optimizing public and private financing and reimbursement for the R&D of pediatric medical devices, and creating a self-sustaining entity that will administer and manage the partnership over the long term to benefit pediatric patients.

PROJECT INTEGRATED WORKSTREAMS



OPPORTUNITIES FOR INVOLVEMENT

The FNIH is actively seeking private-sector participation in this project. To maximize engagement from a wide range of private partners from different sectors, tiered participation options are available based on an organization's annual revenue as shown in the below chart. The one-time contribution covers the entirety of the design phase. The full partnership includes voting representation on the Executive Committee, approval of the final research plan that will define the direction of project implementation, and the option to have representatives in all workstreams. Additionally, we offer a two-workstream option for companies with less than $1 billion in revenue, & 501(c)(3) non-profits. This option includes participating in select workstreams and developing corresponding portions of the white paper and research plan. The FNIH is a 501(c)(3) and contributions to the design phase can serve as charitable contributions.

REVENUE BUDGET	CONTRIBUTION AMOUNT
$21 billion+	$75,000
$11 - $20 billion	$60,000
$1 - $10 billion	$30,000
<$1 billion & 501(c)(3) Non-Profits	$15,000
501(c)(6) Organizations	$5,000

FOCUSED WORKSTREAM OPTIONS FOR <$1 BILLION & 501(C)(3) NON-PROFITS	
Two workstreams	$5,000

BENEFITS OF THE PARTNERSHIP

- Develop a cutting-edge program to accelerate and enhance the development of devices for pediatrics and address an unmet societal need.
- Collaborate with public and private sector colleagues to forge a diverse and sustainable pediatric medical device ecosystem.
- Engage in scientific discussions on safely translating adult test methods to pediatric populations for regulatory submissions.
- Engage with regulatory partners and receive insights on pathways.
- Ensure organization and industry voices are heard in designing a system to serve a broad group of partners with diverse sizes and missions.
- Contribute to lowering the burden of market entry and creating new risk-sharing options.
- Provide inputs addressing health inequities in high-risk/high-benefit areas (e.g., class III devices).
- De-risk and streamline processes to enable the translation of medical advances from bench to bedside.
- Understand the capabilities and resources of federal partners within a more extensive PPP infrastructure.

To learn more about becoming a scientific and funding partner in the PMD Design Phase PPP Project, please contact:

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