New England Pediatric Device Consortium

2017 Target Challenge: Request for Abstracts

New England Pediatric Device Consortium and partners are pleased to announce the 2017 Target Challenge grant opportunity. NEPDC invites grant proposals for the development of novel technologies and improvements to existing technologies to prevent or aid in the prevention of unintended removal of tubes or drains, or unplanned dislodgement of intravenous lines.

DATES

Abstract: Open submission until July 7, 2017

Application (by invitation only): July 24, 2017

Notification of Finalists: August 18, 2017

Notification of Award: Six to eight weeks following the application submission deadline

PURPOSE

Development of technologies or improvements to existing technologies to prevent or aid in the prevention of unintended removal of tubes or drains, or dislodgement complications of intravenous lines.

OPPORTUNITY

- Up to 200 hours of NEPDC resource assistance
- Up to $100,000 in total funding available
- Project funding commensurate with proposed objectives. No single award to exceed $50,000
- 3-12 month project length from the award start date

CONTACT FOR QUESTIONS

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or visit http://nepdc.org/application/target-challenge/

Background

NEPDC seeks technologies that prevent or aid in the prevention of dislodgement or unintended removal of catheters or tubing. The Institute for Pediatric Innovation's Pediatric Hospital Consortium, and members of the NEPDC network have identified this as an area of high unmet pediatric need.

Indications for use of catheters and tubing in pediatrics vary and can include parenteral and enteral feeding, administration of IV fluids, medications, or blood products, and extraventricular drainage of cerebral fluid in pediatric neurosurgical patients.[1,2,3,4] In both adults and children, catheters and tubing may remain fixed to the body for prolonged periods of time ranging from days to months. Dislodgement or unintended removal of these items, particularly in children, can result in death, emergency department visits and admissions, lengthened inpatient stays and treatments, increased costs to hospitals and the healthcare system, and distressing to patients and their families.[5,6]

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Examples of catheters and tubing at risk for dislodgement or unintended removal include, but are not limited to:

- Peripherally inserted central catheters (PICC)
- Peripheral venous catheters (PVC)
- Central venous catheters (CVC)
- Foley catheters
- Gastrostomy Tubes (G-Tube)
- Nasogastric Tubes (NG Tube)
- Endotracheal Intubation (ET) tubes
- Ventriculostomy or extraventricular drainage (EVD) tubes

Pediatric Impact

Catheter dislodgements are closely linked to age and body size.[5] While routine movement of patients by clinical caregivers is necessary, securement cannot withstand the stress of some required medical care movement.

Similarly, common risk factors associated with unplanned extubations include age (accidental removal is more likely to occur in younger patients), and inadequate tube fixation.[6,7,8,9] In a study describing the pediatric emergency medicine management of patients who present with G-tube related complaints, dislodgement was the number one complaint, and 62% of patients needed G-tube replacement.[10]

Opportunity

NEPDC is offering up to $100,000 in discretionary funding for development or advancement of medical devices intended to prevent or aid in prevention of dislodgement or unintended removal of catheters and tubing. For this 2017 Target Challenge, awardees may receive funding and up to 200 hours of commercialization service and support from NEPDC. Commercialization service and support hours will be allocated depending on each awardee's unique background and commercialization requirements. Expert guidance from the consortium's engineers, researchers, clinicians, and entrepreneurs could focus on:

- Engineering design and transfer to manufacturing

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- Development of intellectual property and regulatory strategy
- Pre-clinical and clinical trial design and execution
- Strategic market planning and business development
- Identifying co-funding opportunities

The NEPDC network, which includes links to industry, academia, and the greater clinical community, has been created to help clients overcome the unique challenges surrounding the development and translation of pediatric products for clinical and consumer use.

Anticipated Deliverables

Proposals must present a plan of work that will result in either a fully commercialized product (e.g. available for consumer use within approximately 18 months of the initial grant award) or significant progress towards commercialization (e.g. market verification, design prototype, proven efficacy of the device). For awards where the product is not fully commercialized, a plan must be presented to demonstrate the outcome can be leveraged for subsequent funding opportunities (federal, public, and/or private sources).

Submission Procedures

Due to the diversity and complexity of submitted device development proposals, NEPDC has instituted a three-phase application procedure. Those interested in submitting for the 2017 Target Challenge are required to first submit a templated Abstract electronically through the NEPDC web-based submission system by July 7, 2017. These brief product descriptions will be reviewed by a panel of commercialization experts (business, technical, clinical) on a revolving basis to determine if the product addresses the goal of this 2017 Target Challenge. All Abstracts will be promptly reviewed with feedback typically provided within 5-10 business days.

If selected, applicants will be invited to submit a Full Application. The Full Application template includes both categorical and essay questions to describe the pediatric rehabilitation need, proposed device concept, commercialization strategy, methods for assessing efficacy, and support requested from NEPDC. The deadline for Full Application submission is July 24, 2017.

After Full Application review, finalists will be selected and invited to participate in a video conference with a panel of judges where they will have ten minutes to pitch their device and approach, followed by

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a twenty minute question-and-answer style interview. Interviews will be scheduled and held during the week of August 21-25, 2017.

To be eligible, abstracts must be submitted electronically through the NEPDC web-based submission system by July 7, 2017; however, early submissions are strongly encouraged to provide sufficient time for Full Application preparation. Submission deadlines will not be extended.

Evaluation Criteria

All applications will be reviewed using the following criteria:

- Potential for commercialization
- Impact on pediatric quality of life
- Impact on cost of care
- Market and business potential
- Technical feasibility
- Plan to demonstrate efficacy of device
- Value added by Target Challenge commercialization resources

Each Full Application is evaluated by at least three reviewers and graded on a categorical scale ranging from 1-5 (5 = best). Following review, a summary of reviewer comments is provided to each applicant along with a decision letter.

Eligibility Requirements

Eligibility requirements for the Target Challenge Seed Award include the following:

- Technology/devices must address the Target Challenge topic
- Technology/devices must meet the FDA's definition of a medical device
- Academic or Commercial entities are both encouraged to apply
- Technology/devices that have previously received funding from FDA-funded pediatric device consortia are not eligible
- Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible

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Terms and Conditions

- Notification of Award: six to eight weeks following application submission deadline.
- Award eligibility is restricted to concepts classified as pediatric medical devices. To verify your device eligibility, refer to Federal Food Drug & Cosmetic Act section 201(h) section.
- Intellectual Property associated with devices submitted for review belongs to the inventor. NEPDC and partners and/or sponsors make no claims to that Intellectual Property. Additionally, submission for grant awards does not constitute public disclosure. One component of the Target Challenge assistance process is to help clients ensure that Intellectual Property rights are protected so they can decide the most appropriate commercialization pathway.
- Any public disclosure of work product resulting from Target Challenge support (e.g. publications, presentation, press release, web site, etc.) must acknowledge funding source: "This project was supported by the New England Pediatric Device Consortium (NEPDC) which is part of the FDA Pediatric Device Consortia Grant Program (FDA P50FD004907). The content is solely attributed to the authors and does not necessarily represent the official views of the NEPDC or FDA."
- Additional Grant Terms and Conditions can be found at http://nepdc.org/application/eligibility-terms-conditions/.

About the New England Pediatric Device Consortium (NEPDC)

NEPDC is a non-profit consortium that provides infrastructure, expert consultation to innovators, and execution of technology translation and commercialization of pediatric technologies. NEPDC is funded by the FDA's Office of Orphan Product Development as part of the Pediatric Device Consortium network to accelerate commercialization of safe and effective technologies for pediatric populations. NEPDC fosters commercialization by connecting innovators with an extensive network of clinicians, researchers, technologists, and business development specialists located at institutions throughout New England. NEPDC member institutions include: MassGeneral Hospital for Children, Simbex, CIMIT, Institute for Pediatric Innovation, the Children's Hospital at Dartmouth (CHaD), and The Dartmouth Institute for Health Policy and Clinical Practice. For more information, visit www.NEPDC.org or email info@nepdc.org.

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References

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Target Challenge Supporting Partners

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NEPDC is a non-profit foundation supported by the FDA's Office of Orphan Products Development (OOPD) to promote commercialization of safe and effective technologies for pediatric clinical care. NEPDC accelerates commercialization with its extensive network of clinicians, researchers, technologists, and business development specialists to provide rapid and targeted assistance to innovators seeking to address the needs of children suffering from disease or disabilities.

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