NEPDC
New England
Pediatric Device Consortium

10 Water Street
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www.nepdc.org

Request for Proposals for Target Challenge: 2015-TC-4

The New England Pediatric Device Consortium (NEPDC) is a multidisciplinary, multi-institutional, collaborative consortium that provides rapid and targeted assistance to innovators seeking to address the needs of children suffering from disease or disabilities. NEPDC invites proposals for improvements to existing technologies, or the development of new technologies, with clear potential for commercialization that can be used in-clinic or at home for the diagnosis or identification of *apneic events* in the pediatric population.

Key Dates:

Abstract: Open Submission until August 1, 2015

Application Deadline (invitation only): August 10, 2015

Notification of Award: Approximately one month following application submission deadline

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Opportunity:

- Up to 200 hours of NEPDC resource assistance
- Up to $60,000
- Single Award not to exceed $50,000
- Up to 2 proposals will be funded

QUESTIONS?

Visit us at
www.nepdc.org/challenge.html

Purpose:

Commercial translation of Apnea Monitor device(s) that improve diagnosis and detection of pediatric apnea.

Background

There are a wide range of etiologies that result in apnea in the pediatric population, and, if left undetected, these apneic events can lead to significant health problems, including death.[1,2] Due to the numerous etiologies, the true incidence and prevalence of pediatric apnea is difficult to quantify; however, several major etiologies significantly increase the risk of life-threatening apneic events, including: apnea of prematurity (37 weeks or younger), obstructive sleep apnea, neurologic or metabolic disorders that suppress respiratory drive, epilepsy, head trauma, and episodic situations including certain viruses (e.g. respiratory syncytial virus and pertussis) and the use of sedatives or narcotics, such as in the perioperative period following general anesthesia.[3,4]

The American Academy of Pediatrics (AAP) has determined that apnea monitors are medically indicated for many of these conditions, and recommends their use to help diagnose apnea or detect apneic events both in the hospital and home setting when appropriate.[1] Although apnea monitors are routinely used in the hospital setting for the evaluation of an apparent life threatening event (ALTE), the routine use of home apnea monitors for the prevention of Sudden Infant Death Syndrome (SIDS) is currently not endorsed.

In addition to in-clinic use, apnea monitors may be used within home settings for medical indications such as:

- Premature infants with high-risk for recurrent episodes of apnea, bradycardia, and hypoxemia after hospital discharge
- Patients who have a tracheostomy, unstable airway, or are dependent on continuous positive airway pressure devices
- Patients who have a neurologic, metabolic, or other condition that can affect respiratory drive
- AAP **does not recommend** apnea monitors for the prevention of Sudden Infant Death Syndrome (SIDS)

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Apnea monitors must include simultaneous measurements of one or more sensing modalities that can alert the caregiver of apneic events, and are ideally capable of recording events for retrospective review and analysis.[5] Some of the technologies often include: pulse oximetry, respiratory monitoring (may include effort, airflow, end-tidal CO_2, and/or esophageal pressure), cardiac monitoring (may include heartrate, heartrate variability, and/or arterial tonometry), measures of sleep/wake activity (may include electroencephalography or actigraphy), body position, or other sensors that can quantify cardiovascular/respiratory function. It is the responsibility of physicians to ensure the appropriate capabilities are selected for the specific medical condition of their patients. Users of Apnea Monitors must be trained in observational techniques for symptoms, operation of the monitor, and infant cardiopulmonary resuscitation.

Existing Apnea Monitors developed commercially for both use in clinic and at home have several significant limitations when used in the pediatric population.[2] Some of these limitations include: misinterpretation of data that mistakenly detects body movement or chocking for breathing, tethered sensors and leadwires that become loose or are improperly placed, adhesive materials ill-suited for pediatric skin resulting in formation of ulcers, and employment of sensing modalities that are not sufficiently specific to all physiological parameters of interest. Due to these hardware, software, and implementation deficiencies, it is rather common to either miss or falsely detect apneic events, with some studies identifying true detection rates as low as 7-8%.[6,7]

Due to the *prevalence* and *significance* of these issues related to apnea, *NEPDC is seeking technologies for use in diagnosis of apnea or for real-time identification of apneic events in the pediatric population for use in the clinical setting or at home.* Ideal solutions will be available for commercialization within 18 months of the initial grant award. 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 and orphan products for clinical and consumer use. Through NEPDC grant awards, clients receive both seed funding and access to NEPDC Core Services, providing short-term, concentrated assistance to accelerate the commercialization process. For this Target Challenge NEPDC is offering up to $60,000 in discretionary funding for no more than two devices, with no one device receiving more than $50,000 and 200 hours of in-kind assistance. Depending on each client's unique background and commercialization requirements, our consortium of engineers, researchers, clinicians, and entrepreneurs provide expert guidance in the form of:

- Engineering design and transfer to manufacturing
- 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

Anticipated Deliverables

Proposals must present a plan of work that will result in either a fully commercialized product or output (e.g. preliminary data, design prototype, business plan) that can then be leveraged for subsequent funding opportunities (federal and/or public sources). Desired pediatric apnea devices may include:

- Novel technologies or improvements that increase sensitivity/specificity of apnea monitors for home/clinic
- Novel technologies or Improvements in underlying technologies that are used for apnea monitoring (respiratory and/or cardiac monitors, or pulse oximetry) that specifically address the pediatric population
- Novel technologies or Improvements in apnea monitoring technologies that can be used as part of Polysomnography or pneumography testing

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Submission Procedure

Due to the diversity and complexity of submitted device development proposals, NEPDC has instituted a two-phase application procedure. Those interested in submitting for the NEPDC Target Challenge are required to first submit an Abstract. These brief product descriptions will be reviewed by the NEPDC Leadership Team on a revolving basis to determine if the product falls within NEPDC's expertise and addresses the goal of this Target Challenge. If selected, applicants will be invited to submit a Full Application. To meet the deadline for full applications, abstracts must be submitted by August 01, 2015.

All applications are submitted electronically through the NEPDC web-based submission system.

http://colab-nepdc.fluidreview.com

Evaluation Criteria

All applications will be reviewed against the following criteria:

- Potential commercialization of device(s) that diagnose pediatric apnea or apneic events
- Impact on pediatric quality of life
- Impact on cost of care
- Market and business potential
- Technical feasibility
- Value added by NEPDC assistance

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

Eligibility Requirements

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

- Technology / device must address pediatric apnea
- Technology / device must meet the FDA's definition of a medical device
- 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*

Terms and Conditions

- Pre-Seed Notification of Award: Approximately three to four 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.
- Applicants who have received monetary grants for their device from other FDA-funded pediatric device consortia are not eligible for pre-seed or seed awards. This includes the following:

  - Atlantic Pediatric Device Consortium
  - Boston Pediatric Device Consortium
  - MISTRAL Device Consortium
  - National Capital Consortium for Pediatric Device Innovation
  - Pediatric Cardiovascular Device Consortium
  - Philadelphia Regional Pediatric Medical Device Consortium
  - Southern California Center for Technology and Innovation in Pediatrics
  - University of Michigan Pediatric Device Consortium
  - University of California, San Francisco Pediatric Device Consortium

- Intellectual Property associated with devices submitted for review belongs to the inventor, and NEPDC makes no claims to that Intellectual Property. Additionally, submission for grant awards does not constitute public disclosure. One component of the NEPDC assistance process is to help clients ensure that Intellectual Property rights are protected so they can decide the most appropriate commercialization pathway.

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About NEPDC

The New England Pediatric Device Consortium (NEPDC) is a non-profit foundation supported by the FDA's Office of Orphan Products Development (Grant #: 1P50FD004907). We are a multidisciplinary, multi-institutional, collaborative consortium that provides rapid and targeted assistance to innovators seeking to address the needs of children suffering from disease or disabilities. NEPDC concentrates on disruptive technologies, incremental technology improvements, as well as pediatric technologies that may have limited market size but high potential for improving the life of a child. For further information please visit our website at www.NEPDC.org or contact us at info@NEPDC.org.

References

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