

## **Summary of Mid-Cycle Review of the Pediatric Device Consortia (PDC) Grant Program, August 2016**

The Pediatric Device Consortia (PDC) Grant Program was created by Congress under the Pediatric Medical Device Safety and Improvement Act of 2007 (PMDSIA), and is administered by FDA's Office of Orphan Products Development (OOPD). PMDSIA called for the creation of nonprofit consortia to "facilitate the development, production, and distribution of medical devices."

Under this statute, funded pediatric device consortia were to introduce innovators to potential manufacturing partners; mentor and manage pediatric device projects through the development process; connect innovators and physicians to existing Federal and non-Federal resources; assess the scientific and medical merit of proposed device projects; and provide assistance with business development. The funded consortia were to coordinate device development efforts with both the FDA and NIH.

The PDC Grant Program's 2013 Request for Applications (RFA) required that the 2013 grantees receiving five-year funding undergo a Mid-Cycle Evaluation to assess their progress to support continued funding and to identify areas to improve for the remainder of the grant cycle. The purpose of this report is to relay findings from this mid-cycle program assessment.

The PDC program currently funds a network of eight consortia that are intended to bring together teams with excellence and expertise for advising about the business, regulatory, legal, scientific, engineering, and clinical aspects of developing medical devices for children, at all stages of medical device development.

Since fiscal year (FY) 13, \$13.4M has been awarded, including \$3.0M in FY 16. Consortia funded under the 2013 RFA include: Atlantic Pediatric Device Consortium [\$2.19M total since FY 13]; Boston Pediatric Device Consortium [\$654K total since FY 13]; Southern California Consortium For Pediatric Device Development (CTIP) [\$1.2M since FY 13]; University of Michigan Pediatric Device Consortium (M-PED) [\$1.4M since FY 13]; National Capital Consortium For Pediatric Device Innovation (NCC-PDI) [\$2.8M since FY 13]; New England Pediatric Device Consortium (NEPDC) [\$2.8M since FY 13]; Philadelphia Pediatric Device Consortium [\$1.2 MK since FY 13]; and University of California, San Francisco Pediatric Device Consortium [\$446K since FY 13].

In the course of the mid-cycle review, the funded consortia provided the PDC Program written responses about their experiences and a summary of accomplishments so far. A customer satisfaction survey of innovators to whom assistance was provided was also conducted (hereafter referred to as "Innovator's Survey"). The OOPD PDC Program Project Officers utilized this information to prepare a Mid-Cycle Evaluation about the progress of each consortium, including recommendations for future funding.

The Innovator Survey collected data from the first two years of consortia interactions with the PDC and data on various 'success' metrics was collected through the first QTR of FY 16.

**Accomplishments In Brief Since FY 13:**

**Advising:** The PDC have advised 406 potentially-promising pediatric device projects and innovators, with 148 of these projects remaining actively engaged with the consortia. Eleven projects have been multi-consortia projects, receiving assist from more than one consortium.

**Marketing Clearances:** In addition to many devices under development, from the time of awarding grants under the FY 13 RFA, five devices are now available for use in the care for pediatric patients, due in part to assistance received from the PDC:

- Buzzy—cold and vibration for relief of pain with needle sticks (510K)
- Rhinoguard—Assists in naso-tracheal intubation (510K)
- TIVA (Velano Vascular)—needle-free blood collection device—allows blood draw through peripheral IV (510K)
- SleepWeaver Advance Pediatric CPAP Mask—provides an interface for noninvasive Continuous Positive Airway Pressure (CPAP) ventilation (510K)
- EKO stethoscope—Assists clinical diagnosis by recording and electronically amplifying, filtering, and transferring heart sounds, cardiac murmurs, bruits, respiratory and abdominal sounds (510K)

**Developmental Milestones:** The consortia have helped pediatric device projects achieve the following significant device development-related milestones:

Number of Patents Obtained	10
Number of Licenses or Option Agreements Executed	10
Number of Advanced Prototypes Developed	31
Number of Pre-submission Meetings with FDA	14
Number of Exempted Devices Advised	32
Number of Humanitarian Use Device (HUD) Designations Obtained	2
Number of Investigational Device Exemptions (IDEs) Advised	6
Number of 510Ks Advised	30
Number of 510Ks Cleared	2
Number of Humanitarian Device Exemptions (HDEs) Advised	9

**Leveraged Funding:** As a result of advice about Federal and Non-Federal funding sources provided by the consortia, more than \$69 Million has been raised since FY 13 to support advancement of, and research towards, the consortia’s pediatric medical device projects.

**Pediatric Device Development Awareness:** Additionally, the consortia have established a presence and raised awareness around pediatric medical devices, including publications related to PDC-assisted pediatric device projects and pediatric device-related events such as meetings, Grand Rounds presentations, and conferences. Independent of this grant, several of the consortia leaders have established pediatric device development fellowships, and participated in surgical and engineering curriculum development related to pediatric medical devices.

**Summary from Innovator’s Survey:** Overall, innovators working with the PDC reported favorable interactions and impressions. Assist with the regulatory process, financial support, and advice on funding sources were the predominant types of support provided. The survey revealed a high degree of

innovator satisfaction with ease in obtaining assistance, and the advice and resources provided by the consortia.

**Results:** Based on the input provided by each consortium coupled with the feedback provided by an Innovator's Survey, it was demonstrated that each consortium is achieving the goals of the PDC Program. Minor identified issues were resolved with the consortia. Thus, the PDC awardees will be funded at the present level of three million dollars for the remainder of their competitive cycle (FY 2017). Any additional amounts of funding will be awarded proportionately amongst the consortia.