UROLOGYPRACTICE

urologypracticejournal.com

the Specialty

Pediatric Medical Device Consortia: A Novel Pathway for Pediatric Device Development for Pediatric Urologists and Other Pediatric Specialists

Matthew Grant,* Irina Stanasel* and Chester J. Koh†,‡

From the Texas Children's Hospital, Baylor College of Medicine, Houston, Texas

Abstract

Introduction: A great need currently exists for medical devices designed specifically for children. This gap is most likely a result of economic, clinical and regulatory challenges as well as a lack of established mechanisms for joining pediatric device ideas with qualified individuals/programs and industry partners. We describe our experience with forming a pediatric medical device consortium that originated from the pediatric urology division and the technology transfer office of a university affiliated children's hospital.

Methods: We reviewed the developmental history of a pediatric medical device consortium at a university affiliated children's hospital from March 2011 to June 2013 with emphasis on the organizational aspects of the consortium.

Results: A pediatric medical device consortium was formed with the assistance of university seed funding to encourage faculty collaboration across multiple campuses. The consortium continued its progress as a resource for pediatric device projects to become a Food and Drug Administration supported pediatric device consortium in 2013. This allows the consortium to expand its activities through the P50 PDC Grant Program.

Conclusions: Pediatric urologists can have a major role in organizing pediatric device consortia. Consortia can combine academic centers with the local business, investment, higher education and philanthropic communities to rapidly advance pediatric medical device projects. Novel approaches are necessary for pediatric device projects to overcome current barriers to commercialization, including an extended stay in the academic setting.

Key Words: urology; pediatrics; biomedical engineering; organizations, nonprofit; financing, government

Abbreviations and Acronyms

FDA = Food and Drug Administration

HDE = Humanitarian Device Exemption

PDC = Pediatric Device Consortium

PMDSIA = Pediatric Medical Device Safety and Improvement Act of 2007

USC = University of Southern California

Since children differ from adults in their size, anatomy, body chemistry, and overall growth and development, a great need currently exists for novel medical devices that are designed specifically for children as well as for the adaptation and validation of existing adult devices for children. The United States FDA estimated that the development of pediatric medical devices lags behind the development of adult

Submitted for publication October 21, 2014.

Supported by FDA Grant 1P50FD004896.

* No direct or indirect financial incentive associated with publishing this article.

† Correspondence: Texas Children's Hospital and Baylor College of Medicine, Clinical Care Center, Suite 620, 6701 Fannin St., Houston, Texas 77030 (telephone: 832-822-3160; FAX: 832-825-3159; *e-mail address:* cxkoh@texaschildrens.org).

‡ Financial interest and/or other relationship with HDSono.

2352-0779/15/24-206/0
UROLOGY PRACTICE

http://dx.doi.org/10.1016/j.urpr.2014.11.002
Vol. 2, 206-210, July 2015
Published by Elsevier

devices by 5 to 10 years.[1] This appears to be a result of economic, clinical and regulatory challenges as well as a lack of established mechanisms to join pediatric device ideas with qualified individuals/programs and industry partners. The shortage of pediatric devices has primarily resulted in the practice of altering or modifying adult devices for pediatric use. In the pediatric interventional cardiology field half of all procedures are performed with off-label use of adult devices.[2]

The 2007 PMDSIA authorized the FDA to encourage pediatric medical device development through the creation of nonprofit PDCs that facilitate the development, production, approval and distribution of pediatric medical devices.[3] We describe our experience with forming a PDC that originated from the pediatric urology division and the technology transfer office of a university affiliated children's hospital.

Materials and Methods

The developmental history of SCCTIP (Southern California Center for Technology and Innovation in Pediatrics), a pediatric medical device consortium at a university affiliated children's hospital from March 2011 to June 2013, was reviewed with emphasis on the organizational aspects of the consortium. Founding members of the consortium included faculty and staff in the pediatric urology division and the technology transfer office of Children's Hospital Los Angeles as well as the faculty and staff of the Keck School of Medicine at USC, and the USC Viterbi School of Engineering and the USC Office of Research.

Results

Early pilot funding was provided by the University Office of Research through an internal faculty grant that encouraged collaboration among faculty in different schools and campuses of the university. This provided funding to assemble volunteer experts in medical device development that were committed to pediatric care. Appendix 1 shows internal and external schools and organizations from which the potential partners originated. This also allowed for an internal survey of the current projects that were in progress as well as a discussion of the challenges faced by the local pediatric medical device community. One realization was that pediatric device projects often do not progress through the usual market based approach and, therefore, they may require an extended life cycle in the academic setting before exposure to the external market. The figure shows the common steps of pediatric medical device development. Each step can present a challenge to progression ("valley of death") for a particular pediatric device project.

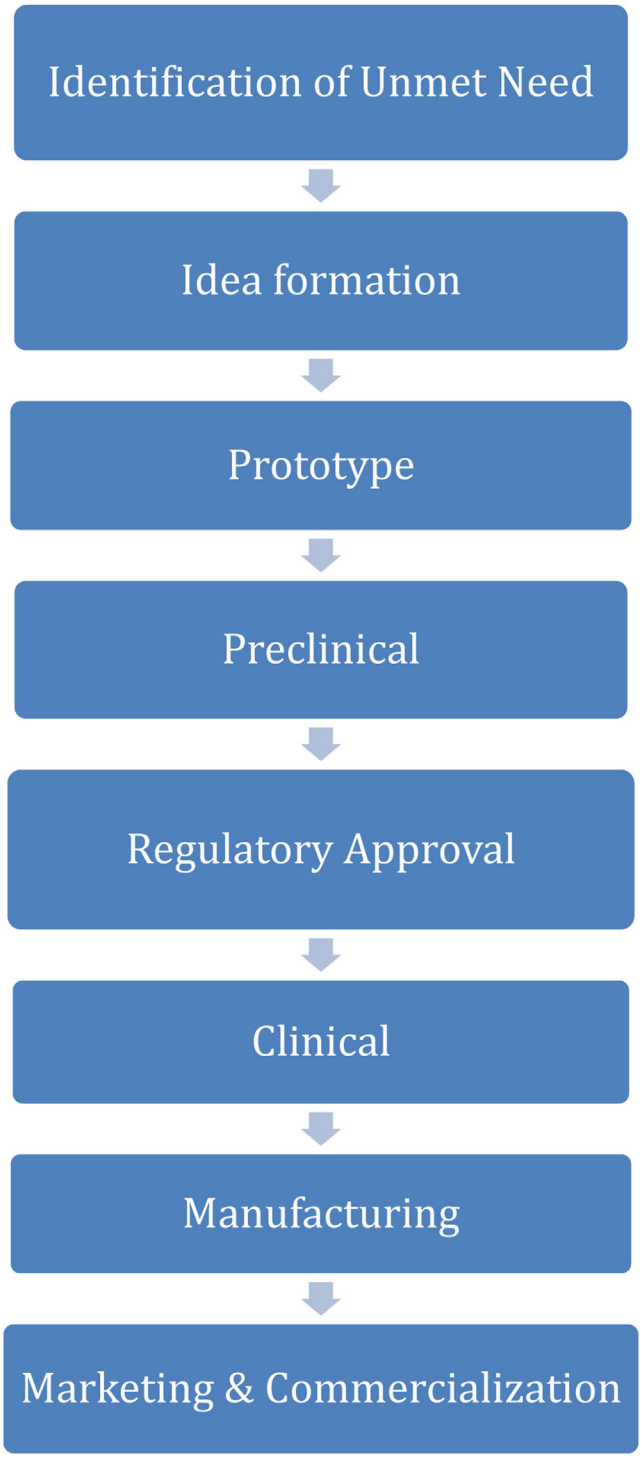

Figure. Common steps of pediatric medical device development pathway.

The consortium continued its progress as a resource for pediatric device projects to become a FDA supported PDC in 2013.

Appendix 2 lists FDA supported PDCs. The consortia serve as a resource for pediatricians, pediatric caregivers and pediatric specialists across the United States if they seek assistance with innovative pediatric medical device projects.