

# Philadelphia Regional Pediatric Medical Device Consortium

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## Executive Summary

Pediatric device development has historically faced and presently faces major barriers. Despite these barriers, unmet needs for childhood illnesses drive us to act. With funding from the United States Food and Drug Administration (FDA), The Children's Hospital of Philadelphia (CHOP) together with Drexel University and the University of Pennsylvania are developing the "Philadelphia Regional Pediatric Medical Device Consortium" (Philadelphia PDC). The mission of the Philadelphia PDC is to provide seed funding and business, legal, marketing, clinical, engineering and scientific resources to inventors of promising pediatric medical devices that will benefit children and have a strong commercialization potential. CHOP is both the nation's and region's premier children's hospital, leading in clinical care and research. The CHOP faculty researchers and research institute infrastructure will be the basis for the broad reaching pediatric device expertise in the Philadelphia PDC. A key partner in the Philadelphia PDC is the Coulter-Drexel Translational Research Partnership at Drexel University. The Coulter-Drexel Partnership promotes, develops, and supports innovations to improve patient care by providing sound business, regulatory, and intellectual property advice from pre-eminent experts, with funding and project oversight, to promising translational projects with commercialization potential. By partnering the Philadelphia PDC with Coulter-Drexel, we form a consortium of experts with both breadth and depth in all critical aspects of pediatric medical device development (business/finance, regulatory, IP, clinical, and science/engineering), reduce costs via shared management responsibilities and resources, and leverage of funding from both the Philadelphia-PDC and Coulter-Drexel on projects that merit large investment.

### ***An optimal approach for project funding decisions and project oversight***

Our vision is for a Consortium that objectively evaluates project proposals upon merit (sound science, clinical need, and marketability) and provides managed funding, expert advice and oversight to ensure success. Our Consortium's funding decision process, which is dovetailed with the successful Coulter-Drexel Partnership, reduces programmatic costs through shared management and consulting resources, and offers dollar-for-dollar matching funds that effectively double the project funding resources available to the Philadelphia PDC projects. The salient features of our proposal evaluation process include:

- Open access to the Philadelphia PDC to projects from any source (not just our members),
- Efficient and timely vetting of proposal ideas via single-page letter of intent,
- Written four page proposals with independent evaluation of regulatory, reimbursement, IP, and market potential,

- An iterative mentoring and coaching framework to refine written proposals before final funding judgment begins, and
- Final funding judgment made by a multidisciplinary Oversight Committee consisting of medical device industry professionals, venture capitalists, and clinician/scientific experts, none of whom are themselves proposers of any projects to the Philadelphia PDC (thus avoiding a conflict of interest).

### ***A Multidisciplinary Consortium of Accomplished Leaders***

Our business advisors, who make up the Oversight Committee for the Philadelphia PDC, have extensive experience and a proven track record in medical device innovation. Collectively, our clinicians, scientists and engineers, who are members of the Clinical and Scientific Advisory Committee of the Philadelphia PDC, hold medical device patents in cardiology, fetal surgery, robotic surgery, near-infrared spectroscopy, and nanotechnology. Our clinicians are current practitioners and thought-leaders in their respective specialties, and our pre-eminent legal team lists as current and past clients, small start-up companies, mid-size companies, large multi-national companies, universities and independent inventors, with hundreds of applications prepared, filed and prosecuted. Our regulatory, marketing, and reimbursement analysts have decades of combined experience, and their expert and objective reports have been used by the Coulter-Drexel Oversight Committee to guide funding decisions leading to the licensure of 10 medical devices in a short 7 years. CHOP's small and large animal vivariums with attached medical/surgical suites and 1.3 million square feet of research space, provide a sound platform for pre-clinical studies; our patient care capabilities, currently peer-ranked #1 in the nation by U.S. News and World Report, supports hundreds of clinical trials per year. The Consortium's current medical device endeavors range from magnetic targeting of nanoparticles to treat vascular injury, to new capnography technology, to devices for fetal surgery.

With breadth and depth in multiple medical specialties and device technologies, expert business, legal, marketing and regulatory consulting, world class facilities for device innovation, engineering, testing and trials, and a proven track record of pediatric medical device success amongst our members, the Philadelphia PDC will serve as a national resource for pediatric medical device innovation.

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