Innovation in Pediatric Medical Devices: Thinking Outside The Box

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University of Minnesota HEALTH
Pediatric Ventricular Assist Device
Adult Ventricular Assist Device
Why the Lag?

- Funding
- Testing
- Regulation
- Patient
Funding-Venture Capital

• Split Rock Criteria for Investment:
  
  – Significant market size
  
  “”typically greater than $500 million”

  – “Rapid development timeline commercialization potential in less than 5 years”

http://www.splitrock.com
Peds versus Adult Device Market

• Adult Global Heart Valve market: $1.2billion

• Pediatric Heart Valve Market: $50-100 million
Testing:
Smaller Test population

United States Population

- Over 15yrs
- Under 15yrs
Regulation: Approval Through the FDA

• Traditionally more stringent requirements

• Testing is difficult on a pediatric population
Traditional Device Pathway

- The average ‘new’ device takes 100 million dollars and 10 years to get to U.S. market
Medical Device Development Plan

- Ideation
- Engineering
- Patent Submission
- Prototyping
- Bench Proof of Concept
- Animal Model Proof of Concept
- First in Man
- Clinical Trials
- Manufacturing Plan
- FDA Submission
- Reimbursement Plan
- Marketing
- Post Market Follow Up
Device Shrink

Children are not small adults
Kids are Complex

- Age and Size variation
- Growth
- Immune Variation
- Dependence on Caretakers
The Traditional Method of Making and Selling Medical Devices Doesn’t Work for Small Market Populations.

So What Now?
Pediatric Device Consortia

- Some funded by FDA
- Collaboration between
  - University
  - Industry
  - Non-profits
  - Private Inventors
PDIC

- Pediatric Device Innovation Consortium at the University of Minnesota: www.pdicmn.org

**KIDS NEED MEDICAL DEVICES:**
Made just for them.
State-of-the-art medical engineering support.

**MEDICAL DEVICE INVENTORS:**
Build. Test. Launch.
Confidential financial and professional help – get it done!

**PHYSICIAN-INVENTORS:**
Get expertise, resources, funding.
Develop your concept in a world-class pediatric medical and engineering environment.

**MEDICAL DEVICES DESIGNED AND BUILT ESPECIALLY FOR KIDS.**
We accelerate ideation, design, development, production and distribution of pediatric medical devices for the purpose of curing, alleviating and preventing pediatric disease.
Humanitarian Use

- Fast track for Devices Designed for Populations of <4,000 per year
- Must prove benefit is more than risk
- 144 products with Humanitarian Use designation
- 44 Approved through Humanitarian Device Exemption
Example of Humanitarian Use-the Melody Valve

• Made by Medtronic
• First approved Transcatheter valve
• Congenital heart disease
• Humanitarian Use designation
Alternative Sources of Funding

• SBIR/STTR

• Crowdsourcing

• University Clinical Translational Science Institutes (CTSI)

• Student Engineering Projects (senior design classes)
Professional Help

On the FDA Webpage
• Atlanta Pediatric Device Consortium
  – http://atlanticpediatricdeviceconsortium.org/
• Michigan Pediatric Device Consortium
  – http://peddev.org/
• National Capital Consortium
  – www.innovate4kids.org
• New England Pediatric Consortium
  – www.nepdc.org
• Southern California Center
  – www.scctip.com
• Philadelphia Pediatric Consortium
  – www.ppdc.org
• UCSF Peds Consortium
  – www.pediatricdeviceconsortium.org

Other Resources
• PDIC
  – www.pdicmn.org
• Pediaworks
  – www.pediaworks.org
Thank you!

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