

Innovation in Pediatric Medical Devices: Thinking Outside The Box

Gwenyth Fischer

University of Minnesota Masonic
Children's Hospital



The Pediatric Device Lag



2005



2015



Pediatric Ventricular Assist Device

Adult Ventricular Assist Device





Why the Lag?

- Funding
- Testing
- Regulation
- Patient



Funding-Venture Capital



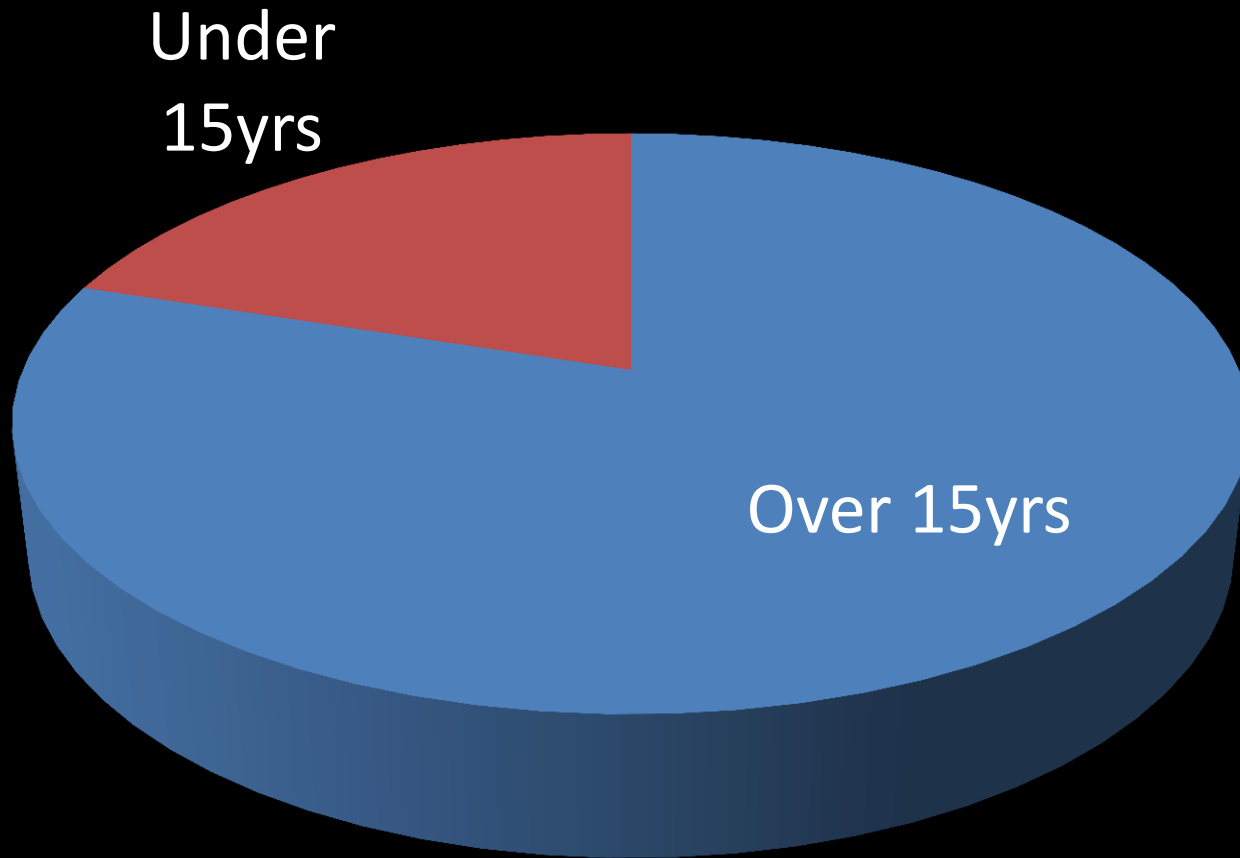
- Split Rock Criteria for Investment:
 - Significant market size
“”typically greater than \$500 million”
 - “Rapid development timeline commercialization potential in less than 5 years”

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

Regulation: Approval Through the FDA

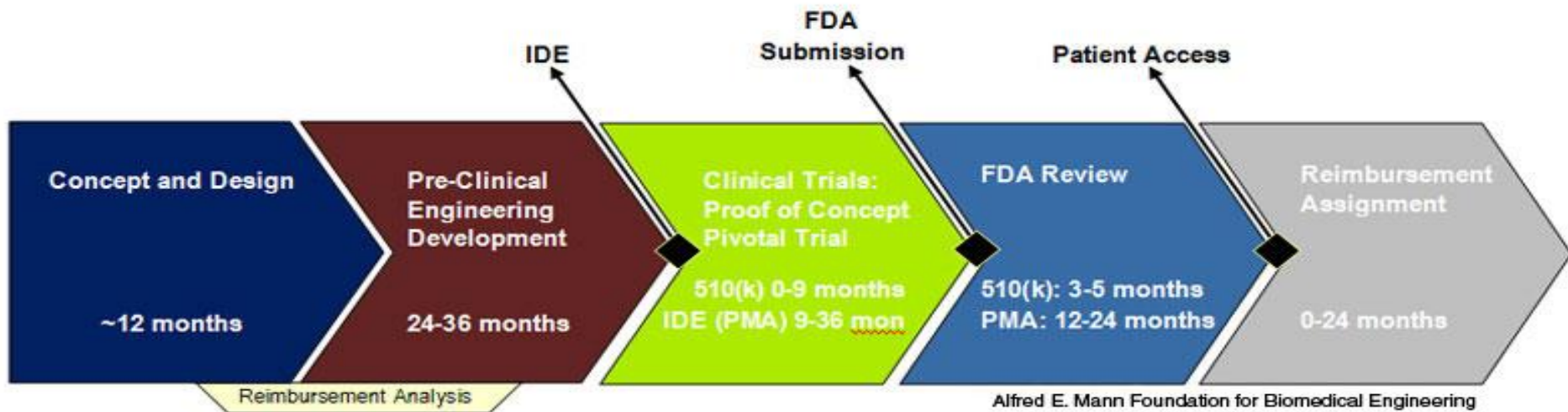
- Traditionally more stringent requirements
- Testing is difficult on a pediatric population



Traditional Device Pathway

- The average 'new' device takes 100 million dollars and 10 years to get to U.S. market

FDA Medical Device Approval Process



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

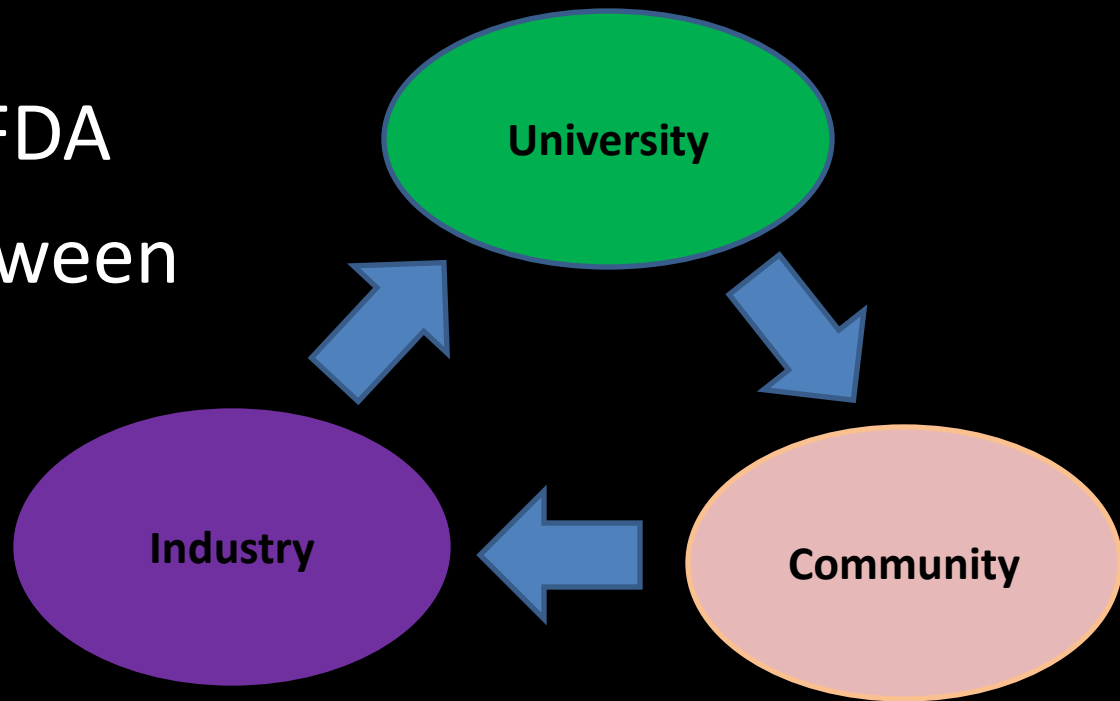


The Traditional Method of Making and Selling
Medical Devices Doesn't Work for Small Market
Populations.

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



Pediatric Device
Innovation Consortium
MINNESOTA

 **HEALTH.**
University of Minnesota
Masonic Children's Hospital

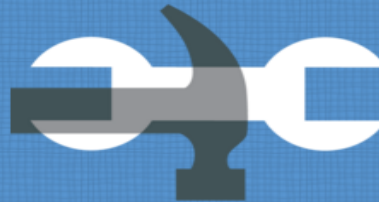
CONNECT WITH PDIC

BECOME A VOLUNTEER



**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!



fisch662@umn.edu