

Pediatric Device  
Consortia Grant Program



Welcome to the FDA OOPD  
Pediatric Medical Devices Workshop!

# Disclaimer

This workshop is intended to encourage discussion of issues related to pediatric medical device development.

We have invited speakers from a variety of professional backgrounds and experiences. Speakers' expressed opinions and slide sets are not an official document, guidance or policy of the US Government, the Department of Health and Human Services, or the Food and Drug Administration, nor should any official endorsement be inferred.

# OOPD Programs and Pediatric Device Development:

---

- Pediatric Device Consortia Grant Program
- HUD Designation Program
- OPD Grants Program

# Pediatric Device Consortia Grant Program

- FDAAA-Pediatric Medical Device Safety and Improvement Act 2007
  - Establish nonprofit consortia to stimulate pediatric device development
- Not a direct research grant
  - fund nonprofit consortia that **support** pediatric device developers
- OOPD is responsible for carrying out the program but:
  - encompasses devices used in all pediatric diseases, not just rare diseases.
- PDC program encompasses ALL aspects of pediatric device development, not just regulatory

# Pediatric Device Consortia

- What is a consortium?

....a network of individuals and organizations:  
business; clinicians; manufacturers;  
engineers

....an information source



“A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of medical devices by--

1. Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers
2. Mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing.
3. Connecting innovators and physicians to existing Federal Sources and non-Federal Resources.
4. Assessing the scientific and medical merit of proposed pediatric device projects
5. Providing assistance as needed on business development, personnel training, prototype development, post-market needs and other activities consistent with the purpose of this section

# WHO?

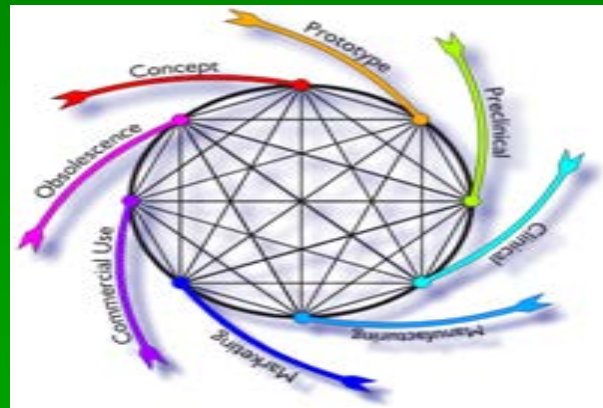
## Recipients of the PDC Grants

(LOOK for the Folks with the ORANGE RIBBONS!)

- James Geiger, MD/ Andre Muelanaer, MD and the Michigan/PMDI Pediatric Device Consortium,
- Michael Harrison, MD and the UCSF Pediatric Device Consortium
- Pedro del Nido, MD and the Pediatric Cardiovascular Device Consortium,
- Pablo Garcia and the MISTRAL Pediatric Device Consortia
- Barbara Boyan and the Atlanta Pediatric Device Consortium



# Advancement of Pediatric Medical Devices: Progress So Far...



Over **180** pediatric device projects have been assisted in their development by the pediatric device consortia since October of 2009.



# Advancement of Pediatric Medical Devices: Progress So Far...

- Now this doesn't mean that we have 180 projects coming to the market because of the program....
- The vast majority of projects assisted by the consortia are in the earliest stages of development— concept formation; prototyping; and early testing on the benchtop or in animals
- The consortia are currently managing 102 **ACTIVE** projects

# Pediatric Device Consortia

---

- Program was re-authorized under the FDA Safety and Improvement Act;
- Waiting to find out about future appropriations
- New RFA anticipated in spring
- Lessons learned to make the program even more effective

# Pediatric Medical Devices Workshop (Today!)

---

- Inspired by consortia
- Challenges faced:
  - Business
  - Regulatory
- Contributions of Major Device Companies Acknowledged and Comments Welcomed