

FDA Panel on Pediatric Devices



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- AGA: Investigator
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Topics For Discussion

- What new devices are needed in pediatric cardiology?
- What are the incentives for development given a small market (or HDE <4000/year)?
- What are the impediments to having new devices manufactured and marketed?
- What can be done to improve the current system?
- Physician directed use of devices.

- Why is the FDA process thought to be so difficult?
- Why is the process perceived to be so much more difficult in the US compared to Europe and Canada?
- Can pediatric trials realistically be blinded and controlled?
- What are the alternatives?
- Are there other sources of data that might be evaluated in lieu of an FDA study for device approval?

Universities and IRB's

- As bad as the IRB process may be
- The contracting process can be worse
- Could there be a “Universal IRB”?

- Current impetus for doing trials is to have early access to potential devices
- The desire to use the device often overshadows the need for the trial
- This often leads to protocol deviations which impact the approval process.

- Desire to take part in the trial is usually to have the device as opposed to the alternative.
- Once the procedure has been done, the commitment to follow-up may disappear.
- The informed consent process is too arduous.

Litigious Issues

- How much of the difficulty is caused by potential litigation issues?
- Can things improve as long as unforeseen problems not apparent during trials that occur 5,10 or 15 years later are subject to litigious actions?
- Should Legislation protect the process?

- The Unique Patient Identifier
- We need this in order to track our patients whether or not they are in studies, registries or just in order to understand the longitudinal outcomes of a patient cohort.