

# Pediatrics & Medical Device Development

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# Barriers?

- Identification of needs
- Research needs for pediatric uses
- Development issues

# Pediatric Devices

- If available in the market:
  - Size
  - Performance
  - Risks
- Unavailable:
  - Need and population
  - Issues that need to be addressed

# Investments in Development

- Design – inputs for the specific use, populations
- Materials – selection and testing
- Bench testing – the actual product
- Animal testing – appropriate for populations
- Human testing – when and where needed
- Manufacturing – number, shelf life, difficult build

# Needs

- Descriptions of specific populations, diseases, co-morbidities, population size, other therapies available with impact
- Good potential user input to design and other phases, e.g., testing, human factors, efficacy, safety
- Clear regulatory pathways with specific expectations