

# Update of HBD for Children Activities

**Nicole Ibrahim, PhD**

Division of Circulatory Support, Structural and Vascular Devices

Office of Cardiovascular Devices

Office of Product Evaluation and Quality

CDRH/FDA

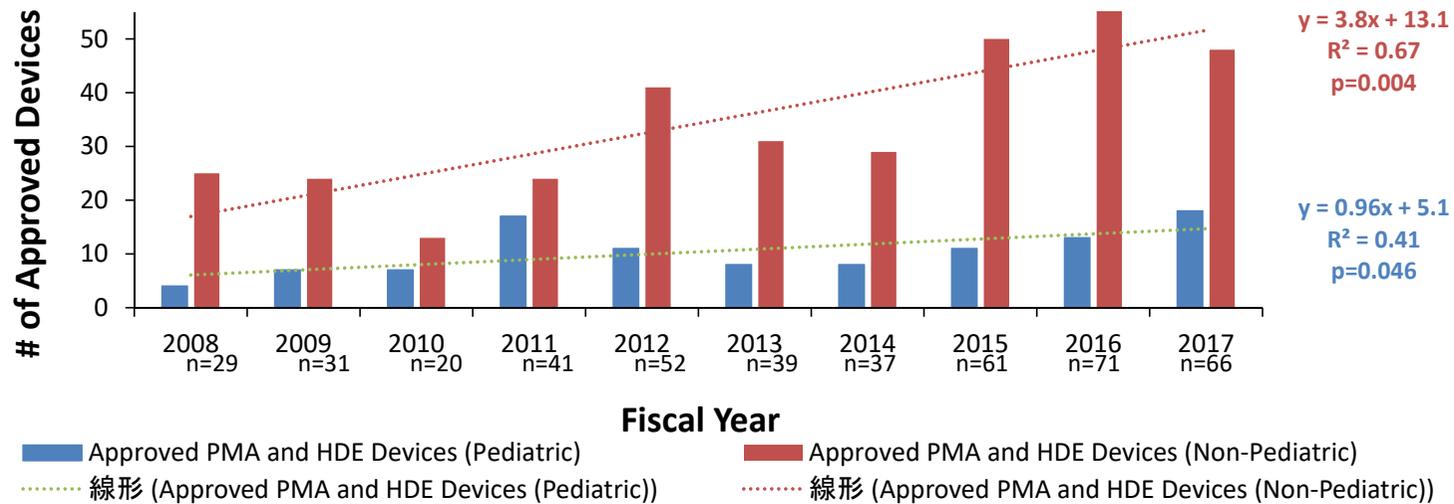


# Background

- HBD program established nearly 2 decades ago
- Discuss the challenges and solutions for accommodating the local regulations in both US and Japan by conducting proof-of-concept (POC) projects, i.e., “by Doing”
- Identify and pursue actual, practical applications of harmonization
- Experience has largely been in the coronary and peripheral vascular device areas to treat diseases in adults

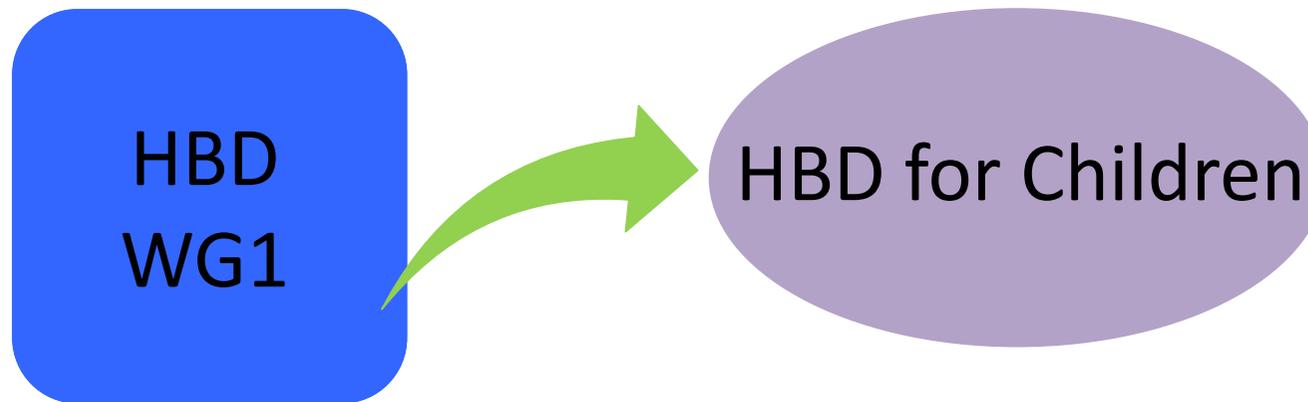


# In the US Adult Device Approvals Increasing Faster than Pediatric

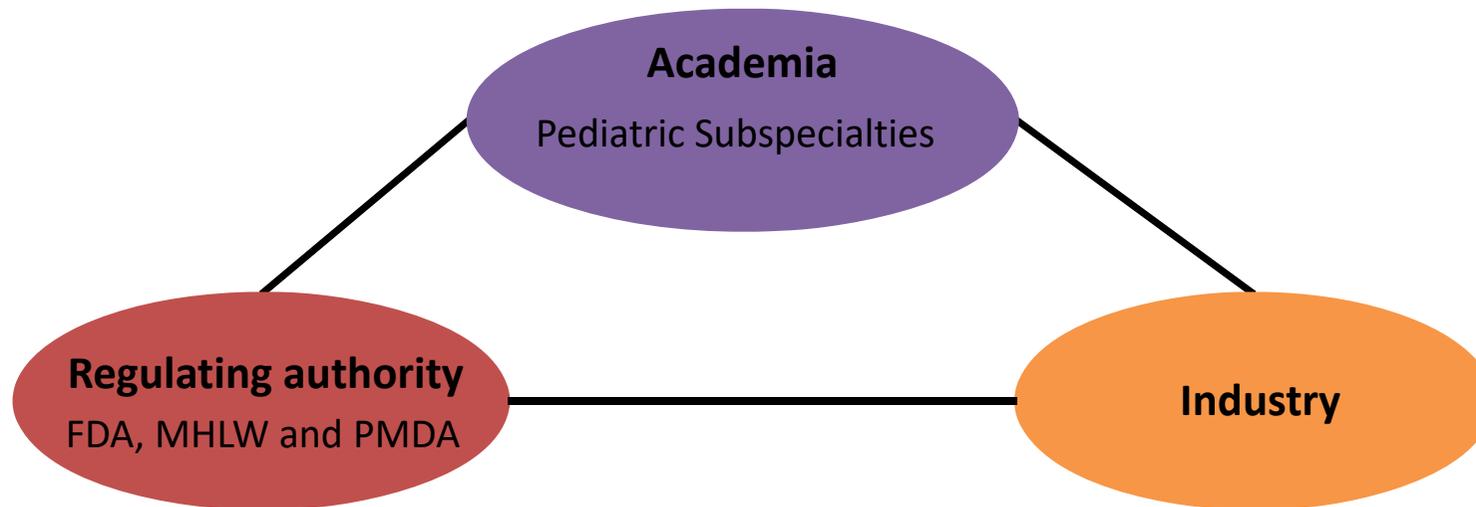


**Upward trajectory in the total number of PMA and HDE applications**  
**Adult approvals significantly greater than pediatric approvals**

# New Working Group



# HBD Construct



- Teleconferences once every quarter to discuss how to advance the development of pediatric devices and provide updates on current POC project(s).
- HBD sessions and face to face meetings at cardiology / pediatric conferences in the U.S. and Japan twice every year.



## HBD for Children Initial Goals

- Better understand the barriers to pediatric device development in the US and Japan
- Assess the current state of needs in pediatric congenital heart disease
- Characterize current state of device availability and use in the US, Japan and other geographies
- Identify specific multi-stakeholder projects (POC or other) that address the needs

# Survey to Industry

Japan

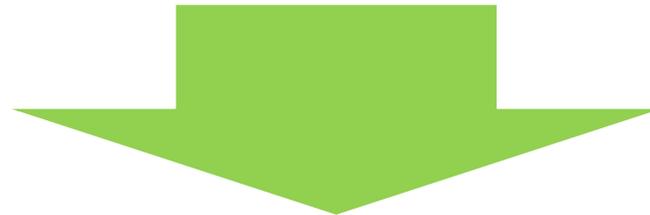


1 <sup>st</sup>	<b><u>The market is too small.</u></b>
2 <sup>nd</sup>	Development cost is too high.
3 <sup>rd</sup>	High barriers for application and approval.

USA



1 <sup>st</sup>	<b><u>The market is too small.</u></b>
2 <sup>nd</sup>	Difficult to conduct a clinical trial.



The aim of “HBD-for-children” is to find solutions to support development and approval of pediatric medical devices that serve an unmet need.



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## Areas of Unmet Need

- Stents for coarctation of the aorta
- Stents for pulmonary artery stenosis
- Transcatheter pulmonary valve for native RVOT
- PDA closure devices
- Stents for PDA in young children with duct dependent congenital heart disease



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# Device Landscape

- 1. Approved in US but not approved in Japan**
  - Potential use of clinical data in US for approval in Japan
  
- 2. Not indicated for CHD in US and Japan but used Off-label in US or Japan**
  - Evidence needed for approval in both countries.
  
- 3. Not approved in US or Japan but used/approved in other countries**
  - Process for approval in US and Japan
  
- 4. Under development**
  - Process for conducting global development and an international clinical trial
  
- 5. Approved in Japan but not approved in the US**
  - Potential use of clinical data in Japan for approval in the US



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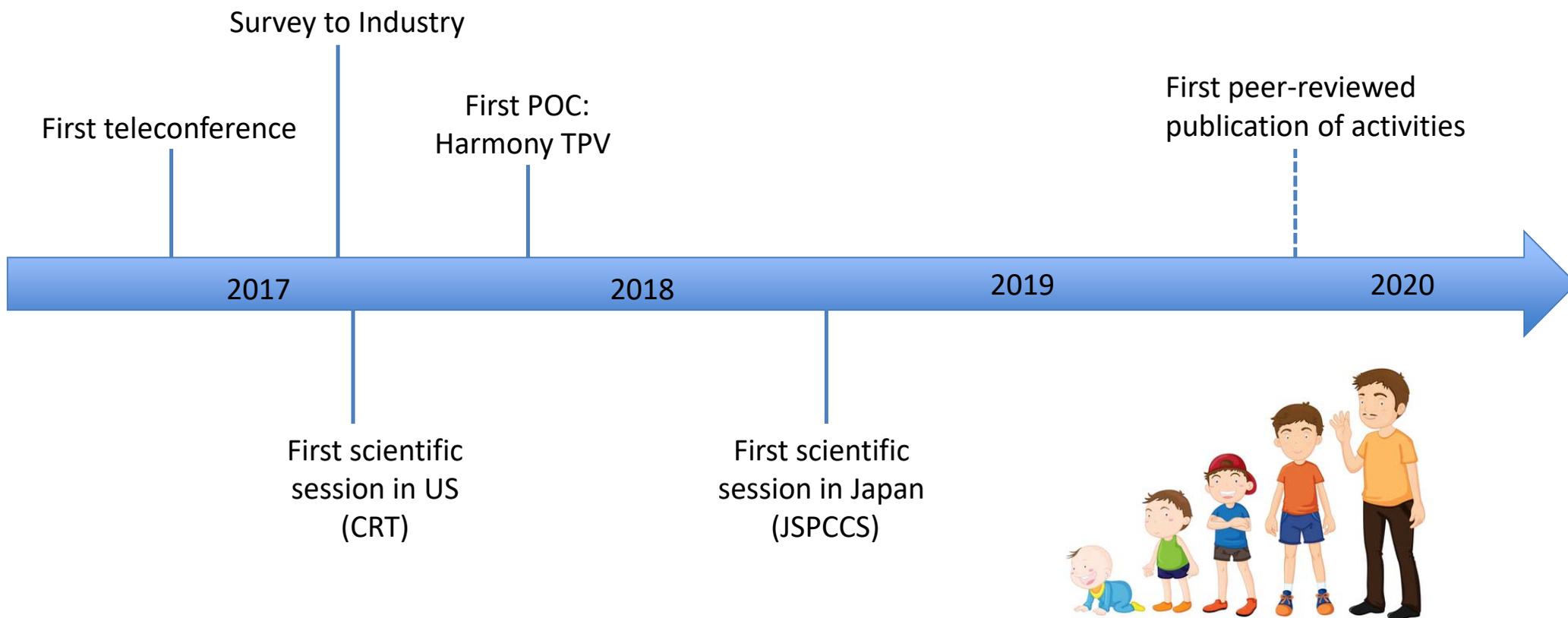
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## First POC: Harmony TPV

- Medtronic Harmony Transcatheter Pulmonary Valve
- Patients with symptomatic severe pulmonary regurgitation with a surgically repaired right ventricular outflow tract
- First US-Japan global clinical trial of pediatric medical device
- Up to 15 sites in US and 2 sites in Japan
- Enrollment complete



# HBD for Children Activities



# The Future of HBD for Children

- Continue to discuss the use of existing data to support regulatory decisions
  - Use of JPIC, CCISC, ACTION and other registries
  - Better understand regulatory evaluation of registry data
- Identify new POCs
- Expand to other cardiovascular subspecialties
  - Pediatric heart failure
  - Pediatric electrophysiology





# Thank you!

Contact information:

Email: [Nicole.Ibrahim@fda.hhs.gov](mailto:Nicole.Ibrahim@fda.hhs.gov)

