Update of HBD for Children Activities

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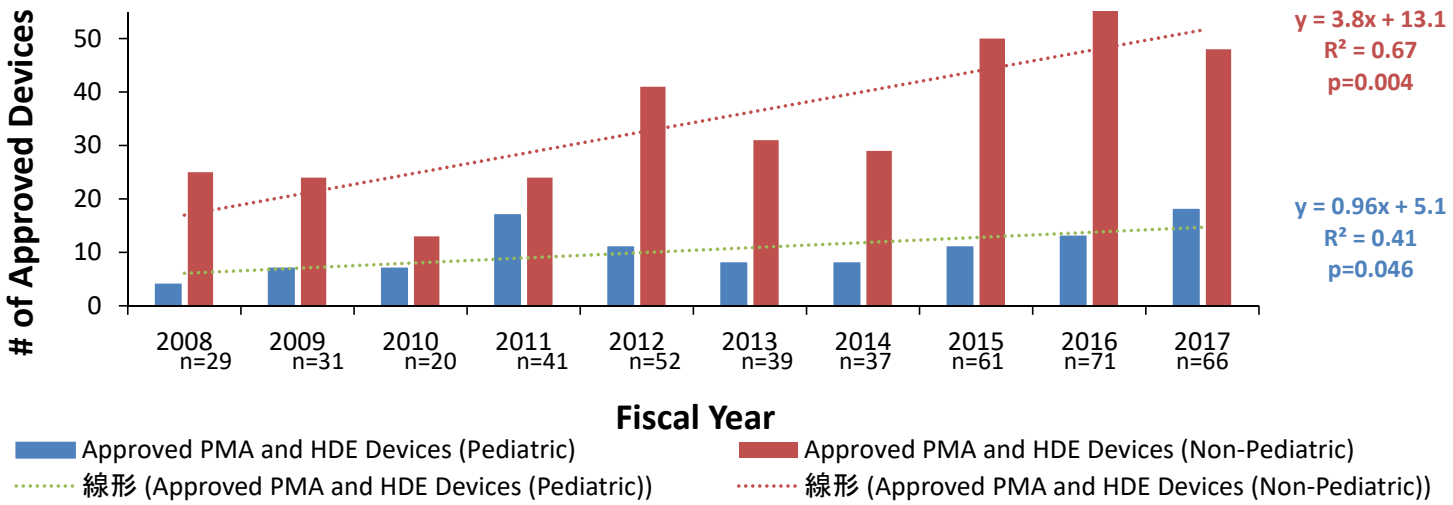
Background

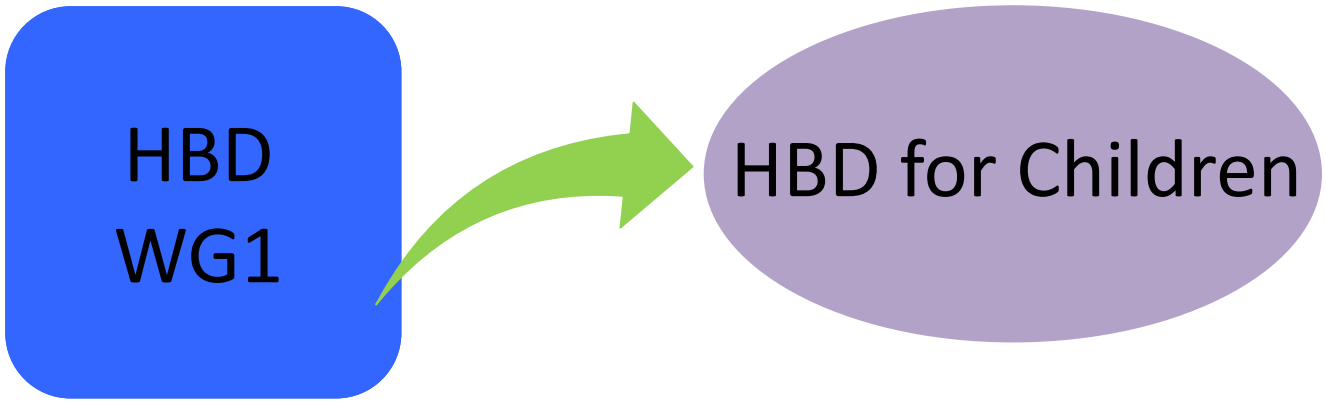
- HBD program established nearly 2 decades ago
- Discuss the challenges and solutions for accommodating the local regulations in both US and Japan by conducting proof-of-concept (POC) projects, i.e.,“by Doing”
- Identify and pursue actual, practical applications of harmonization
- Experience has largely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

In the US Adult Device Approvals Increasing Faster than Pediatric

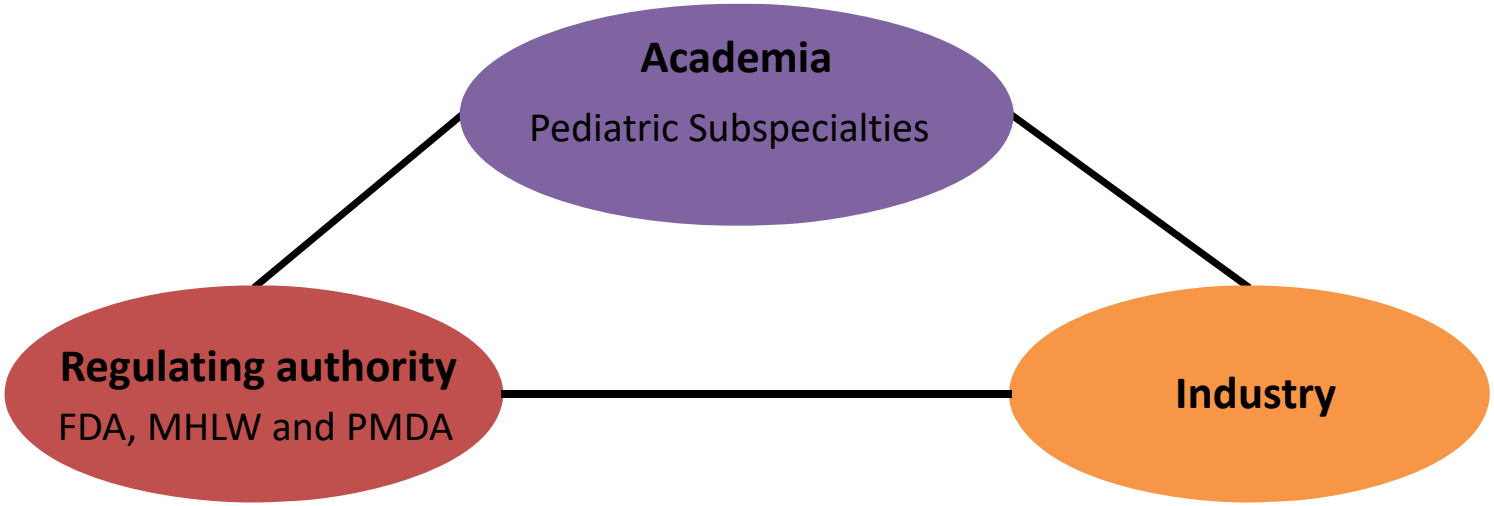


Upward trajectory in the total number of PMA and HDE applications
Adult approvals significantly greater than pediatric approvals

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.

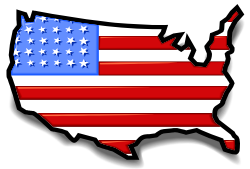
HBD for Children Initial Goals

- 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 

1st	**The market is too small.**
2nd	Development cost is too high.
3rd	High barriers for application and approval.

USA 

1st	**The market is too small.**
2nd	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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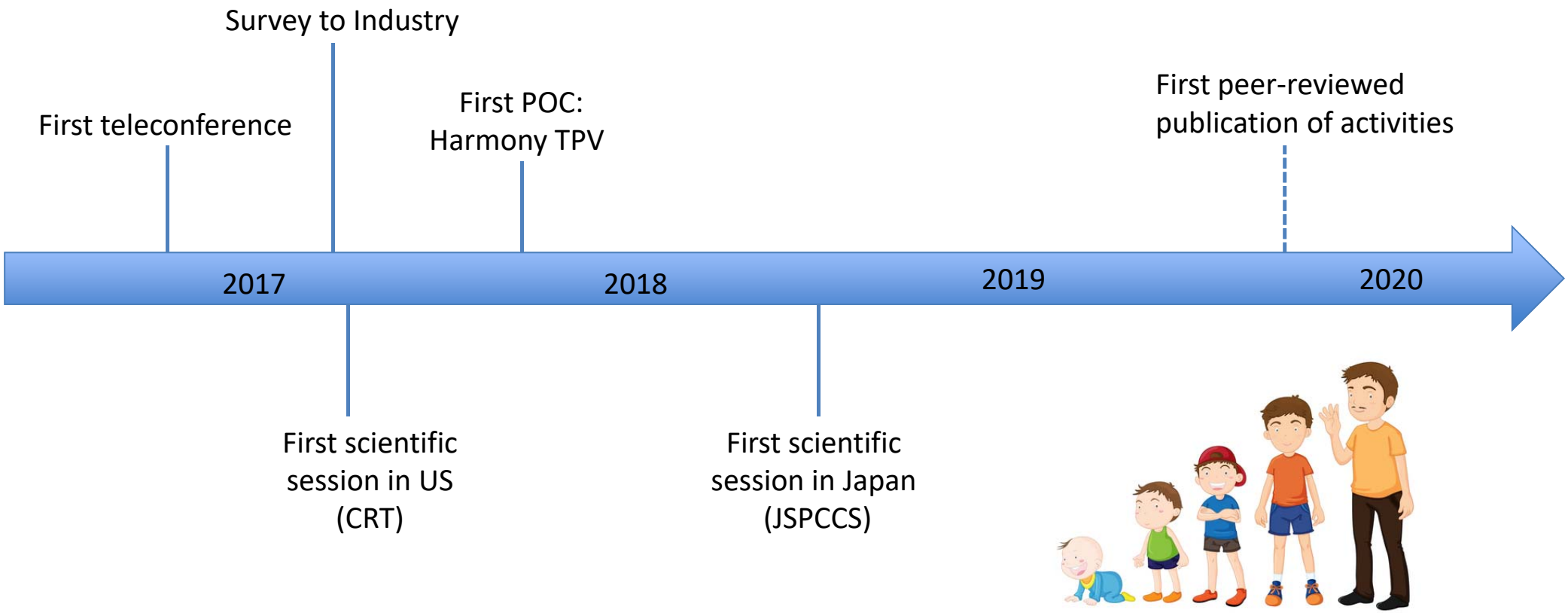
First POC: Harmony TPV

- 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!

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