Update of HBD for Children Activities

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Background

- HBD program established nearly 2 decades ago
- Objectives
  - Discuss the challenges and solutions for accommodating the local regulations both in the 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.

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

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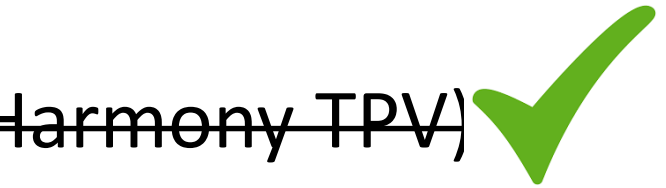
Areas of Unmet Need

- Stents for coarctation of the aorta
- Stents for pulmonary artery stenosis
- ~~Transcatheter pulmonary valve for native RVOT (Harmony TPV)~~ 
- PDA closure devices
- Stents for PDA in young children with duct dependent congenital heart disease
- Mechanical Circulatory Support for Pediatrics

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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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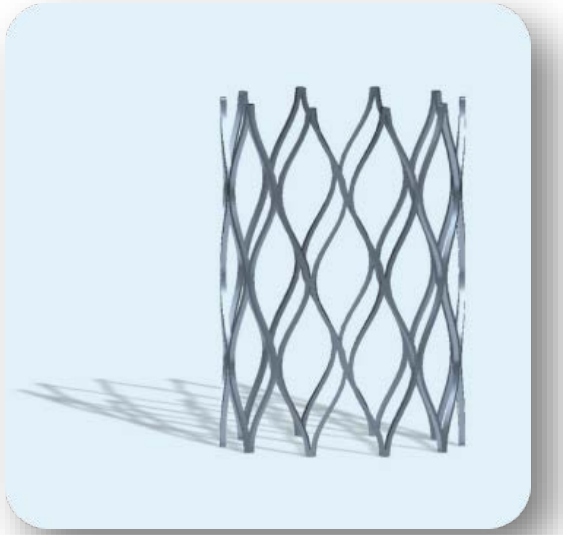
First POC: Harmony TPV

- 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
- **Approved** in US (P200046 - March 2021) and Japan (August 2021)

Current POC: Renata

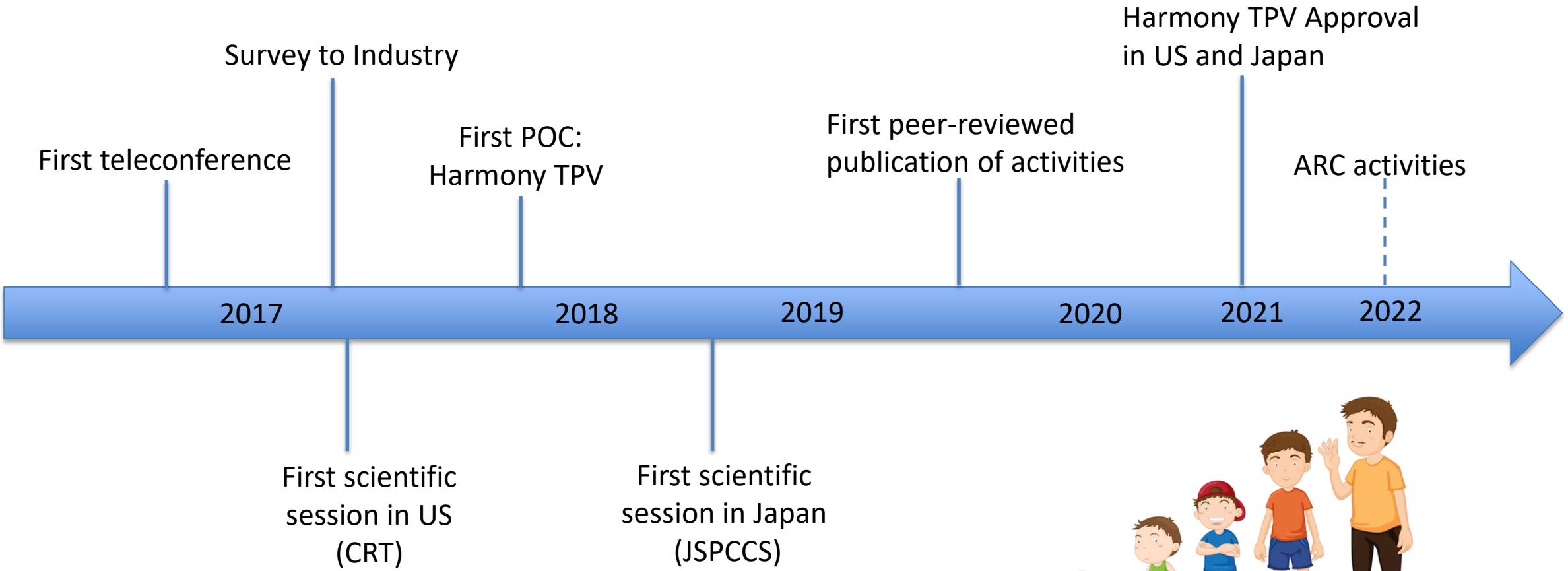
- Renata Medical - Accepted to POC in Nov 2021
- It is an adjustable stent that has been purposefully designed for pediatrics to last a lifetime.
- The stent is inserted in the patient at birth and may eliminate the need for ongoing surgery due to the device's ability to be re-expanded.



Summary of Major Updates

- First POC Harmony TPV got **Approved**
- Additional POC in the pipeline. E.g., Renata
- Academic Research Consortium (ARC) efforts
  - ❖Working on Definition and Endpoints
  - ❖Planning to focus on Valve and Congenital heart Diseases
    - Vascular Stenting
    - Mechanical Circulatory Support for Pediatrics
- GCP and BIMO requirements
  - Early stage, Comparison table between US & Japan requirements

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
  - ➢ Renata …
- ARC Efforts
- Expand to other cardiovascular subspecialties
  - ➢ Pediatric Heart Failure
  - ➢ Pediatric Electrophysiology

Thank you!

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