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
WG1

HBD for Children
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

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

2017
First teleconference

2018
First POC: Harmony TPV
First scientific session in US (CRT)

2019
First scientific session in Japan (JSPCCS)

2020
First peer-reviewed publication of activities
Survey to Industry
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