



Update from HBD for Children WG

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I have no relevant financial relationships

Topics


1. **What is “HBD-for-children”?**
2. **Update from HBD-for-children activities**
 - ✓ What is the most challenging burden to develop pediatric medical devices for industries?
 - ✓ Classification of developmental status of pediatric medical devices
 - ✓ Implementation of pediatric medical device global clinical trial
3. **Recent support from government and other organizations**

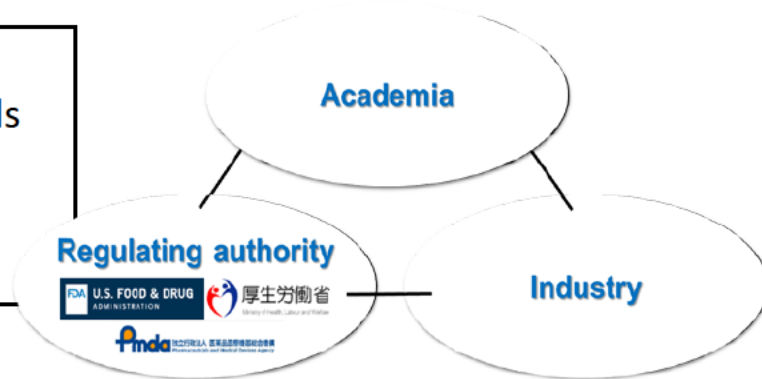
What is “HBD-for-children”?

※Harmonization-By Doing

2003~ HBD activities launched

Background

- 
- Development of pediatric medical device tends to delay in the U.S. and Japan but there are high needs in clinical sites.
 - Regulatory authorities have to resolve problems in the U.S. and Japan.



2016~ HBD-for-children activities launched

Sub-WG of HBD activity

- We can utilize experiences and schemes of HBD activity for development of pediatric medical devices and extend HBD activity to pediatric cure.
- We can find problems of development of pediatric medical devices in the U.S. and Japan and propose solutions *by Doing*.

What is the most challenging burden to develop pediatric medical devices for industries?

We did a questionnaire to industries in the U.S. and Japan in 2017.

Japan



1 st	<u>Small market</u>
2 nd	High development cost
3 rd	High barriers for application and approval

USA



1 st	<u>Small market</u>
	Other (please specify)
2 nd	High barriers for a clinical trial



The aim of “HBD-for-children” is to consider solutions to support getting marketing approval of high-need pediatric medical devices.

Classification of developmental status of pediatric medical devices

We classified pediatric medical devices as five groups by grovel clinical trials

1. Under development
2. Acquisition of CE marking but no clinical experience
3. Acquisition of CE marking and clinical experience as off-label use in Japan and the U.S.
4. Approval in the U.S. (non-approved in Japan)
5. Non-approved in the U.S. (approved in Japan)

The classification is useful for finding pathway for regulatory approval in both countries.

Achievement of the HBD-for-children activity

The collaboration among regulatory, industry, and academia in both Japan and the U.S. makes the U.S. it easier to conduct global clinical trials.

The First Japan-US global clinical trial of pediatric medical device is ongoing!

The Harmony™ TPV system (Medtronic, Inc)

Self-Expanding Stent Graft

Porcine Pericardial Tissue Valve

✂ group 1 : Under development

Publication of the HBD-for-children activity



Circulation Journal
doi:10.1253/circj.CJ-19-1092

ORIGINAL ARTICLE

Pediatric Cardiology and Adult Congenital Heart Disease

Partnership Between Japan and the United States for Early Development of Pediatric Medical Devices — Harmonization By Doing for Children —

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Frank Ing, MD; Hideshi Tomita, MD; Hisashi Sugiyama, MD; Masaaki Yamagishi, MD;
Thomas J. Forbes, MD; Sung-Hae Kim, MD; Mami Ho, MD; Nicole Gillette;
Yasuko Nakamura; Koji Mineta; Neal Fearnott, PhD; Declan Dineen;
Eric Vang, PhD; Russel Haskin; Lisa A. M. Becker, PhD; Kazuaki Sekiguchi, PhD;
Kisaburo Sakamoto, MD; Carlos E. Ruiz, MD, PhD
on behalf of the Harmonization by Doing for Children Working Group

Measures to meet unmet medical needs in Japan

2006

- *Program for requesting medical devices with high clinical needs started in 2006*
- *Application with a clinical evaluation report started in 2008 (Notification by MHLW, No. 0804001)*

2013

- *Support program for medical device used for treatment of orphan disease started in 2013*
- *New Ministerial Ordinance for Enforcement of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics in 2014*
- *Scientific advisory board about pediatric medical devices was held in 2014-2015*
- *SAKIGAKE Designation System started in 2015*
- *Fast-break scheme for innovative medical devices started in 2017*
- *Subsidization program for application of pediatric medical device started in 2019*

2021

SDGs of HBD-for-Children activity

1st step: Find POC

- Find needs and seeds of pediatric medical devices

2nd step: Select POC product

- Classify devices by possibility of conducting global clinical trial
- Find existing data of devices

4th step: Application and approval

- Application and approval in the U.S. and Japan together

3rd step: POC By Doing

- Discussion about protocol of clinical trial and how to apply with existing data, etc.

HBD-for-Children



- Appropriate clinical evaluation
- Using real world data
- Efficient support

Ongoing activities

- **Collaboration with other organizations**

Collaboration with other organizations from early development phase to regulatory approval of pediatric medical devices to promotion of a global medical device development

USA: FDA, Pediatric Development Consortium (PDC) grant programs ,etc.

Japan: MHLW, PMDA, Academic Research Organization (ARO), Japan Agency for Medical Research and Development (AMED) (*Research on Development of New Medical Devices*), etc.

- **Research supported by funding from AMED**

“Research project for promotion of early development of pediatric medical devices”

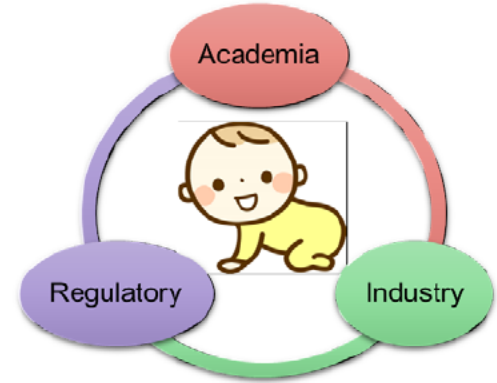
1. *Finding issues and solutions of clinical trials in the pediatric field*
2. *Utilization of real world evidence*

Apr, 2020 ~Mar, 2022

Conclusion

- HBD-for-children activity contributes to the development of pediatric medical devices by supporting the Japan-US global clinical trial.
- We approach to collaborate with other organizations for accelerating the global development.

We will continue to seek real problems and solutions in Japan and the U.S. It is important to aggressively share the information and discuss between academia, industry and regulatory.



Please join the HBD-for-children activities for the happiness of children!

Thank you for your attention.

If you have questions, please contact us.



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