Challenges and Achievement: Japanese Regulatory View

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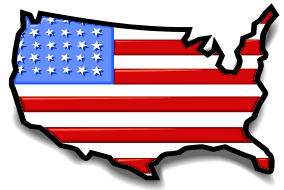
Agenda

1. Background: What is burdens for development of pediatric medical devices ?
2. Measures to meet unmet medical needs in Japan
3. Significance of HBD-for-children activity
4. Conclusion

What is the burdens for development of pediatric medical devices?

We have done a questionnaires about development of pediatric medical devices to industries in the Japan and U.S. through HBD for children activities.

Japan 

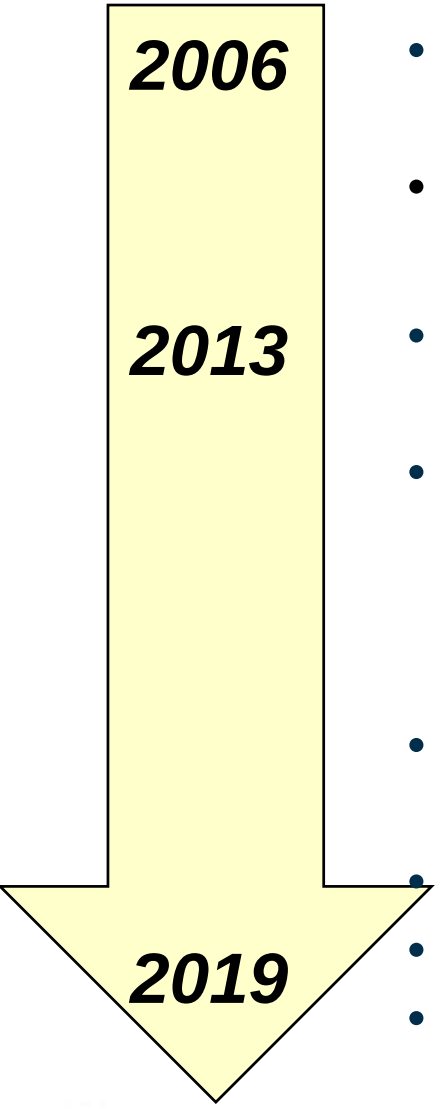
USA 

“Small market” is majority opinion.

Variety of opinions are expressed.

- Development cost
- Application and approval
- Clinical trial
- Designing of device

Measures to meet unmet medical needs in Japan



- ***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)***
- ***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***

Fast-break scheme for innovative medical devices

	Original	Fast-break scheme
Clinical data which is submitted when the device is applied	**a prospective clinical trial under GCP or clinical evaluation report**	**Reliable clinical data (GCP trial is not always necessary)**
Review term	**12 months (if brand-new medical device)**	**—**
Post-marketing surveillance	**If need**	**Necessary**
Collaboration with academic society at the post-marketing phase	**If need**	**Necessary**
Increase facilities by stages for safety use of the medical device at the post-marketing phase	**If need**	**Necessary**

The program was legalized in the Pharmaceutical and Medical Device Act last month!

Collaboration between regulatory, clinicians and manufactures is necessary!

Subsidization program

Very new!

◆Target devices

A medical device for treatment of pediatric or congenital disease which was selected by a program for requesting medical devices with high clinical needs

◆Subsidization

MHLW subsidizes maximum 90% of a regulatory application fee of pediatric medical devices.

(The fund is limited.)

The program just started in September 2019!!

Significance of the HBD-for-children activity

Scientific sessions related in the activity were held in following conferences!

PICS-AICS
Pediatric and Adult Interventional Cardiac Symposium

CVIT

tct2019

Japanese society of Pediatric Interventional Cardiology
一般社団法人 日本 Pediatric Interventional Cardiology 学会(JPIC)

Activity of HBD-for-children has been globally recognized.

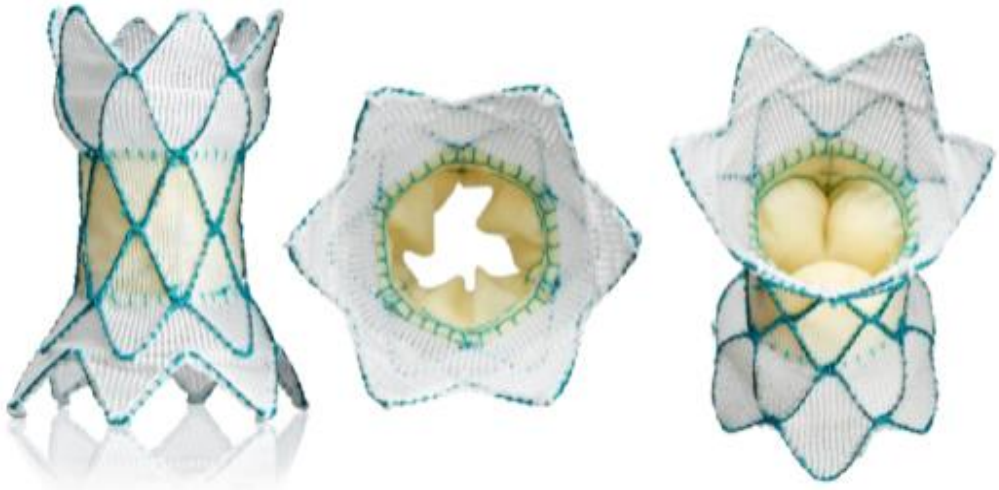
Significance of the HBD-for-children activity

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

First Japan-US global clinical trial of pediatric medical device started!

The Harmony™ TPV system (Medtronic, Inc)

Self-Expanding Stent Graft
Porcine Pericardial Tissue Valve



Significance of the HBD-for-children activity

Title: "Research project for promotion of early development of pediatric medical devices"

1. *Finding issues and solutions of clinical trials in the pediatric field*

- Capturing the issues around Japan-US clinical trial of pediatric medical devices and proposing the solutions by the following actions
  - Questionnaire to pediatricians and industries
  - Clarifying the burdens
  - Proposal for the solutions to the challenges
- Finding similarities and differences of GCP inspection processes between Japan and USA by observing the GCP inspection by FDA and PMDA each other

2. Utilization of real world evidence

- Proposing requirements for utilization of real-world-data of pediatric medical devices by the following actions
  - Hearing survey from registries of Japan-US
  - Investigation past experiences of using registry data for regulatory use
  - Measuring for assuring minimum quality and quantity of registry data

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Goal of the research project

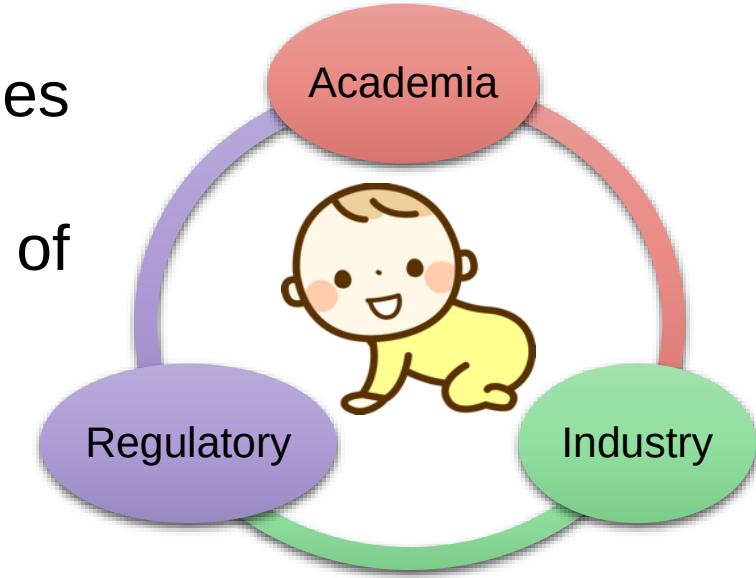
Making suggestions for effective development

1. **Streamlining the process of clinical trial**
   - Infrastructure development of clinical trial
   - Efficient GCP inspection for global clinical trial
2. **Utilization of registry database**
   - Use for post-marketing surveillance
   - Continual organizational operation of registry
3. **Proposal for consistent rational evaluation methods for pre- and post-marketing of pediatric medical devices**

Conclusion

- Japanese regulatory carried out some enforcement of policies to support the development of pediatric medical devices .
- On the issue of funds, Japanese regulatory remits the 90% of fee for review and inspection.
- HBD-for-children activity contributes to the development of pediatric medical devices by supporting the Japan-US global clinical trial.
- Research project related in the activity has started.

We will continue to seek a possibility of global clinical trials of pediatric medical devices and utilization of real-world evidence for an early approval of pediatric medical devices in the Japan and U.S..



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

Thanks for your kind listening!

Please contact me or HBD secretariat, if you have any questions.

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Let's continue to think about highly feasible measures together by sharing information through industry-regulatory-academia and conducting frank discussions.