

Update of HBD Activity

HBD Steering Committee

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**Pharmaceuticals and Medical Devices Agency
(PMDA)**

Today's Agenda

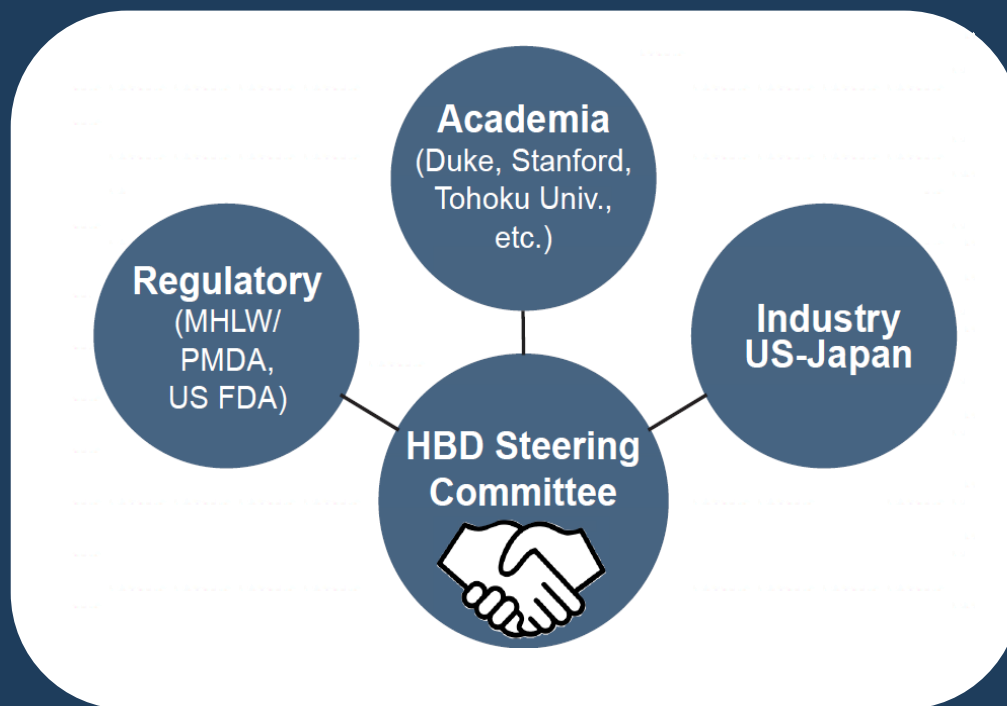
1. HBD and HBD Steering Committee
2. Current HBD Projects including POC Projects
3. Next Stage of HBD Activities

1. HBD and HBD Steering Committee

What Is Harmonization by Doing(HBD)?

<This activity's purpose>

- To find more appropriate way for breaking through the developmental barrier (harmonize) between the US and Japan **by taking a real action**, not just discussing hypothetically.



2. Current HBD Projects including POC Projects

Overview of HBD Steering Committee Activity

1

Scientific
sessions

- Discussions on each region of interest among stakeholders at several conferences

2

POC*
project

- Global Clinical Trials
- Development Guidelines
- Rare Intractable Diseases (Children etc.)

*: Proof of concept

3

Publication
activity

- Publication of paper about achievements of HBD activities

① Scientific Sessions

<This activity's purposes>

- To detect new tasks
- To clarify hurdles in individual tasks
- To find the candidate of next POC project

>5

Scientific sessions have been held in...

- US side: TCT, CRT, VIVA
- JP side: JCS, CVIT, JPIC

>10

Topics have been discussed...

Real world evidence, Global clinical trial,
Heart failure treatment devices, Venus stents,
Paclitaxel issue, Critical limb ischemia



CVIT: Japanese Association of Cardiovascular Intervention and Therapeutics JCS: Japanese Circulation Society

TCT: Transcatheter Cardiovascular Therapeutics

CRT: Cardiovascular Research Technologies

VIVA: Vascular Interventional Advances Conference

JPIC: Japanese Society of Pediatric Interventional Cardiology

② Proof of Concept (POC) Project

<This activity's purposes>

- To promote the convergence of parallel clinical trials in the US and Japan toward single protocol
- To encourage global development.

<Achievements>

1. Coronary Orbital Atherectomy System (OAS)

- Cardiovascular Systems, Inc. had conducted a global clinical trial with single protocol in the U.S. and Japan.
- On the same day, the device was approved in US and JP in 2017.
- The achievement of HBD POC project has been published in 2021.



Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

ELSEVIER

CRM

Japan-USA orbital atherectomy for calcific coronary lesions: COAST study, a Harmonization by Doing proof-of-concept: The Japanese and US regulatory perspective

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② Proof of Concept (POC) Project

<Achievements>

2. Harmony Valve from HBD-for-Children

- Transcatheter pulmonary valve replacement system for severe pulmonary valve regurgitation.
- The first pediatric device to conduct a global clinical trial.
- The device has been approved in US and JP in 2021.
→The details will be presented in “HBD for Children”

Ref:<https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-pulmonary-valve-therapy/harmony.html>

<Ongoing projects>

- Transcatheter mitral valve replacement (4C Medical)
- Device for CLTI treatment (Lim Flow)
- Device for treatment of heart failure (Corvia Medical)



How to Join the POC Project

POC process

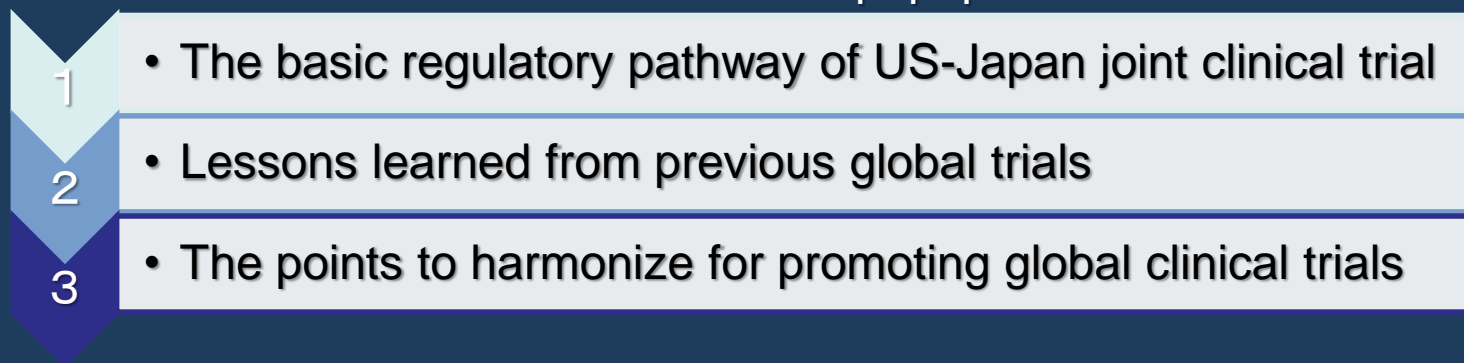
- 1**
 - Email to general contact (hbd.contact@pmda.go.jp)
- 2**
 - Submit **a concept proposal** to HBD SC
 - ✓ An overview of the device description
 - ✓ The future plan
 - ✓ How the project relates to HBD activities
- 3**
 - Introduce the proposed POC project in HBD SC teleconference (every other month)/face to face meeting
 - HBD SC will discuss and make a decision

③ Publication Activity

1. Publication of a concept paper about US- JP joint trials

- Based on our experiences through this activity, a concept paper will be submitted.

< Overview of the concept paper >



2. Publication of a paper comparing the latest regulation system in US and Japan

- Promotion of the use of specific programs intended to promote innovation based on points to note and utilization example of those programs.
- This paper has been drafting with US-JP stakeholders.

3. Next Stage of HBD Activities

Challenges for the future

1. Promotion of early patient access to medical devices by using new regulatory pathways.



The topic will be discussed..

“Initiatives to improve patient access to new medical devices”

2. Mutual Utilization of the real world evidence including several registry data.



The topic will be discussed..

“Sustainable Development Goals in Real-world data collection”

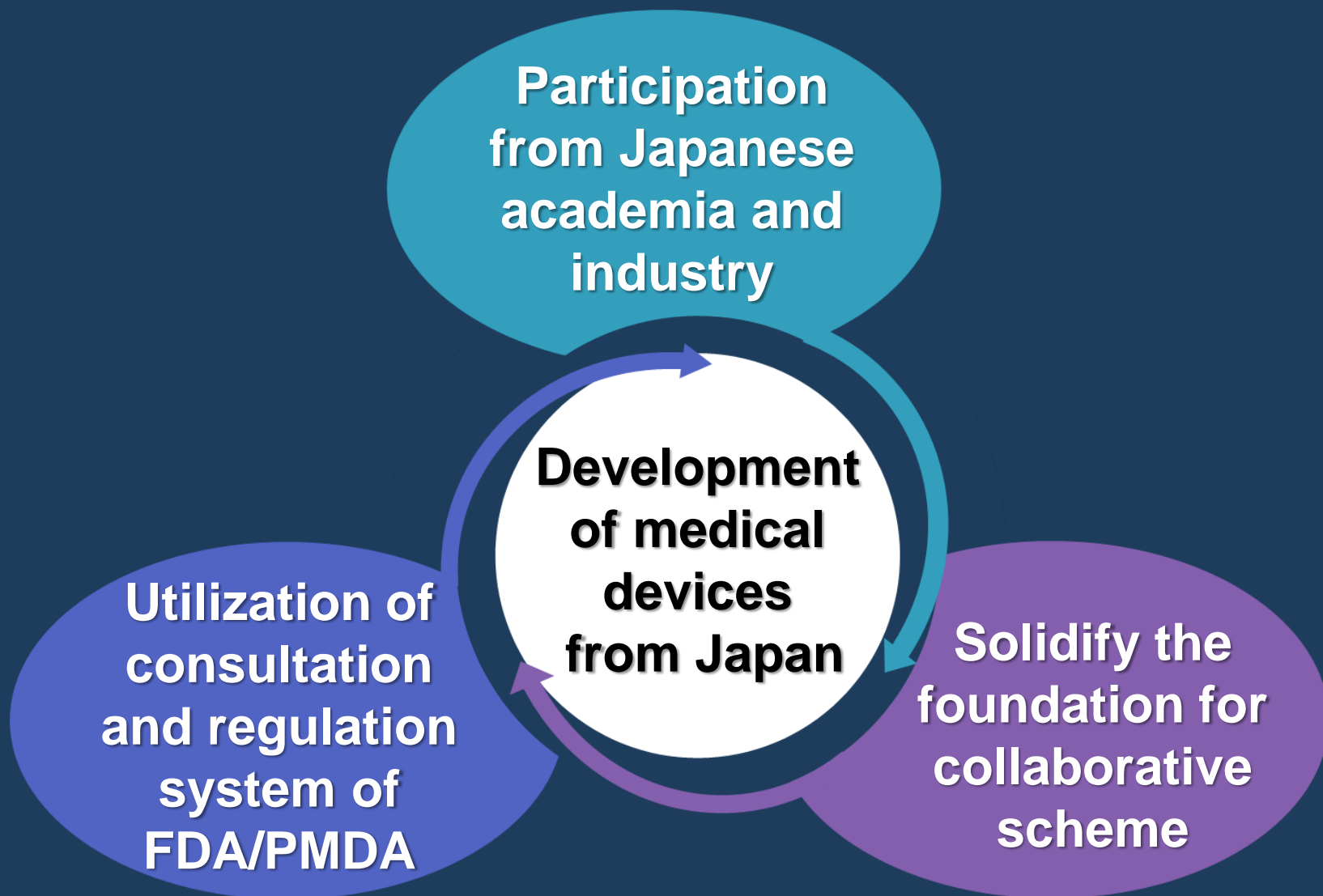
3. Sharing new topics (e.g. Software as a Medical Device)



The topic will be discussed..

“Introduction of US – Japan regulatory system for software as a medical device”

PMDA's perspective



Thank you for your kind attention!



**If you have any questions, please contact to us !
(mail: hbd.contact@pmda.go.jp)**

PMDA HP (English)

<http://www.pmda.go.jp/english/index.html>