

Update of HBD Activity

HBD Steering Committee

Moe OHASHI

Reviewer, Office of Medical Devices I

Pharmaceuticals and Medical Devices Agency (PMDA)

Today's Agenda

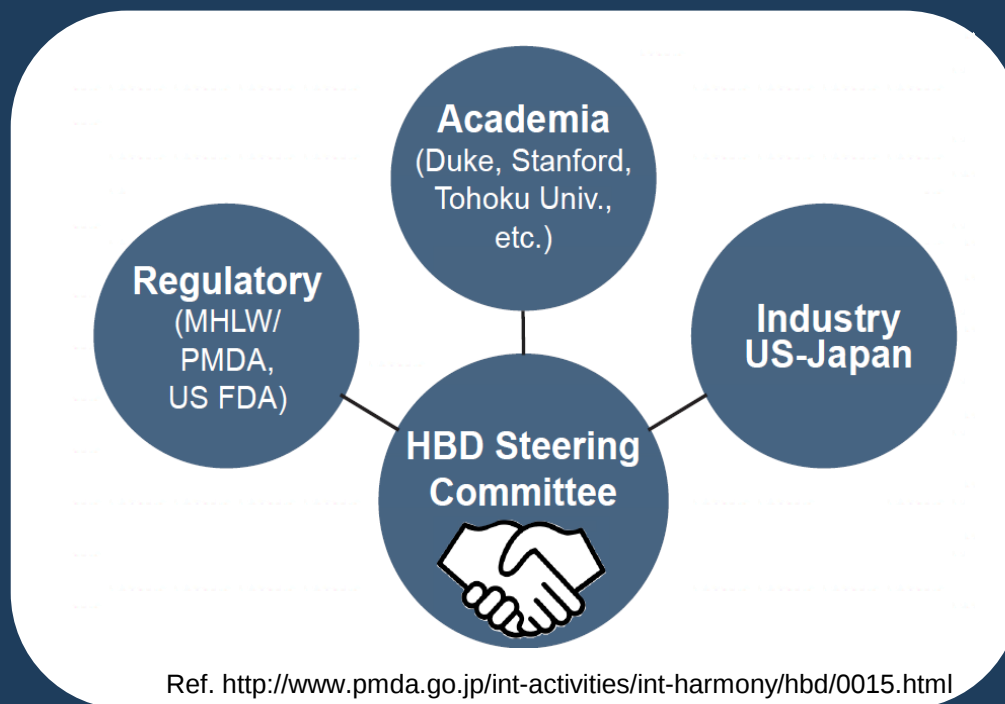
1. Structure of HBD Steering Committee
2. Current HBD Projects including POC Projects
3. Next Stage of HBD Activities

1. Structure of 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.



Overview of HBD Steering Committee Activity

1

Scientific
session

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

2

POC
project^{*1}

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

3

Expert
SWG^{*2}

- Discussion on obstacles to establish single protocol with academic experts

*1: Proof of concept *2: Sub-working group

5

2. Current HBD Projects including POC Projects

1. Scientific Sessions

<This activity's purpose>

- Detection of 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
- High risk bleeding patients, Heart failure treatment devices,
- Paclitaxel issue, Critical limb ischemia
- Renal Denervation, Venus stents



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

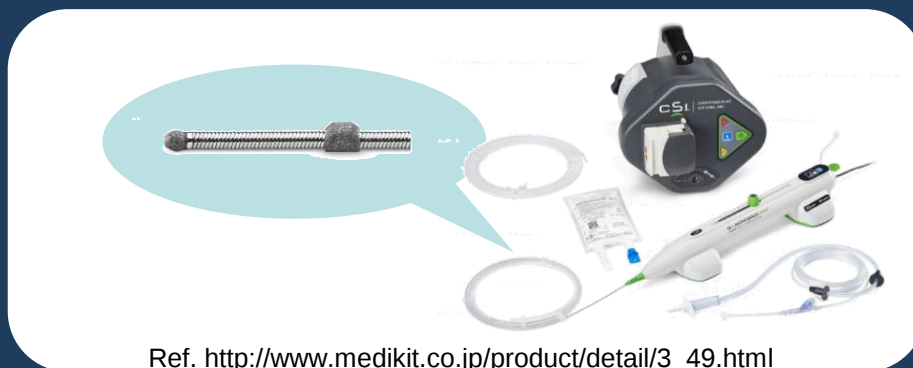
<This activity's purpose>

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

<Achievements>

1. Coronary Orbital Atherectomy System (OAS)

- Cardiovascular Systems, Inc. has conducted a global clinical trial with single protocol in the U.S. and Japan.
- On the same day, the device was approved in 2017 b/t US and JP.



Ref. http://www.medikit.co.jp/product/detail/3_49.html

2. Proof of Concept(POC) Project

<Achievements>

2. CD34 antibody coated coronary drug eluting stent

- OrbusNeich. has conducted a global clinical trial with single protocol in the U.S. and Japan.
- In Japan, this product has just been approved on September, 2019

Ref: <https://www.orbusneich.jp/news-190918.html>

- Key points: Consistent communications with the FDA and PMDA.

<On going projects>

- Transcatheter mitral valve replacement (4C Medical)
- Device for CLI treatment (Lim Flow)
- HBD for Children (Development of pediatric medical devices)



How to join the POC project

POC process

- 1
 - Email to general contact
(hbd.contact@pmda.go.jp)
 - Introduction by HBD members
- 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

PMDA HP (English) <http://www.pmda.go.jp/english/index.html>

3. Expert Sub-Working Group

<This activity's purpose>

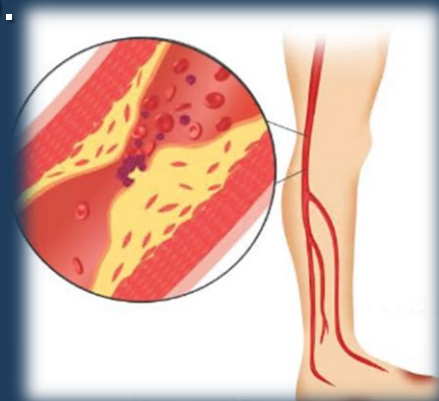
- Intensive discussion on a specific region and/or device by HBD members and academic experts in each field.
- Publication of discussion summary.

<Achievements>

- Basic concept of global trials for Evaluation of Endovascular devices for Critical Limb Ischemia (CLI)
 - We have discussed the trial's designs including the target patients and primary endpoints with VIVA group and JET group.
 - **The summary has published as a paper.**

Hiroyoshi Yokoi et al. Circ J. 2018; 82 (9) : 2233 – 2239.

Design Strategies for Global Clinical Trials of Endovascular Devices for Critical Limb Ischemia (CLI) - A Joint USA-Japanese Perspective -



Ref. <https://www.pluristem.com/cli-study/>

Challenges for Promoting HBD Activity-1/2

1. Low publicity of the current status and achievement
2. The small number of HBD members from JP Industries.



<Publication of HBD activity related achievements>

- Organization of publication support team in HBD SC to help a paper publication on each achievement.
- On going projects are...
 - Lessons learned from the global clinical trial for coronary atherectomy system.
 - Introduction of current HBD POC projects.



<Update of website related to HBD activities >

- Overview of the HBD activity
- Current activities including ongoing POC projects
- How to join the HBD activity as a POC project
- Summary of discussion in this meeting will be uploaded!

Challenges for Promoting HBD Activity-2/2

1. Low publicity of the current status and achievement
2. The small number of HBD members from JP Industries.



<Advertisements of HBD activity>

- At several conferences, advertisements of HBD activity.
- Making the HBD brochure and release it to PMDA website.
- Introduction of process for joining the HBD activity in PMDA website

<Publication of a concept paper about US- JP joint trials>

- Based on our experiences through this activity, a concept paper has been drafting with US-JP stakeholders.

< Overview of the concept paper>

- 1 • The basic pathway of a global clinical trial
- 2 • Lessons learned from previous global trials
- 3 • The points to harmonize for promoting global clinical trials

3. Next Stage of HBD Activities

Challenges for the future

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



The topic will be discussed..

➤ From 1:40 pm

➤ Session title: How Can We Generate Robust Real-World Evidence from Real-World Data?

2. Promotion of early patient access to medical devices in any fields including broadening the fields of HBD.



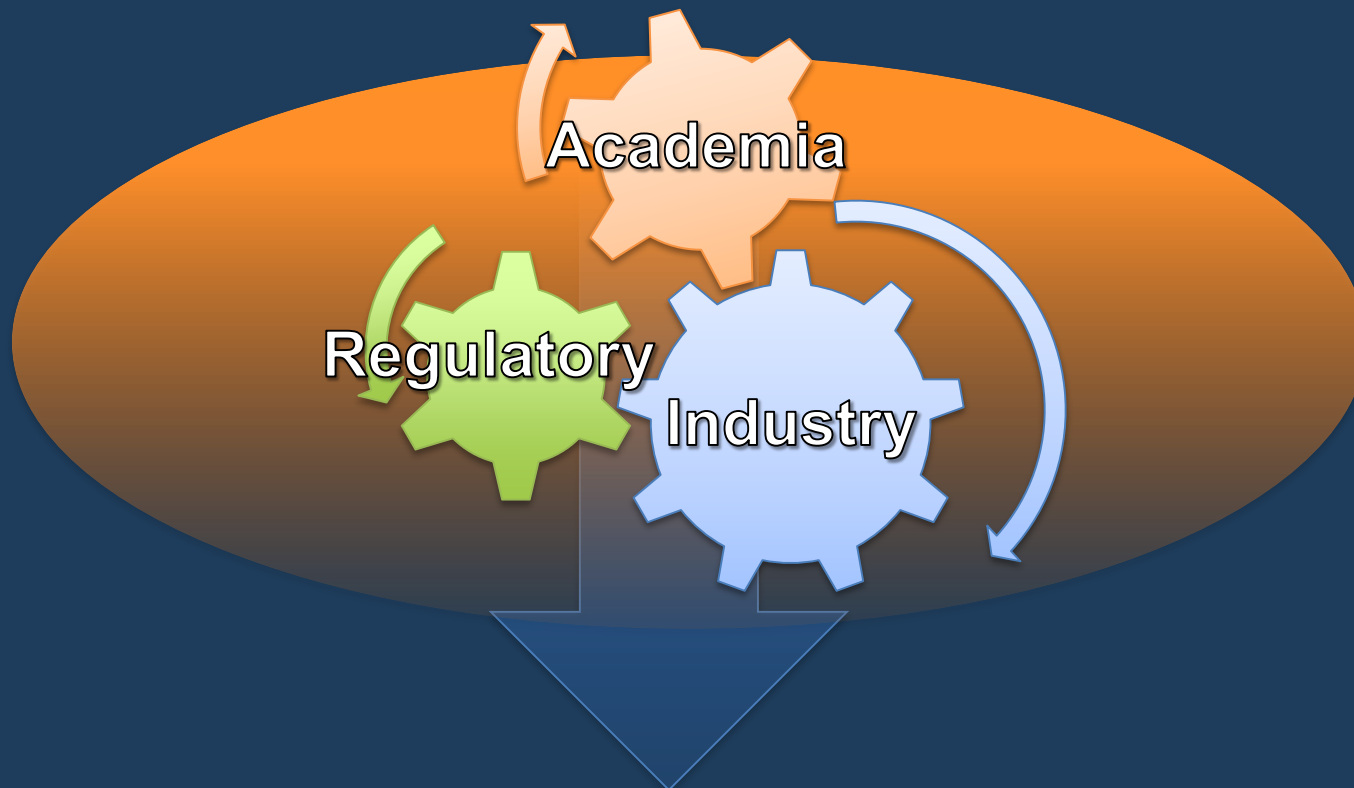
The topic will be discussed..

➤ From 3:40 pm

➤ Session title: Promotion of Early Patient Access to Medical Devices in US and Japan

For Early Patient Access

- Constructive discussions among the stakeholders can enhance mutual understanding and help solving problems



Contribution to the development of medical devices

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>**