

# **Update of HBD Activity**

## **HBD Steering Committee**

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

# Today's Agenda

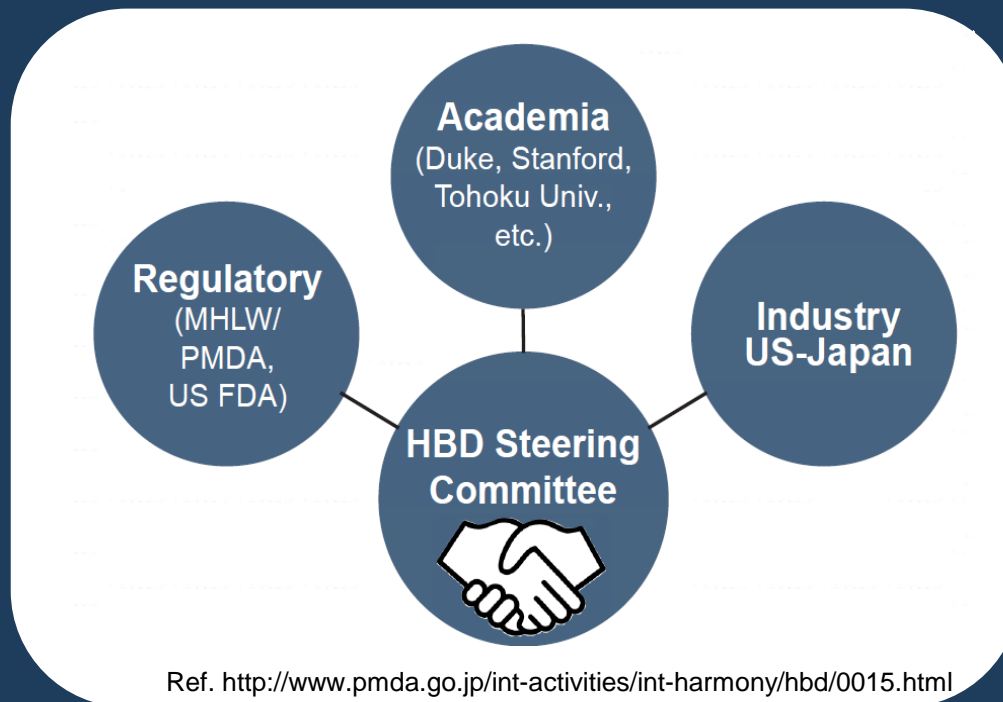
1. Structure of HBD Steering Committee
2. Current HBD Projects including POC Projects
3. Next Stage of HBD Activities

# 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<sup>\*1</sup>

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

3

Expert  
SWG<sup>\*2</sup>

- 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

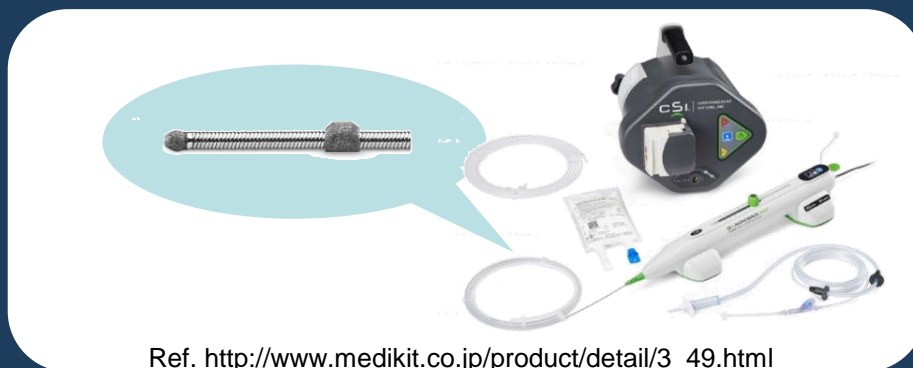
### <This activity's purpose>

- 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](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](mailto: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>

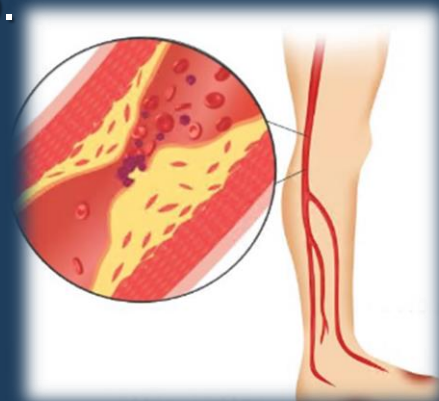
- Intensive discussion on a specific region and/or device by HBD members and academic experts in each field.
- Publication of discussion summary.

#### <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.



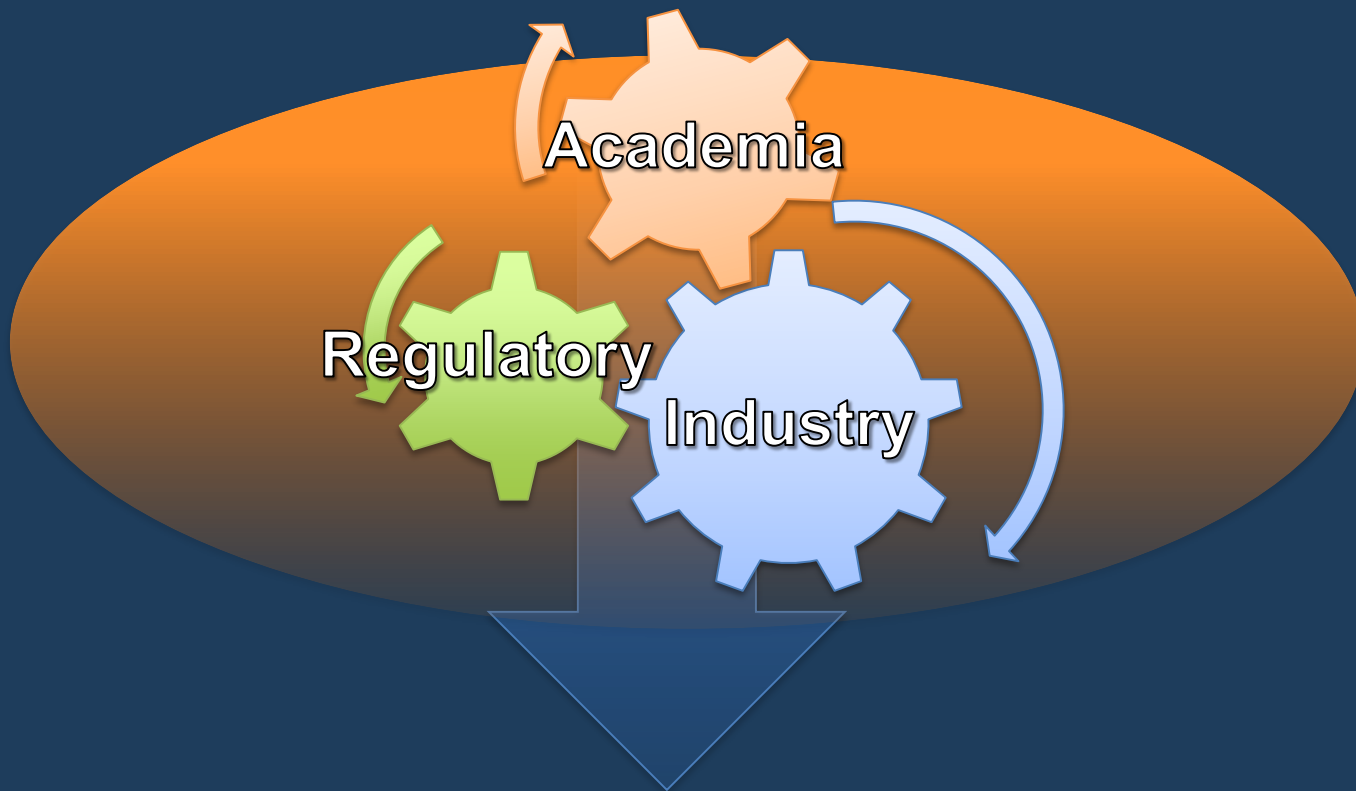
The topic will be discussed..

➤ 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](mailto:hbd.contact@pmda.go.jp))**

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