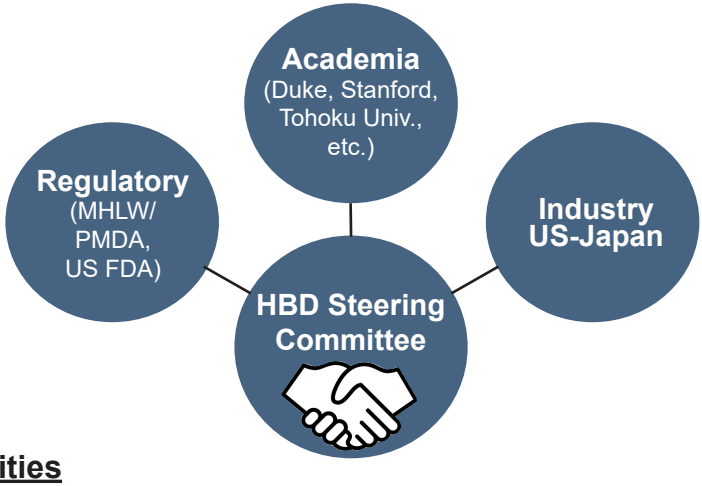
Japan-US Harmonization by Doing

Harmonization of clinical and regulatory approaches in the US and Japan

What is Harmonization by Doing (HBD)?

“Harmonization by Doing” (HBD) is the industry-academia-regulators collaborative project between the US and Japan. Our goal is to contribute to the promotion of medical device development through convergence in evaluation and regulatory strategy. We have discussed how to promote medical device development in the cardiovascular area and have had great success. In addition, anew goal is to explore new proof of concept (POC) projects beyond the cardiovascular specialty.



Activities

Scientific Sessions

HBD has had several discussions on how to develop and evaluate challenging devices. CRT, TCT, VIVA, and PICS sessions have been held in the US, while CVIT and JCS is held in Japan. Additional meetings are organized with expert sub working groups, such as an HBD POC project if a topic needs further discussion after the session takes place.

Proof of Concept (POC) Projects

- Global Clinical Trial, Global Collaborative Development
- Development Guidelines
- Registries, Real World Evidence
- Rare Intractable Diseases (Children etc.)

Achievements

Publications

The achievements of HBD activity have been published in many journals, such as:

- *Comparing GCP Requirements for Medical Device Clinical Trials in the US and Japan*- **RAPS Regulatory Focus 2010**
- *Design Strategies for Global Clinical Trials of Endovascular Devices for Critical Limb Ischemia*- **Circ J. 2018**
- *Rapid Globalization of Medical Device Clinical Development Programs in Japan* – **Cir J.2017**

Past POC Activities

Global Clinical Trials

- Conducted global clinical trials for Coronary Drug Eluting Stents
- Conducted global clinical trials with single protocols for SFA stents with review and approval, eliminating device lag between US/Japan approval.

Harmonized Registry

- Harmonized the registry for Ventricular Assist Devices (INTERMACS and J-MACS) and TAVR

Current POC Activities

HBD has accelerated the medical device development process by solving issues that were identified in the early stages of development, evaluating potential solutions for POC projects. Discussing how to successfully conduct Early Feasibility studies is valuable in this process.

- Atherectomy device (CSI)
- CD34 antibody coated drug eluted stent (OrbusNeich)
- AV shunt construction device (TVA Medical)
- Transcatheter mitral valve replacement (4C Medical)
- Device for CLI treatment (Lim Flow)
- HBD for Children (Development of pediatric medical devices)

Collaborative Scheme

There are some activities derived from HBD with sharing information about consultation and approval review of MHLW, PMDA, and FDA for medical device.

HBD Harmonization by Doing

HBD Think Tank Meetings

HBD Think Tank Meetings have been held to present achievements since 2005. These meetings alternate between the US and Japan each year to identify barriers to device development and propose POC projects to evaluate potential solutions.

The 2017 Think Tank Meeting covered recent hot topics, such as early feasibility studies and real-world evidence, and pediatric devices, in addition to WG activity update. In the Round Table Discussion, HBD members and other experts shared their experiences and had an open discussion to overcome the challenges in medical device clinical trials.

164 participants from many stakeholders joined the meeting and had fruitful discussions towards the U.S. - Japan Medical Device Harmonization.

Contact us
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Website: https://www.pmda.go.jp/int-activities/int-harmony/hbd/0015.html
https://www.fda.gov/MedicalDevices/InternationalPrograms/USJapanRegulatoryCollaboration/default.htm

If you are interested in HBD, join us!