

HBD Project

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Harmonization by Doing

■ CONCEPT

HBD project is an unique initiative that aims to converge regulatory requirements and practices between FDA and MHLW/PMDA through concrete experiences “by doing.”

■ GOAL

Parallel development of clinical trials, simultaneous application reviews and marketing approval of new devices for the benefit of patients in the U.S. and Japan.

GHTF and HBD

■ GHTF

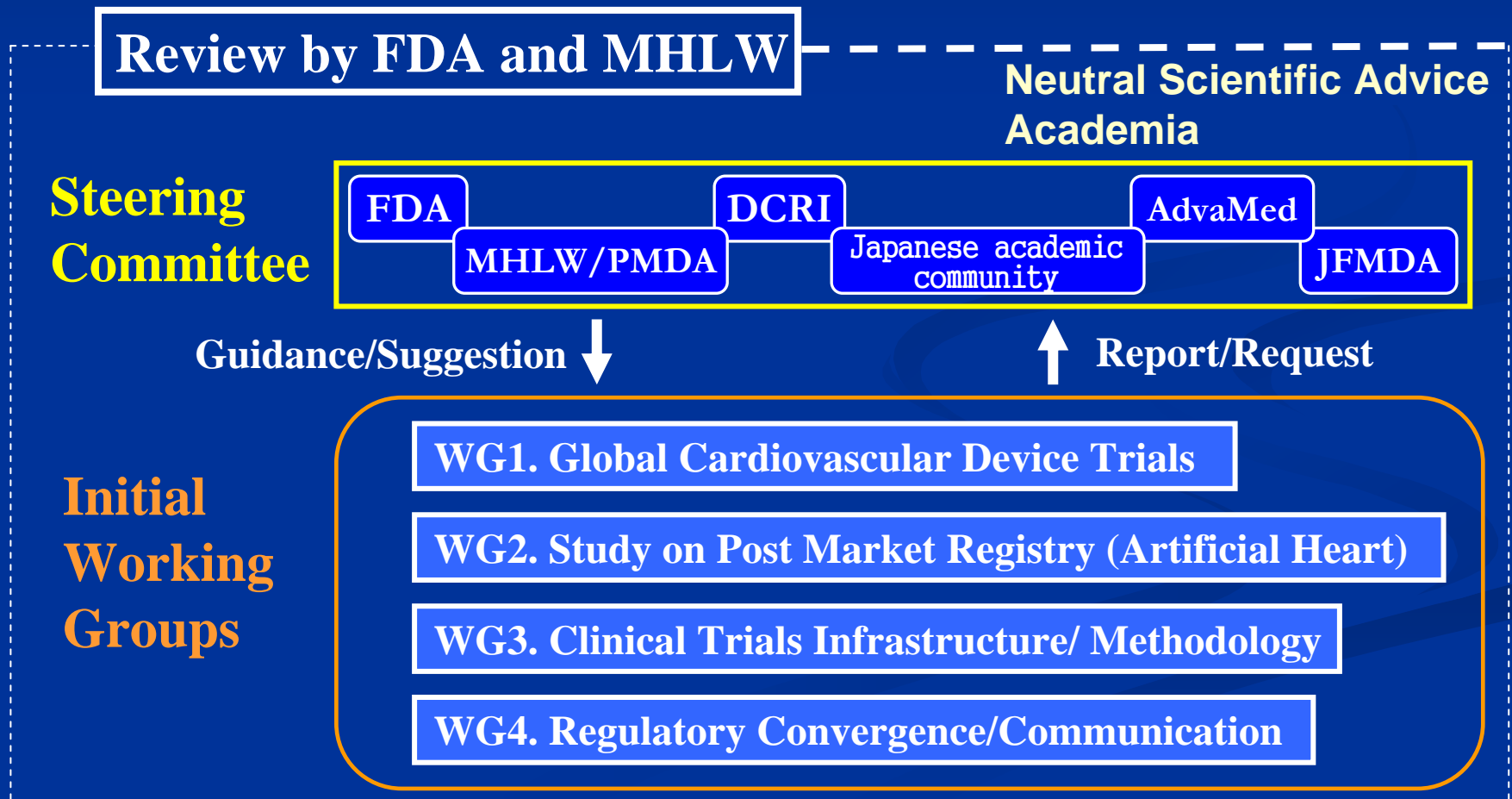
- **Developing harmonized regulatory guidance to encourage the convergence of regulatory practices in medical device field**
- **For example,**
 - **Principles of medical device classification**
 - **Essential principles of safety and performance of medical devices**
 - **Role of standards in the assessment of medical devices**
 - **Clinical evaluation**

■ HBD

- **Experience-based approach to resolve the real problems that the US and Japan specifically share in providing timely approvals of medical devices.**

HBD Structure and Working Groups

The steering committee coordinates works between the working groups on common issue. The working groups work jointly and collaborate to find solutions to the shared issue.



WG 1

Global Cardiovascular Device Trials

- **Target: Executing single clinical protocols**
- **Co-Chairs: Mitchell Krucoff, Duke Clinical Research Institute**
Shigeru Saito, Shonan Kamakura General Hospital
- **Discussing the following issues through developing a drug eluting stent protocol.**
 - **Definition of what is a single protocol study**
 - **Issues of data poolability**
 - **Challenges of multi-national randomization**
 - **Integrated submission strategies**

WG 2

Post Market Registries

- **Target: Utilizing post-market data for pre-market review of implant devices**
- **Co-chair: Eric Chen, US FDA**
Kazuhiro Sase, Juntendo University Medical School
- **Identifying specific pre and post-market barriers :**
Can post-market data be considered historical control data for pre-market clinical trial designs?
- **Focusing on post-market LV assist devices registry in cooperation with NIH-sponsored INTERMACS program.**

WG 3

Clinical Research Infrastructure

- **Target: Improving clinical trial infrastructure in both countries**
- **Co-chair : John Alexander, Duke Clinical Research Institute**
Yoshihiro Arakawa, Tokyo University Hospital
- **Analyzing the current CT infrastructure in both countries to identify problems and develop necessary steps to improve it.**

WG 4

Regulatory Convergence and Communication

- **Target : Achievement of regulatory convergence and cooperative consultation & review**
- **Co-chair : Carole Carey, US FDA**
Hiroshi Yaginuma, Japan MHLW
- **To identify and share information on similarities and differences between the U.S. and Japan in terms of regulations**
- **To find regulatory-related obstacles in conducting CT, filing and reviewing applications**
- **To formulate recommendations, suggestions or points to consider in resolving difficulties**

WG 4' s

Possible Regulatory Target Areas

- **Medical Device GCP (good clinical practices)**
- **STED (Summary Technical Documentation)**
- **Early Consultations between regulatory authorities and applicants**
- **Application review practices, including modular approach**
- **Communication (regulator/applicant, regulator/regulator)**

Future schedule on HBD activity

- **Monthly teleconference among stakeholders**
- **HBD Think Tank East Meeting
in Spring 2008 or later, in Japan**