

# **The MHLW Approach to Provide Innovative Medical Devices Speedy to Patients**

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# **Our Mission**

**“To provide innovative,  
safe & effective**

**Medical Devices to patients  
in speedy manner”**

# Comparison of Review Time between Japan and USA

(Japan: median values, U.S.: average values)

Months

40

35

30

25

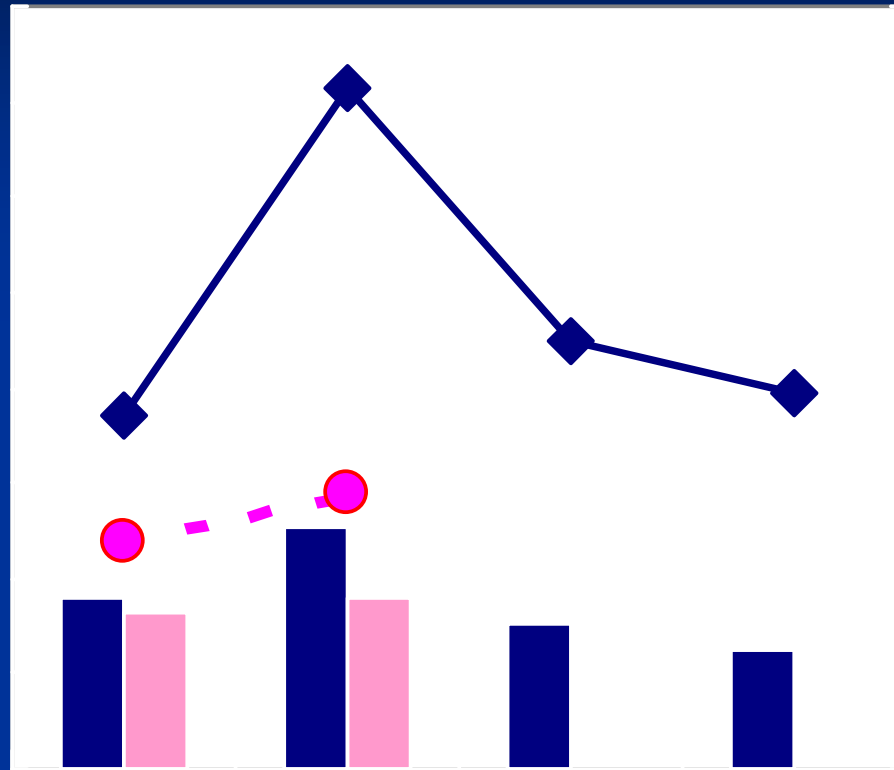
20

15

10

5

0



2003

2004

2005

2006

Year

月

40

35

30

25

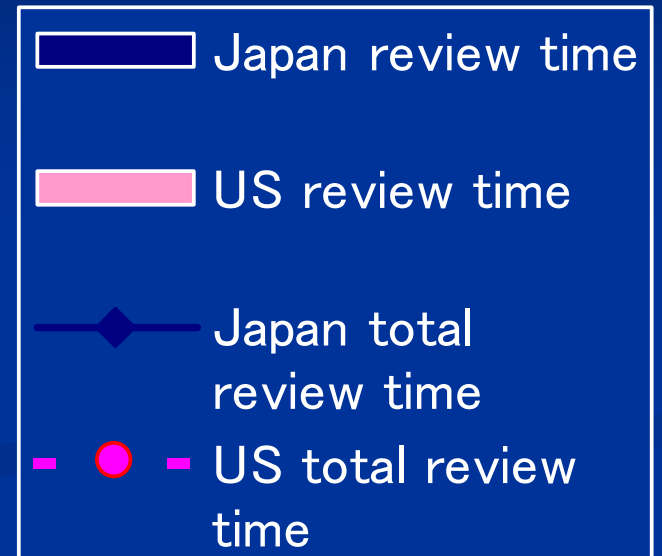
20

15

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0



Note 1: For statistical purposes the year in the U.S. is from Oct.1st the year before to Sep. 30.

Note 2: U.S. figures for 2003 including IVDs.

# Medical Devices Classification and Standards

Risk-based Classification		Marketing Authorization	Standards
Class I	Extremely Low Risk (X-Ray films)	No approval necessary	
Class II	Low Risk (MRI, urological catheters)	Third-Party Certification	<b>396 Standards</b> have been established.
Class III	Medium Risk (artificial bones, dialyzer)	MHLW's Approval necessary	<b>25 Standards</b> have been established.
Class IV	High Risk (pacemaker, heart valves)		

# **MHLW Activities for the speedy introduction of innovative Medical Devices**

- **Establishing Committee for early  
introduction of innovative Medical Devices  
highly needed**
- **Developing Guidance for Medical Devices  
with New Technology**
- **HBD Program**

# Establishing the Committee for Speedy Introduction of Highly Needed Medical Devices

- MHLW set up the Committee in October 2006 for prompt introduction of highly needed medical devices.
- The purpose is
  - to identify highly needed medical devices that have been approved in other countries(U.S. EU,etc) but not in Japan and,
  - to find out the most quick pathway for approval (Utilization of the existing data, Fast-track review)
- 13 kinds of medical devices has been selected as first priority for quick introduction.

# Developing Guidance for Medical Devices with New Technology

- Guidance documents for innovative MDs with new technology is beneficial for
  - Effective R&D
  - Quick review
- 5 Medical Device Categories are targeted in 2006:
  - Total Artificial heart
  - DNA chip
  - Robot navigation system
  - Tissue engineered product
  - Bio-compatible implant

# Harmonization by Doing

## ■ GOAL

Parallel development, clinical trial, submission, review and approval in the U.S. and Japan for the U.S./Japan patients benefit

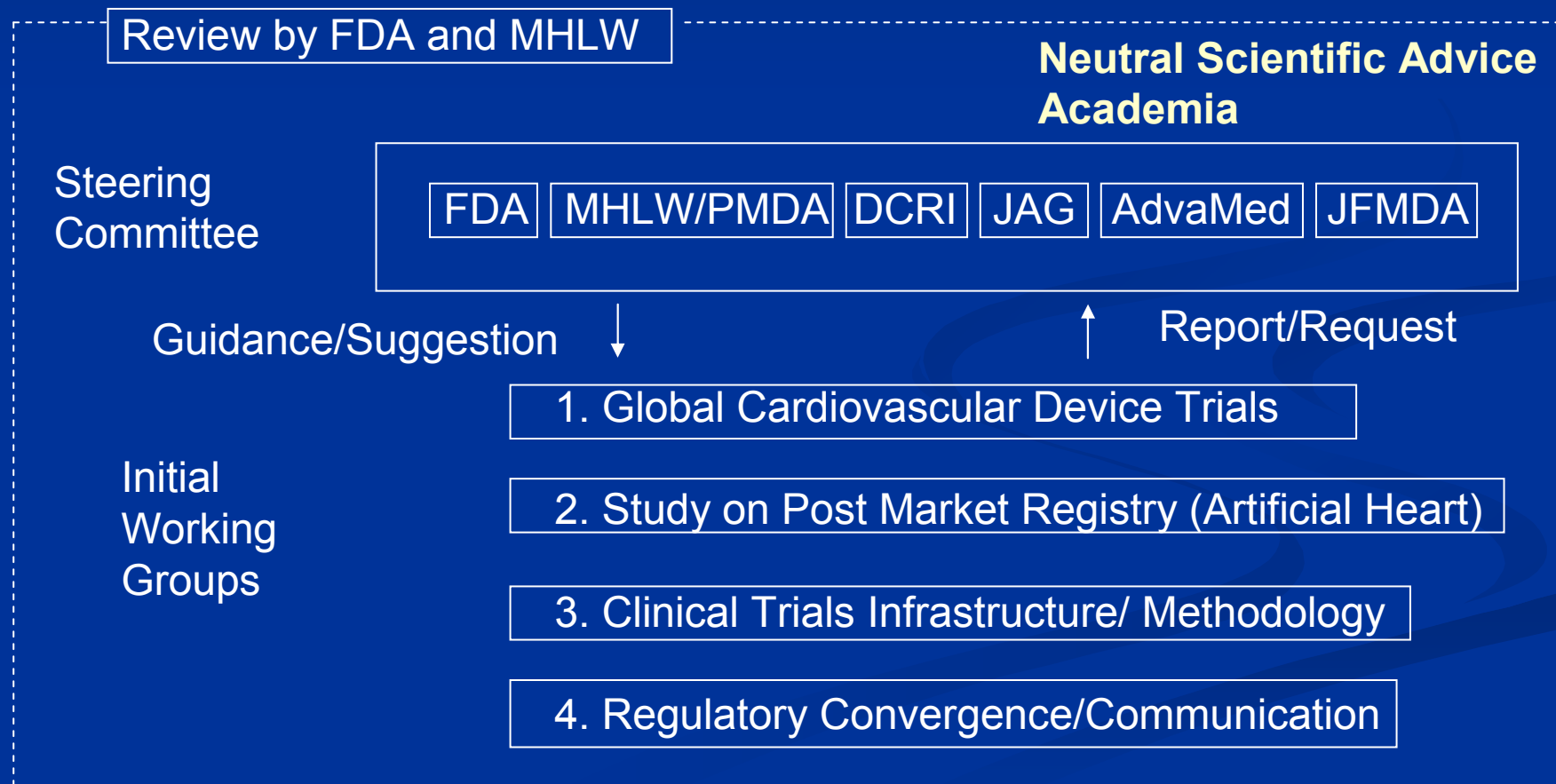
## ■ Identify similarities and differences between the U.S. and Japan in terms of regulations

- Pre-consultation system

- GCP

- Application documents (STED)

# HBD Structure and Working Groups



**Keep close communication  
among all stakeholders!!**

