CRT23 CARDIOVASCULAR RESEARCH TECHNOLOGIES

Update on Japanese medical device regulatory initiatives

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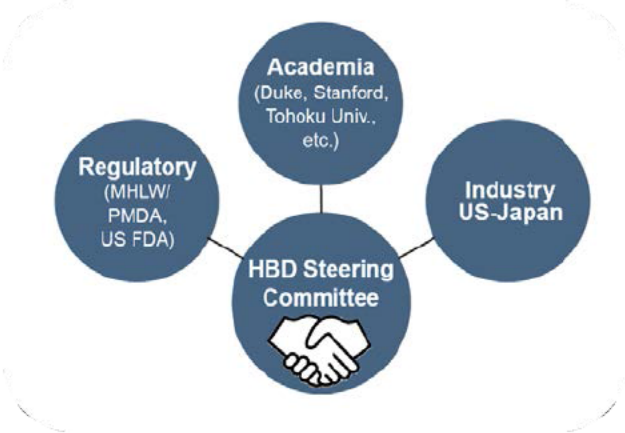
I have no relevant financial relationships

Objectives of this presentation

One of the goals of Harmonization By Doing (HBD) activity is to promote efficient development through greater understanding of clinical and regulatory environments in the U.S. and Japan.



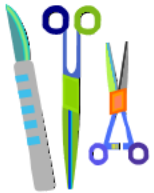
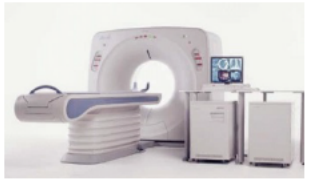
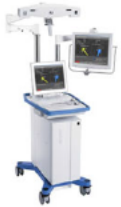
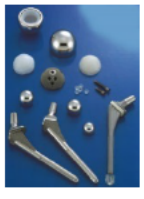
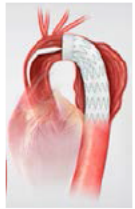
HBD members are trying to make and publish a scientific paper comparing the latest regulation system in the U.S. and Japan.

Today's topic

Focusing on Japanese regulatory systems and new initiatives,

1. **Japanese medical device regulations**
2. **Specific programs intended to promote innovation**
   - ① SAKIGAKE designation system
   - ② Priority review for specific uses
   - ③ Conditional approval system
   - ④ Post-Approval Change Management Protocol (PACMP) for medical devices
   - ⑤ Others

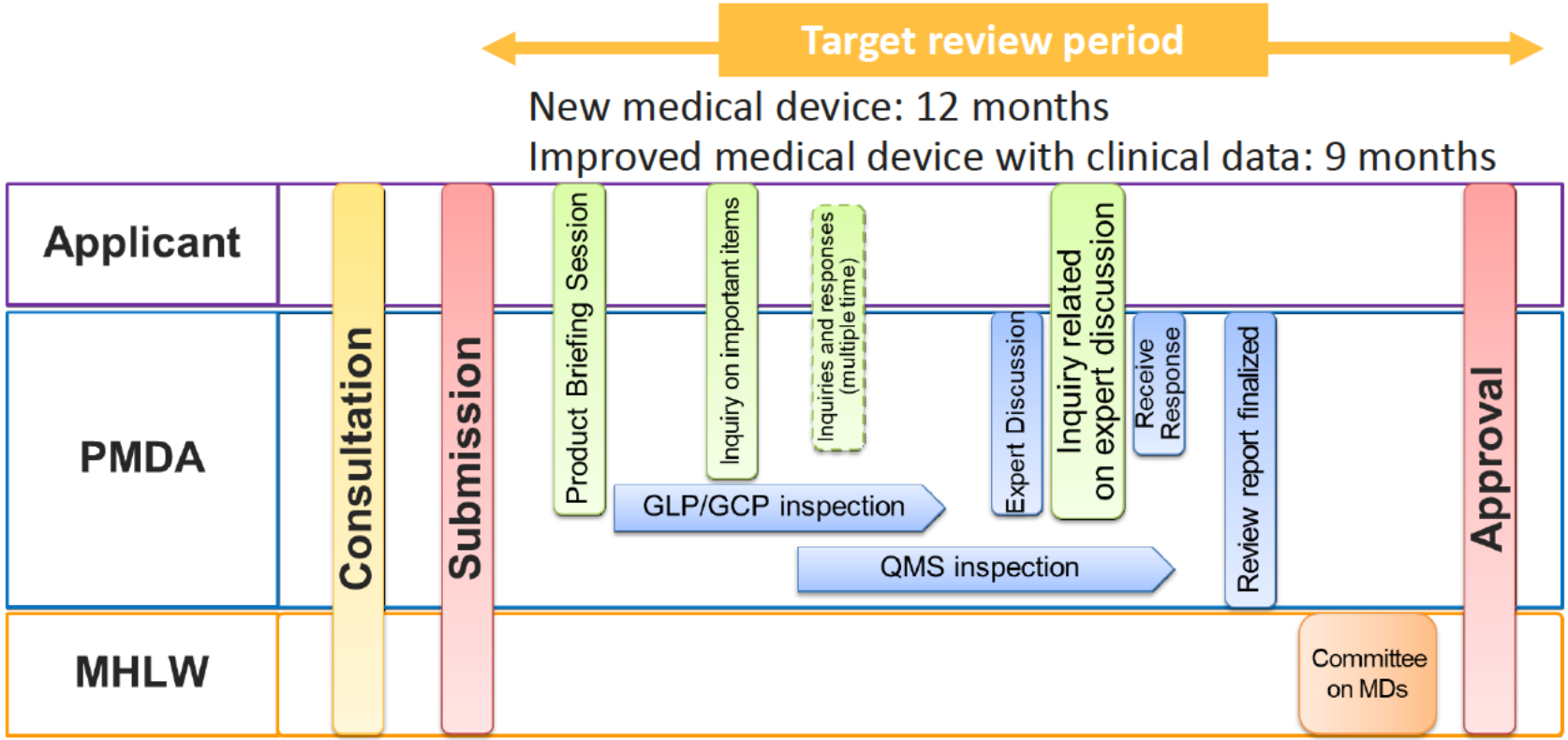
Medical Device (MD) Regulations in Japan

Classification	Class I	Class II	Class III	Class IV
Category	General MDs	Controlled MDs	Specially controlled MDs	
Premarket regulation	Self-declaration	Third party certification	MHLW approval (PMDA review)	
Example			 	  
Post market safety (vigilance/surveillance)	PMDA and MHLW			

Submission types for medical devices in Japan

	Generic medical devices	Improved medical devices	Brand-new medical devices
Device classification	Class II-IV	Class II-IV	Class II-IV
Performance requirements	Substantial equivalence to a legally marketed medical device	Reasonable assurance of safety and effectiveness for the intended use	Reasonable assurance of safety and effectiveness for the intended use
Pre-market clinical data?	Unnecessary	Depending on improved points from approved devices	Necessary
Post-market studies?	Not typical	Not typical	Possible, depending on regulatory controls
Targeted PMDA review time	4 months	6-9 months	12 months

Review process for approval in Japan



Review process for approval in Japan

Regulatory authorities provide opportunities for consultations to help the development process for new devices.

Experiences working with regulators in conducting a US-Japan harmonized clinical trial will be introduced…

Day1 8:40 AM

“The Pros and Cons of Global Clinical Studies”

Specific programs intended to promote innovation

Following provisions are introduced for earlier approval of medical devices:

① **SAKIGAKE designation system**

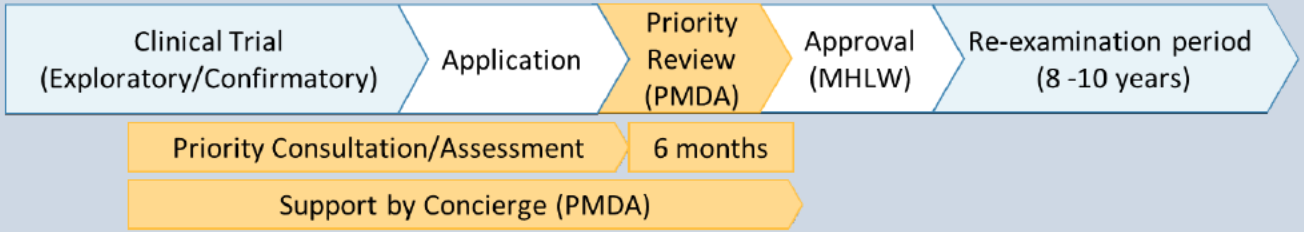
② **Priority review for specific uses**

③ **Conditional approval system**

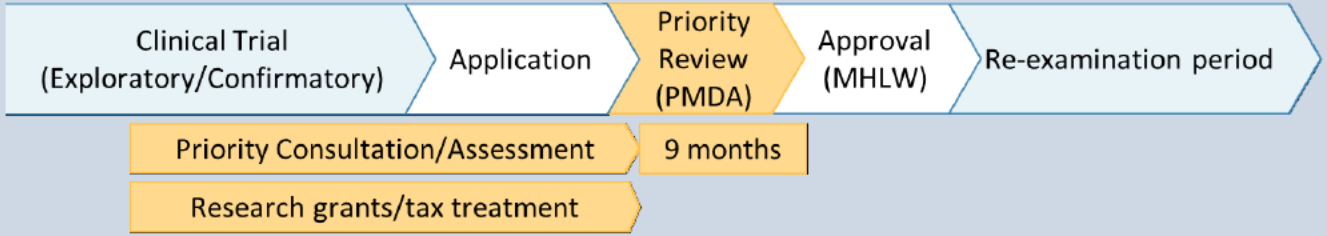
④ **Post-Approval Change Management Protocol (PACMP) for medical devices**

⑤ **Others**

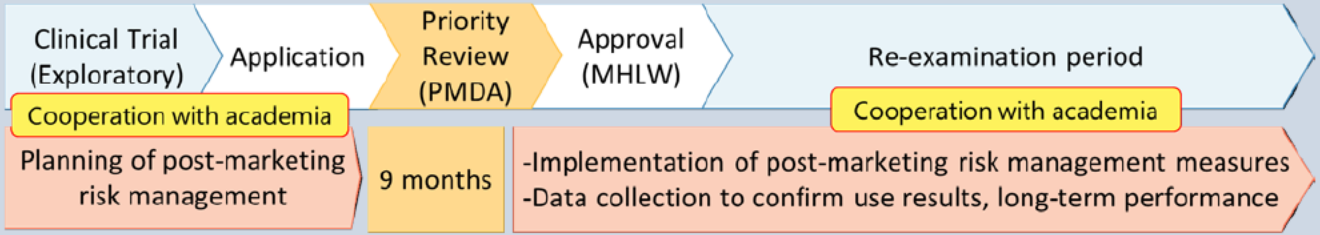
① SAKIGAKE designation system

Purpose	Providing cutting edge treatments to Japanese patients in first place in the world.
Designation criteria	① Innovativeness ② Severity of disease ③ Prominent effectiveness and safety ④ Willingness to firstly development in Japan
Process	
Advantages for manufacturers	✓ Prioritized consultation ✓ Pre-application consultation ✓ Prioritized review ✓ Review partner system

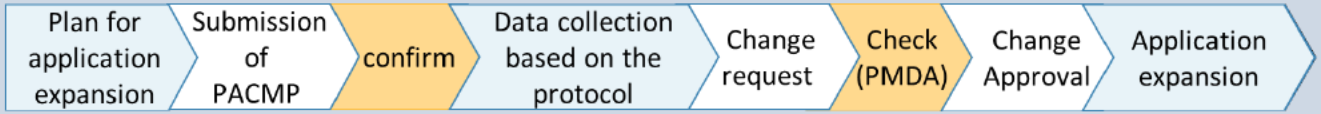
② Priority review for specific uses

Purpose	Promoting research and development of medical devices, which are not satisfied medical needs remarkably, such as pediatric medical devices.
Designation criteria	① Products for pediatric use, AMR, etc. ② Highly unmet medical needs ③ Prominent effectiveness and safety
Process	
Advantages for manufacturers	✓ Prioritized review ✓ Tax benefits and grants of subsidy for product development ✓ An addition to the reimbursement price

③ Conditional approval system

Purpose	Accelerating patient access to medical devices with particularly serious medical needs.
Designation criteria	① Severity of disease ② Prominent effectiveness and safety ③ Confirmatory clinical trials are not feasible ④ A certain degree of efficacy/safety is confirmed
Process	
Advantages for manufacturers	✓ Mitigate the burden of clinical development before approval application

④ Post-Approval Change Management Protocol (PACMP) for medical devices

Purpose	To enable continuous improvements through product lifecycle.
Designation criteria	① Changes of size, performance, manufacturing method, etc. ② Agreement on predictability and transparency in terms of the requirements and studies needed to implement a change
Process	
Advantages for manufacturers	✓ By checking the change management protocol in the review process this enables swifter approval of partial changes of already approved matter within the planned range and to continuously improve the specifications of the medical devices. ✓ The PACMP is expected to be applied to AI medical devices which are continuously improved by machine learning.

⑤ Others

1. Utilization of Registry Data

- **Basic principles on Utilization of Registry for Applications**
  (https://www.pmda.go.jp/files/000240810.pdf)

- **Points to Consider for Ensuring the Reliability in Utilization of Registry Data for Applications**
  (https://www.pmda.go.jp/files/000240811.pdf)

2. Utilization of performance evaluation test using existing medical information

- **Handling on performance evaluation test for diagnostic medical devices using existing medical information without additional invasive/intervention procedures**
  (https://www.pmda.go.jp/files/000243890.pdf) (Japanese only)

Related topics will be discussed…

② Priority review for specific uses

- **Day2 8:10 AM**
  “HBD For Children – Promotion of Pediatric Device Development and Access”

④ Post-Approval Change Management Protocol (PACMP) for medical devices

- **Day2 10:30 AM**
  “Digital Health and Artificial Intelligence”

⑤ Others -Utilization of Registry Data-

- **Day1 10:30 AM**
  “Practice Approaches to Applying Real-World Clinical Evidence”

Summary

- Japan has introduced several novel regulatory programs intended to support the appropriate evaluation of innovative medical devices.
- The new system is expected to facilitate development of and access to novel medical devices by balancing pre-/post-market requirements.
- We would like to provide device developers and other stakeholders with insight into potentially beneficial opportunities to pursue global device development strategies by leveraging regulatory synergies in each region.

Thank you for your kind attention.

If you have any questions, please contact us.

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