

Regulatory Innovation for Safe and Early Access to medical devices in Japan

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Amendment of Pharmaceutical and Medical Device Act (PMD Act)

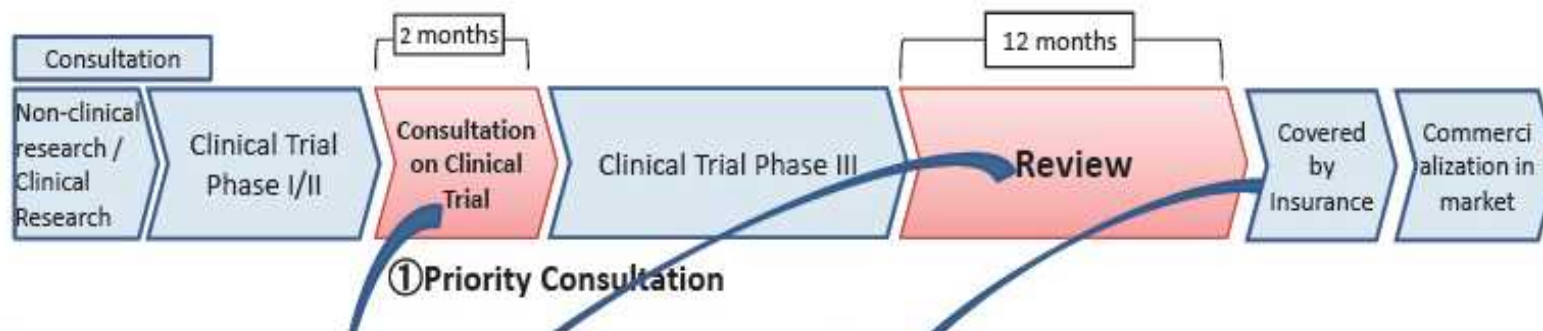
- Enacted on Nov. 27, 2019 and published on Dec. 4
- Following provisions are introduced for early approval of medical devices of high medical needs:
 1. SAKIGAKE designation system
 2. Priority review for specific uses, e.g. pediatric use
 3. Conditional early approval system
 4. Early realization of improvement in post-marketing (including for *Artificial Intelligence*)

1. SAKIGAKE Designation System

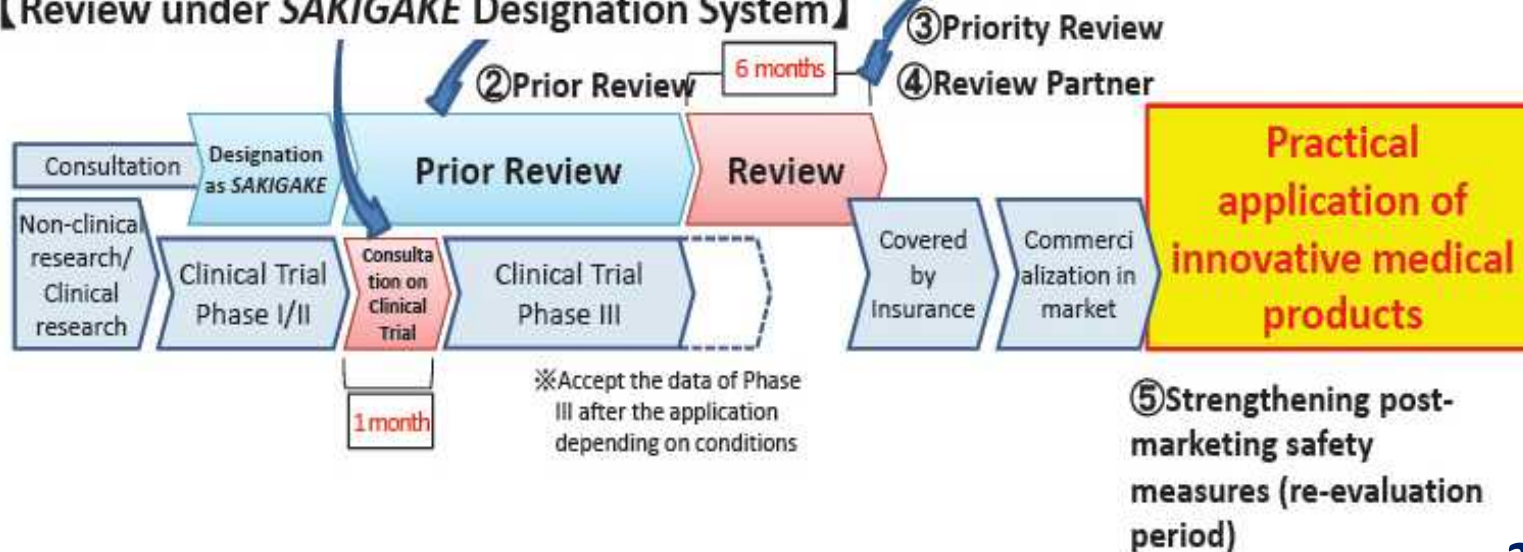
pilot started in 2015

Criteria: 1. Innovativeness, 2. Severity of targeted disease,
3. High Effectiveness, 4. Development plan in Japan

【Ordinal Review】



【Review under SAKIGAKE Designation System】



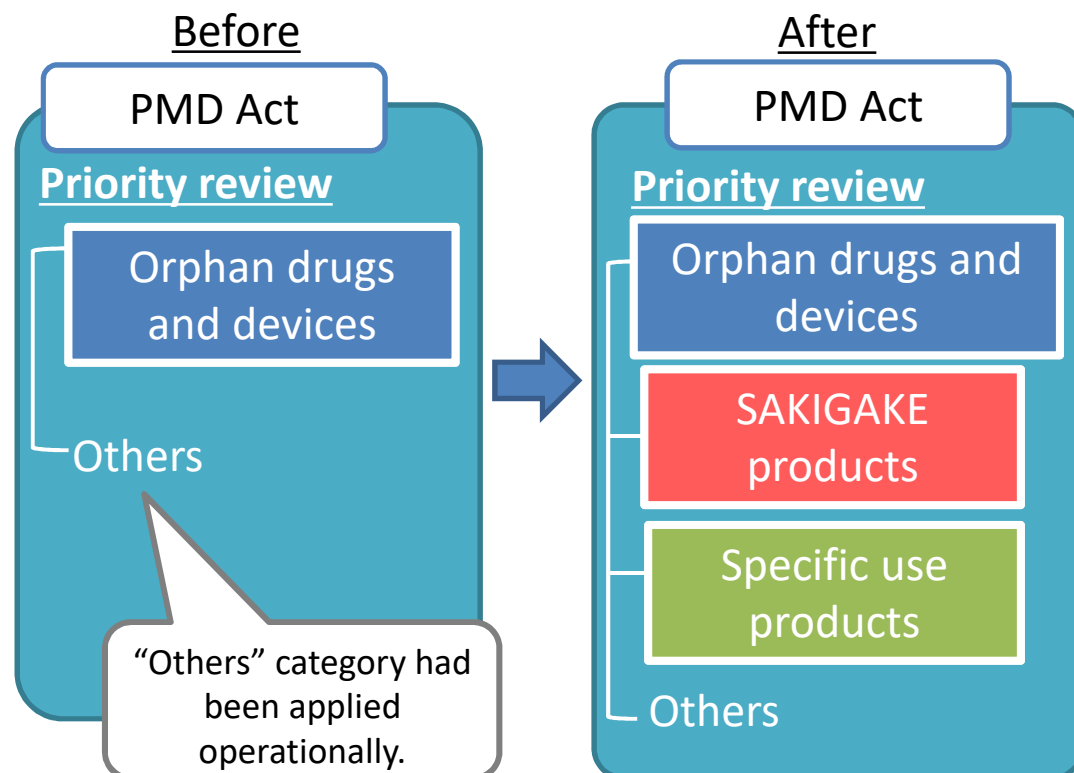
4th Round of pilot SAKIGAKE Designation (on Apr. 8, 2019)

- Medical Devices -

No.	Name of product (tentative)	Applicant	Planned indication
1	Microwave mammography	Integral Geometry Science Inc.	Identify the tissues suspected to be breast cancer by microwave and provide the information to the doctor
2	Molds of vascular graft for lower extremity arterial bypass	Biotube Co., Ltd	Improvement of blood circulation failure below the knee by surgical reconstruction and maintenance of its long-term patency by self revascularization in patients with severe lower limb ischemia
3	Phosphorylated pullulan bioadhesive	BioARC Co., LTD.	Improvement of usability and retainability of the adhesive to bone defects with better formativeness and adhesiveness by mixing it with autologous bones, allogeneic bones, heterogeneous bones, artificial bones or their mixtures. Moreover, due to its volumizing effect, using this adhesive can reduce the amount of autologous bone to be collected.

2. Priority review for specific uses, e.g. pediatric use

- Designation of “Specific use product” for highly unmet medical needs, e.g. pediatric use and AMR.
- Priority review (6 months) and other supportive measures are applied to designated products for specific use.



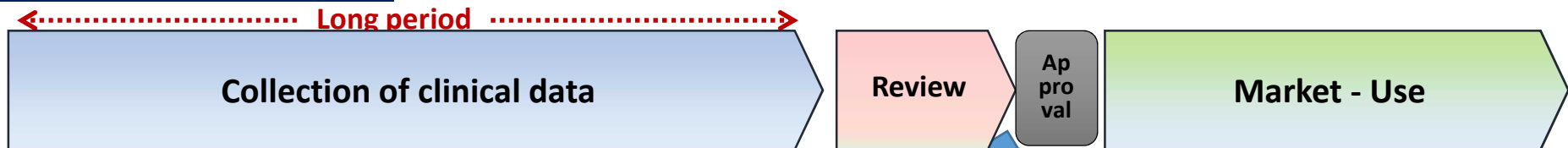
Criteria of specific use

1. Products for pediatric use, AMR, etc.
2. Highly unmet medical needs
3. High effectiveness and/or safety

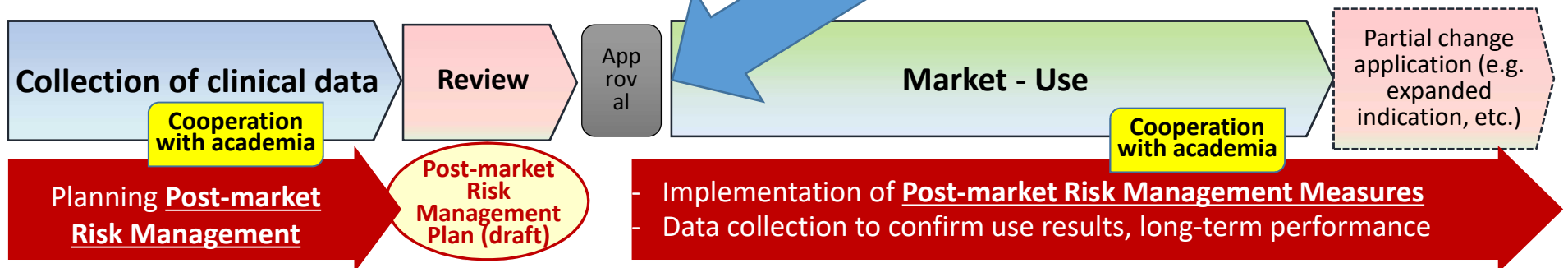
3. Conditional Early Approval for innovative MDs

Accelerate approval of MDs of high clinical needs by balancing the pre- and post-market requirements, based on the lifecycle management of the MDs.

■ Ordinary review



■ Conditional Early Approval for Innovative MDs

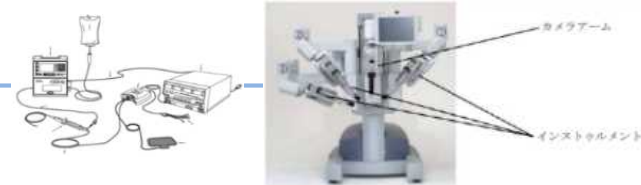


Possible type of Conditional Early Approval

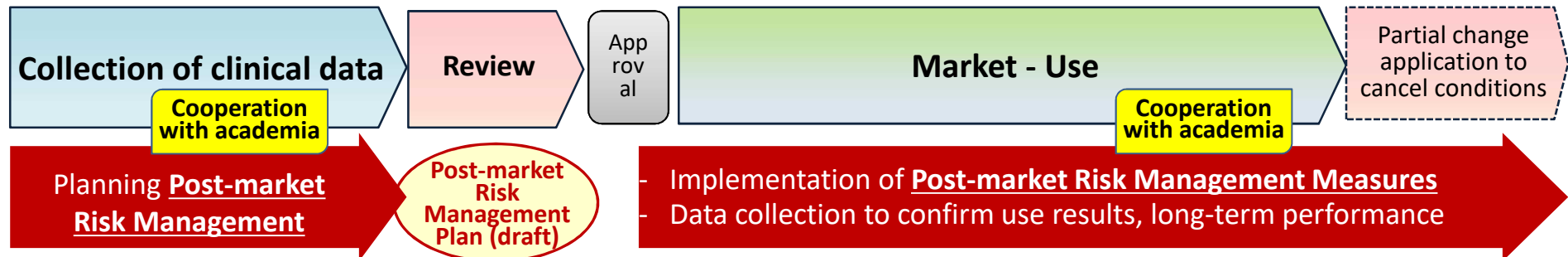
Extrapolation of indication to other therapeutic areas based on the function

Conditions:

- For devices which performs physical function on human body, e.g. ablation, freezing and shielding
- Clinical evidence on a specific therapeutic area which can be extrapolated to other areas
- Clinical use standards and risk management plan developed in collaboration with academic society

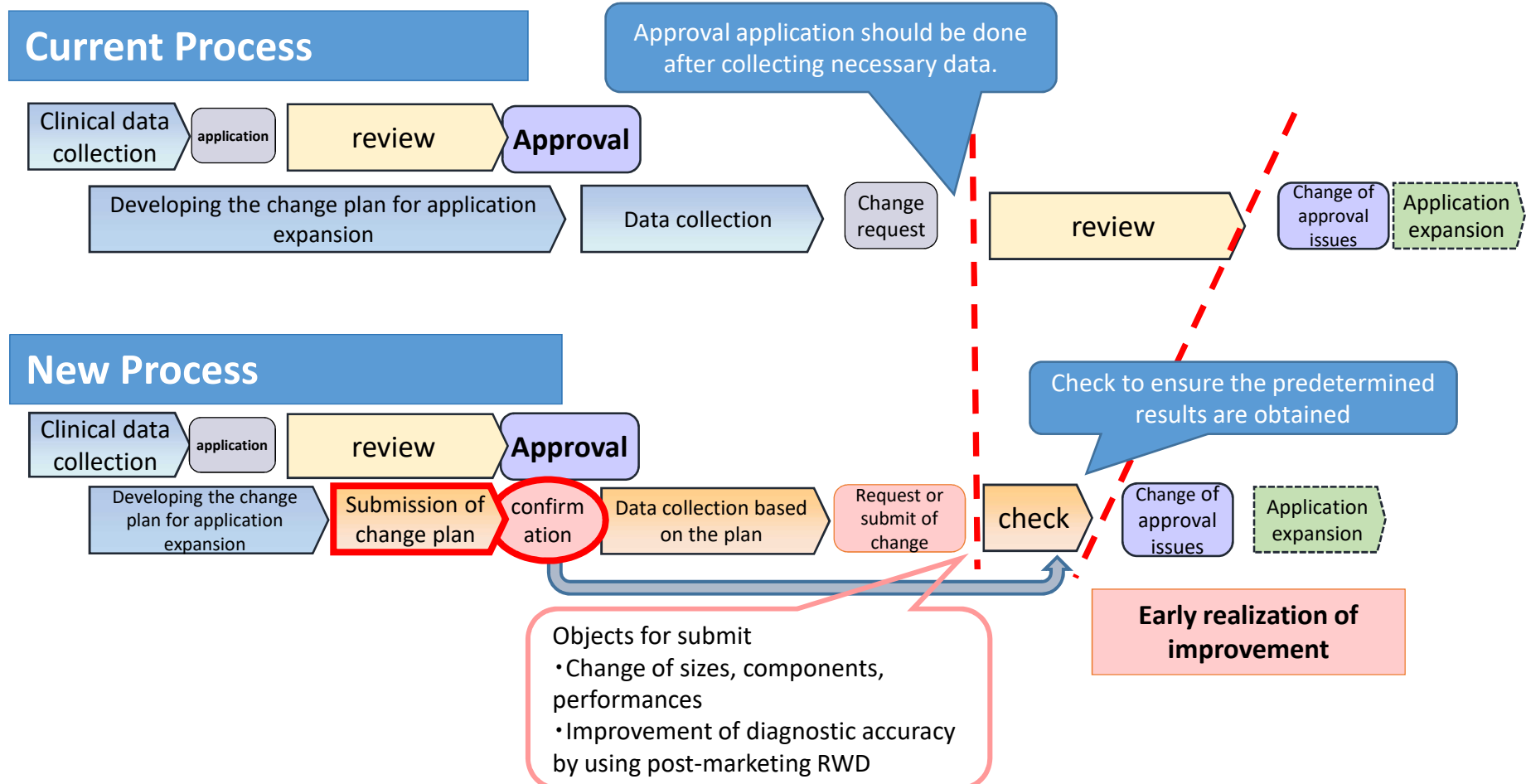


Early realization of application of device to other organs and body parts based on the function by risk management measures in the post-marketing phase.



4. Early realization of Improvement in Post-marketing

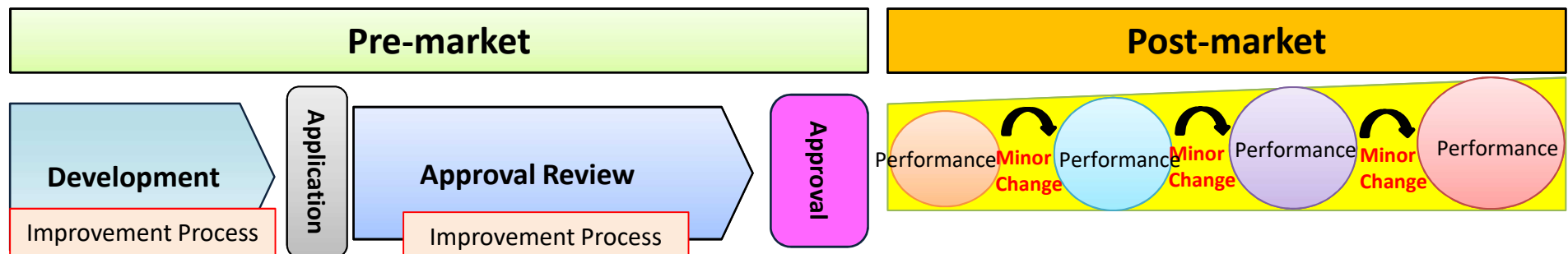
Post-Approval Change Management Protocol will be introduced for medical devices to enable continuous improvements.



Post-market change process for devices with AI

Approval review process which enables continuous improvement of performance of SaMD using AI

- Changes of performance must be in one-direction (improvement) and be managed by MAH.
- MAH may develop a process which ensures such performance changes as “Improvement Process”, and submit in the approval review process.



“Improvement Process” is developed and reviewed in the approval review process.

Post-market changes in line with the Improvement Process can be made by minor change notification, which does not require approval process.

*Compliance is checked in QMS audits.

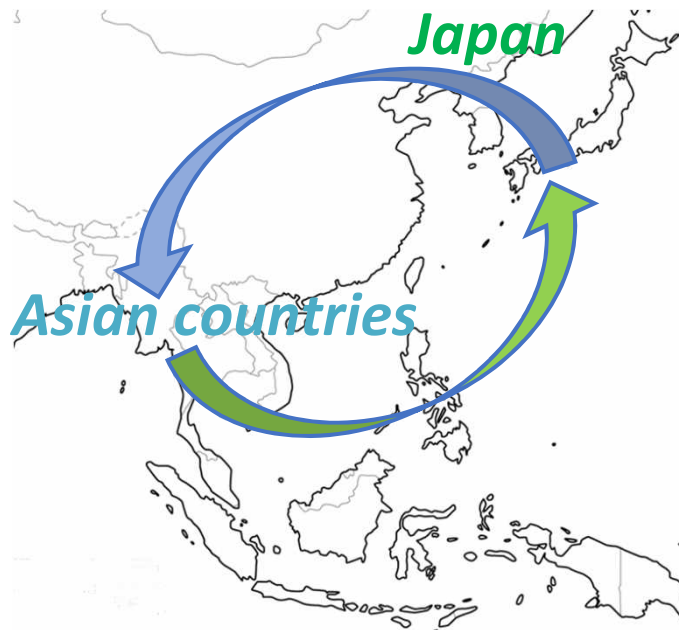
International regulatory harmonization in medical devices



GHTF (1992-);
IMDRF (2011-)



IMDRF International Medical
Device Regulators Forum



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US/Japan Regulatory Collaboration

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Through the [U.S. - Japan Medical Device Harmonization by Doing \(HBD\)](#), the FDA, Japanese regulators, academia, and industry developed internationally agreed upon standards for global clinical trials related to cardiovascular devices, and addressed regulatory barriers that may delay timely medical device approvals in both countries.

The U.S. and Japan are also committed partners in the [International Medical Device Regulators Forum](#), which is a group that works together to accelerate international medical device regulatory harmonization and convergence.

US-JP HBD (2003-)

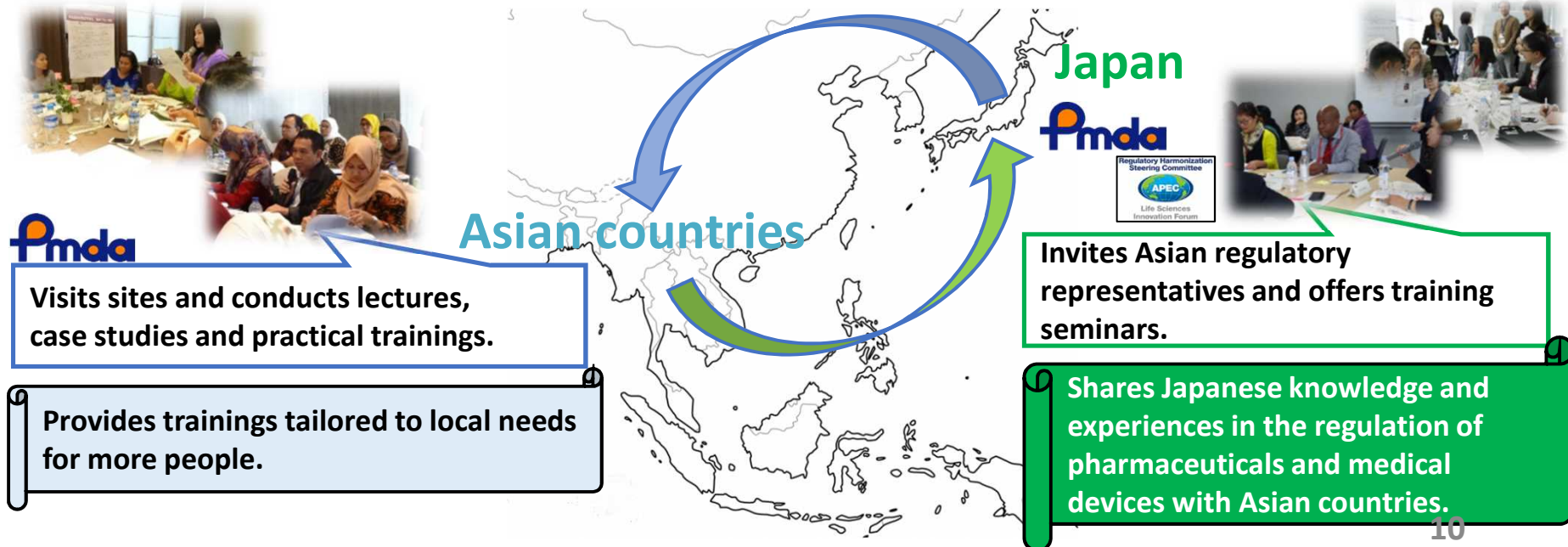
PMDA Asia Training Center
(2016-)

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

- PMDA-ATC was established (April 2016).
PMDA-ATC has also been approved as Centers of Excellence (CoE) of APEC.
- Promote capacity building and human resource development through training seminars for Asian regulators.

Action Policy of PMDA-ATC

Contribute to universal health coverage in Asia through developing a foundation for regulatory harmonization in the Asian region.



Expectation for HBD

- Further US-JP regulatory harmonization is expected based on experiences in both sides. Drafting US-JP joint guidance is one possible idea.
- More companies and products should join in HBD, especially from Japan. Expansion of scope from cardiovascular area is a proposal.



Summary

1. Japan enacted the amendment of PMD Act, which includes SAKIGAKE and other systems for early and safe approval of innovative products.
2. Japan is willing to share our knowledge and experience internationally through HBD, IMDRF and Asia Training Center for harmonization.
3. HBD can be further activated by more companies & products joining in the collaborative scheme.

