Overview of US-Japan Pilot Program Regarding Collaborative Consultation and Review

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Launch of the pilot program

- FDA and MHLW announced the launch of pilot program regarding collaborative consultation and review on June 15, 2009.

"Aligning" the Regulatory Roadmaps

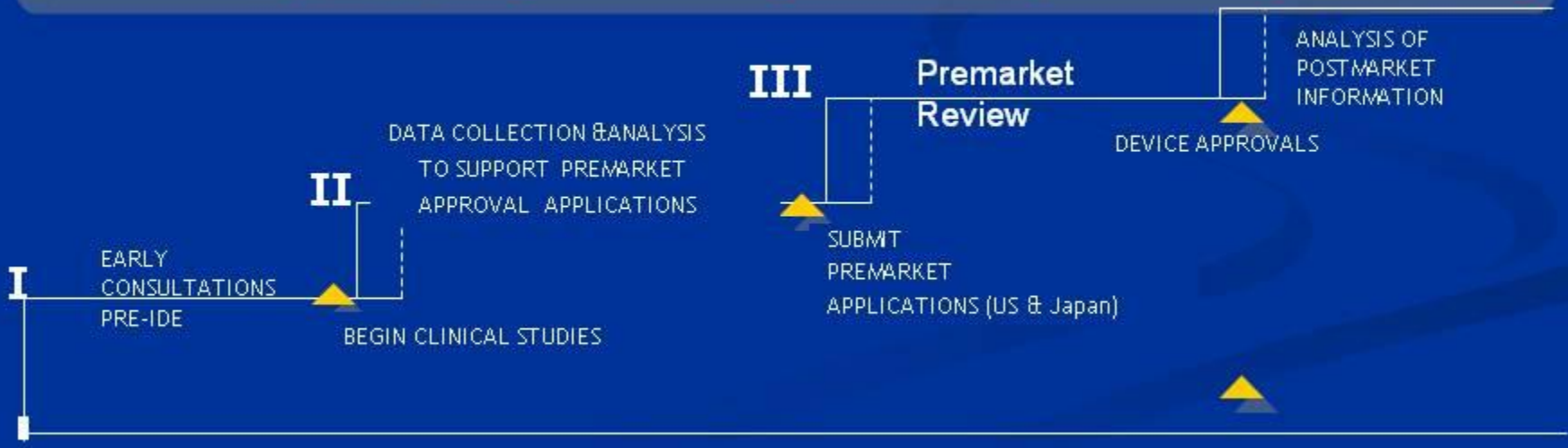
Tools already exist in both countries.

FDA

Pre-IDE	IDE & Clinical Trial	Pre-PMA	PMA Review	PMA Approval	Postmarket

MHLW/PMDA

Consultations	Clinical Trial Notification & Study	Pre-Application Consultation	Application Review	*Shonin*	"Postmarket"



Aim of the pilot

- To bring out advantage of involvement of the regulators in both countries.

- This collaboration would permit to discuss the contents of an individual submission in order to gain valuable regulatory information pertaining to device development and clinical trial design.

* The pilot does not affect each Agency's ability to make its decision independently.

3-way interaction of the pilot

- Face to face meeting
- Teleconference
- E-mail

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Advantages for the sponsor

- US and JP Regulators work together with sponsor toward solutions (usual MHLW/PMDA consultation fees apply)
- Sharing of scientific and regulatory views expected to enhance (not hinder) review process

Sponsor

The Pilot doesn't impair sponsor's interest

- FDA's MDUFMA II Goals are unaffected.
- Sponsor's proprietary/trade secret information remain confidential under the Confidentiality Agreement between FDA-MHLW/PMDA.*
- A participating sponsor may withdraw from the pilot program at any time. The sponsor is free to pursue the normal regulatory process in each agency.

* The sponsor of the selected medical device will be requested to submit an "Authorization to Share Confidential and/or Trade Secret Information with a Foreign Government" that authorizes FDA to share information with MHLW/PMDA. The sponsor must also contact MHLW/PMDA and submit a similar authorization letter to MHLW/PMDA.

Participation of a sponsor in the pilot

- Application according to the announcement

MHLW/PMDA

http://view.pmda.go.jp/operations/shonin/info/iryokiki/collaboration.html

FDA

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/InternationalInformation/ucm203552.htm

- Sponsor inclusion criteria
  - New device is intended for marketing approval in both US and JP.
  - Development status is similar.
  - Must have early consultations with both agencies before conducting the trials.
  - Same information provided to both US and JP.

Selection results

Result of recruitment in FY2009

- 2 medical devices of Japanese company and US company were selected as subjects for the continuous consultation and review pilot program
- Others : one-time interaction if sponsors wish to participate

Result of recruitment in FY2010

- more medical devices of Japanese company and US company were selected as subject for the continuous consultation and review pilot program

Public recruitment of the pilot was concluded, but “ad hoc” regulatory discussion will be set on request.

Lessons learned

- Impact of differences of regulations or organization in US/JP agencies
  - presence of module review
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Found potentially low risk of review process to obstruct global simultaneous development/application

- US/JP review processes are found similarly developed and matured
- Mutual communication between MHLW/PMDA, FDA and the sponsor was improved

Conclusion

- The pilot brought the opportunity of multilateral discussion with rapidity and quality, then regulatory benefits to both agencies and sponsors.
- Obstacles are relevant to review operations and can be improved through efforts with agencies and sponsors, when development/application/clinical evaluation stage were similar between US/JP

Conclusion

- The pilot brought the opportunity of multilateral discussion with rapidity and quality, then
- development/application/clinical evaluation stage were similar between US/JP

US/JP regulatory agencies will continue to support MD development through initiatives such as the pilot program or other appropriate collaborative activities.

Thank you for your attention

- For more information, contact our staff

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