

US-Japan Pilot Program regarding Collaborative Consultation and Review

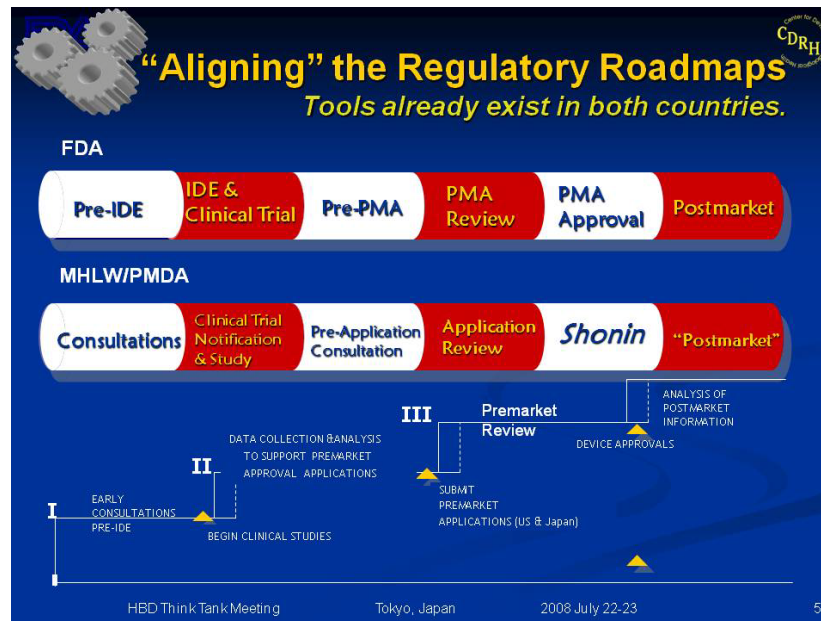
Carole Carey, CDRH

Hiroshi Yaginuma, MHLW &

Kentaro Azuma, MHLW

Launch of the pilot program

- FDA and MHLW announced the launch of pilot program regarding collaborative consultation and review on June 15, 2009, which is evolved from rough idea presented at last HBD Think Tank in Tokyo.



Aim of the pilot

- This collaboration would permit the regulatory review staff of both MHLW/PMDA and FDA 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.

- The aim is to bring out advantage of involvement of the regulators in both countries. For example, under the pilot, regulators can help design of the clinical trials which can be accepted by both agencies, in order to eliminate redundant clinical trials.

Advantages of Participating in the Pilot

□ Regulator Collaboration

- US and Japanese Regulators work together with sponsor toward solutions
 - eg. 3-way teleconferences (US and Japanese Regulators & sponsor) as appropriate – usual MHLW/PMDA consultation fees apply
- Sharing of scientific and regulatory views expected to enhance (not hinder) review process

The Pilot doesn't impair sponsor's interest

- ❑ FDA's MDUFMA II & MHLW/PMDA Goals are unaffected.
- ❑ A Confidentiality Agreement between FDA-MHLW/PMDA already exists. In addition, Sponsor's proprietary/trade secret information remain confidential under a signed sponsor agreement, SMG 2830.3 Attachment E.*
- ❑ 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.

Please contact FDA and PMDA-MHLW as early as possible if interested

- ❑ Regulators are soliciting for sponsors who are interested in participating in the pilot.
- ❑ Interested sponsors should submit an application letter to the FDA and MHLW/PMDA by July 31, 2009.

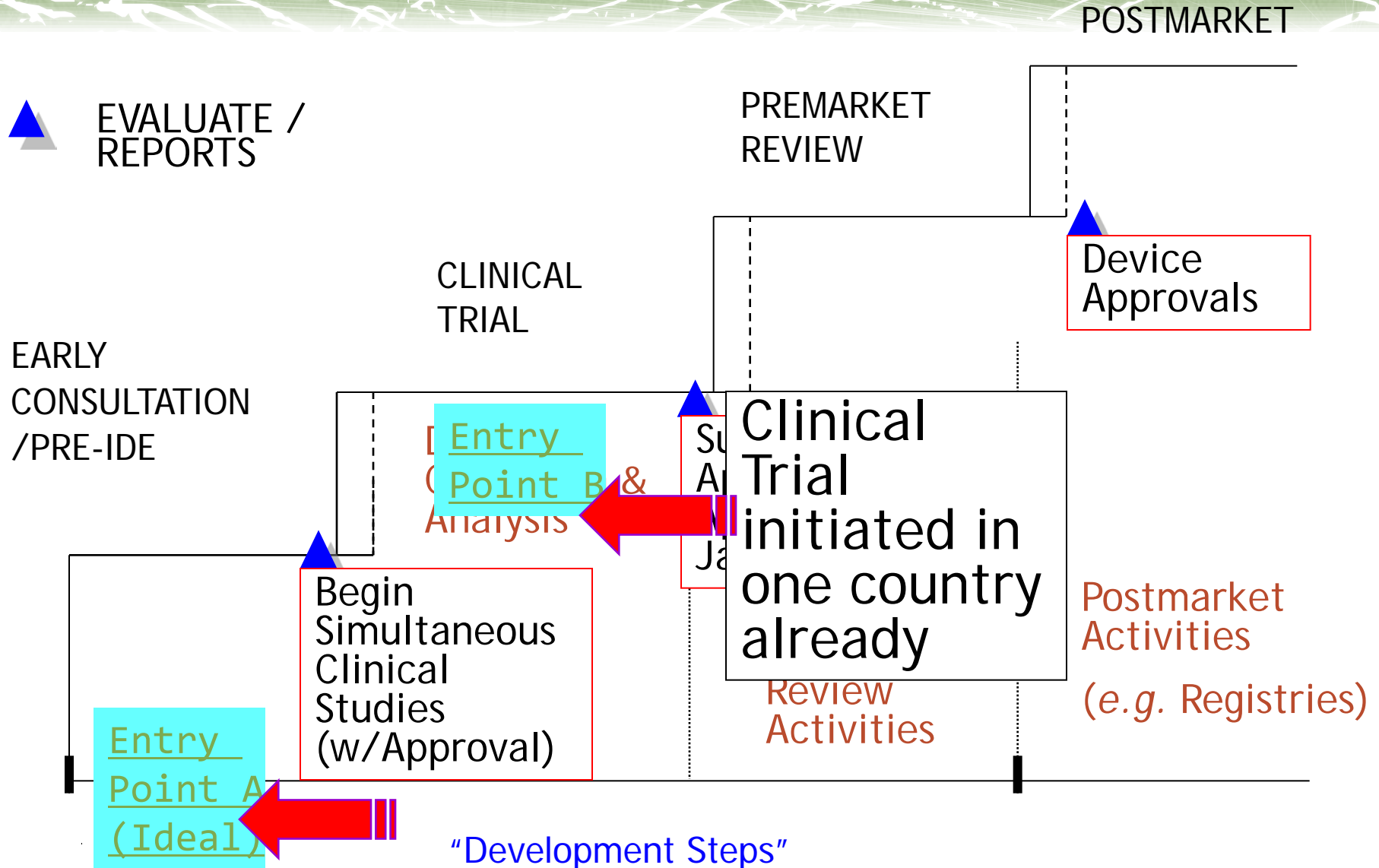
Inclusion Criteria

- New device in the cardiovascular/endovascular field and is intended for marketing approval in both the US and Japan.
- Development status of the device is similar in the US and Japan. Clinical trials of the device will be conducted with a single (or similar) protocol in the US and Japan.

Inclusion Criteria (Cont.)

- ❑ The sponsor of the candidate device must have early consultations with PMDA and FDA/CDRH when planning clinical trials, unless the clinical trials for the device are already being conducted in Japan and/or the US.
- ❑ The sponsor of the candidate medical device should provide the same information to MHLW/PMDA and US FDA.

FAQ: At what points of development can my device enter the Pilot?



Selection Process

- MHLW/PMDA and FDA will consider medical devices from the pool of Japanese and US industry sponsors who submitted an application nominating their device for this pilot program.
- MHLW/PMDA and FDA will conduct a joint evaluation of the nominated medical device for eligibility to participate in the pilot program; one or two medical devices will be initially selected.
MHLW/PMDA and FDA will balance the selection process between Japan and US.

Who should I contact?

In FDA

- Carole Carey, Director, International Relations & External Affairs Staff, Division of Small Manufacturers, International and Consumer Assistance, carole.carey@fda.hhs.gov, 301-796-5708
- Dr. Bram Zuckerman, Director, Division of Cardiovascular Devices, bram.zuckerman@fda.hhs.gov

In MHLW

- Kentaro Azuma, Specialist for New Material, Office of Medical Devices Evaluation, MHLW, azuma-kentarou@mhlw.go.jp
- Koji Ikeda, Deputy Review Director, Pharmaceuticals and Medical Devices Agency, PMDA, ikeda-koji@pmda.go.jp

For detailed information

- Pilot Program Regarding Medical Device Collaborative Consultation and Review of Premarketing Approval, (June 15, 2009)
<http://www.fda.gov/InternationalPrograms/HarmonizationInitiatives/ucm167858.htm>
- “Pilot program on exchanging information between MHLH/PMDA and US FDA regarding medical device consultation and review”, Notification from Director of the OMDE (*Yakusyokuki-hatsu* #0615001, June 15, 2009)
<http://www.ourei.mhlw.go.jp/ourei/doc/tsuchi/T090623I001.pdf>