RAPS 2022 Convergence

Achievement and prospective of HBD-for-Children activity

Marika Doi

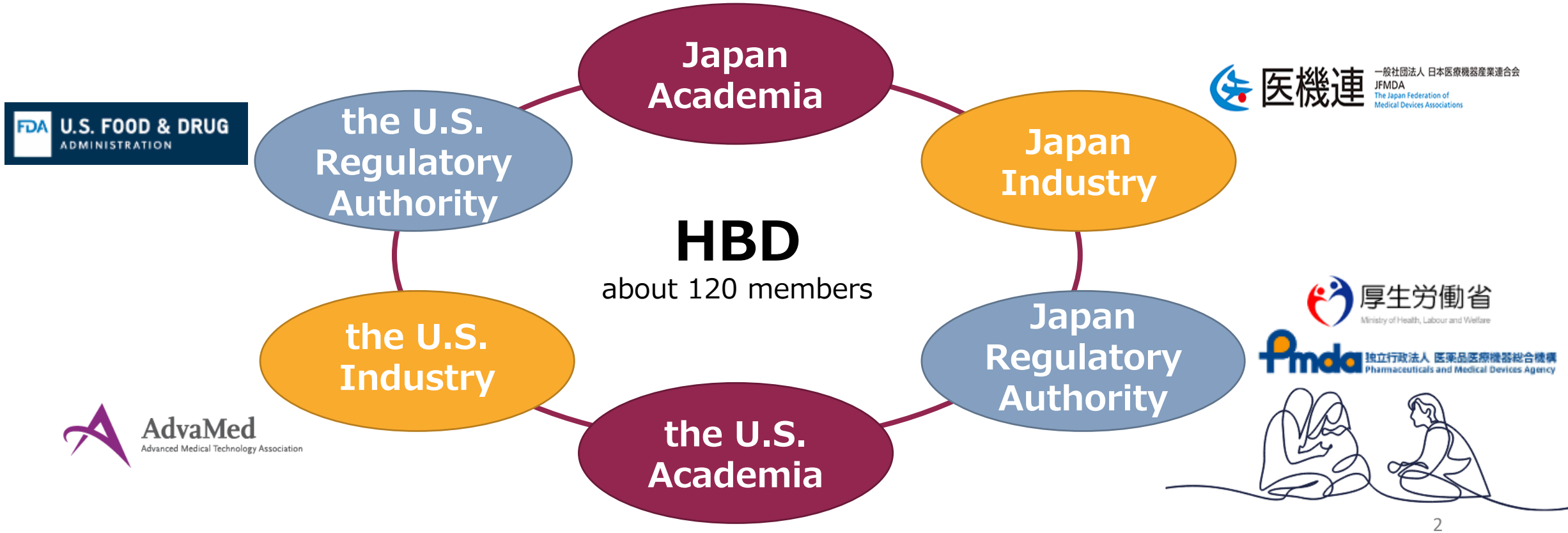
Reviewer

Office of Medical Device II

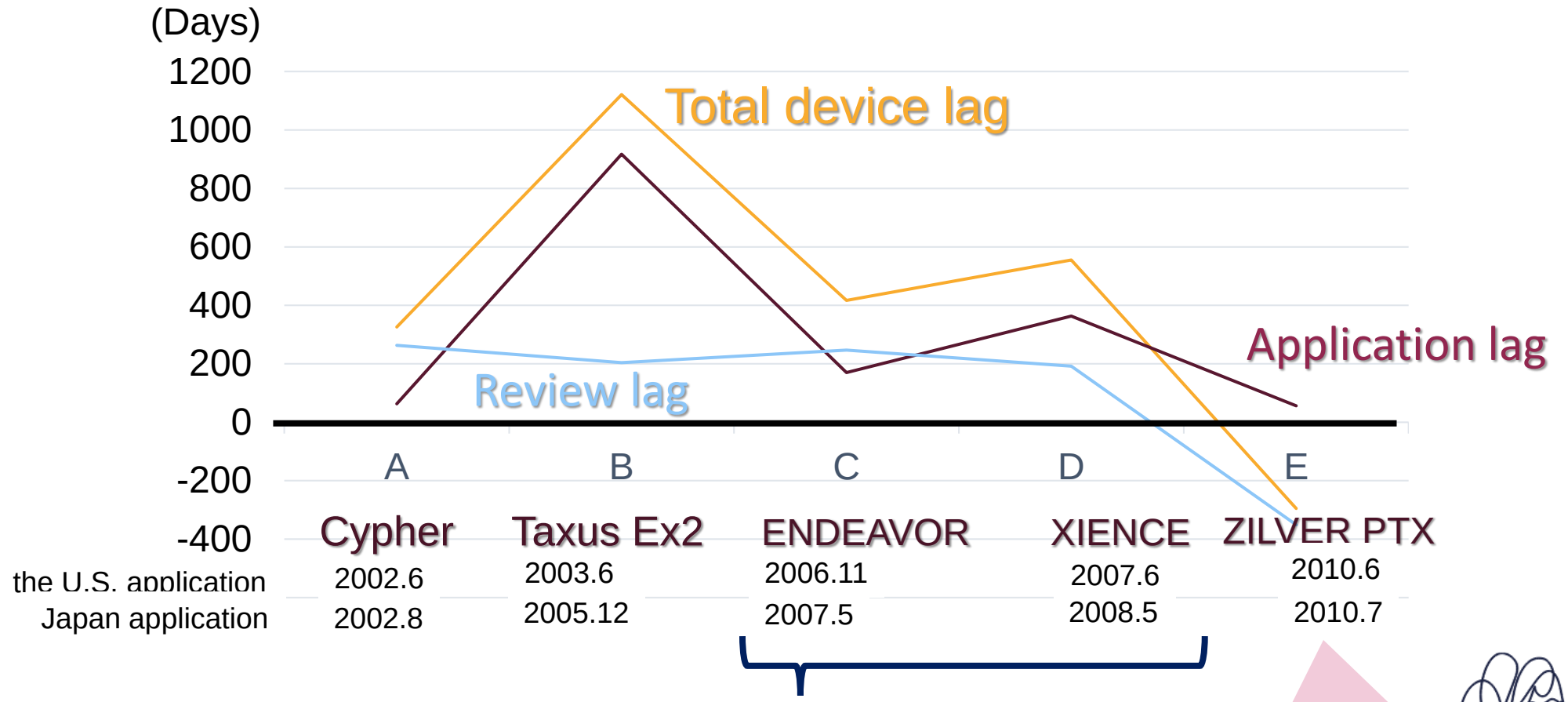
Pharmaceuticals and Medical Devices Agency, Japan

What is Harmonization by Doing (HBD)?

Purpose: Stakeholders of Regulatory agency, academia and industry in Japan and the U.S. initiated a dialogue to promote a global clinical trial for developing innovative medical devices in 2003.



Background: the U.S.-Japan Device Lags for Drug Eluting Stents



- HBD POC project
- the U.S. pivotal trial and Japan trial

- **Global Clinical trial**
- the U.S./Japan collaborative scheme project

Circ J 2018; 82: 636-643

RAPS 2022 Convergence

Achievement of HBD Activity

2003 Establishment of HBD

- Conducted the U.S.-Japan joint clinical trials for two drug eluting stents
  - ENDEAVOR (Medtronic Japan Co., Ltd.)
  - XIENCE V (Guidant Japan K.K. (former name))

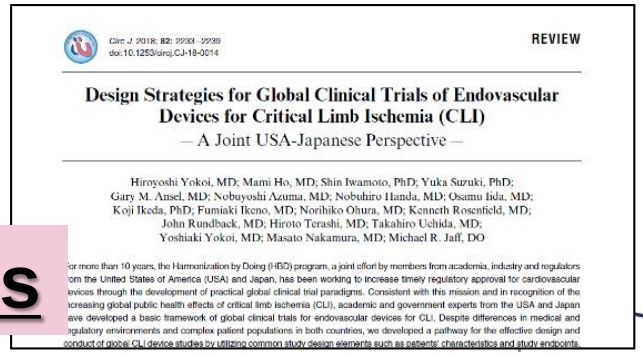
2005 First Think Tank meeting in Tokyo

2010 Simultaneous application for marketing approval of Zilver PTX in the U.S. and Japan

2016 **Launched “HBD-for-Children” activity**

2018 Published the guidance for evaluating endovascular devices for Critical Limb Ischemia

Circ J. 2018; 82: 2233-2239.



REVIEW

Design Strategies for Global Clinical Trials of Endovascular Devices for Critical Limb Ischemia (CLI)

— A Joint USA-Japanese Perspective —

Hiroyoshi Yokoi, MD; Mami Ho, MD; Shin Iwamoto, PhD; Yuka Suzuki, PhD; Gary M. Ansel, MD; Nobuyoshi Azuma, MD; Nobuhiro Handa, MD; Osamu Iida, MD; Koji Ikeda, PhD; Fumiaki Ikeno, MD; Norihiko Ohura, MD; Kenneth Rosenfield, MD; John Rundback, MD; Hiroto Terashi, MD; Takahiro Uchida, MD; Yoshiaki Yokoi, MD; Masato Nakamura, MD; Michael R. Jaff, DO

Paved the way for the global clinical trials

HBD-for-Children – What we do?

- Through the HBD experience, we recognized the importance of collaboration to promote the development of innovative medical devices.
- Development of pediatric medical device tends to delay both in the U.S. and Japan.
- We had discussion to find problems and solutions for the early development of pediatric medical devices at face-to-face meetings in conferences and teleconferences.

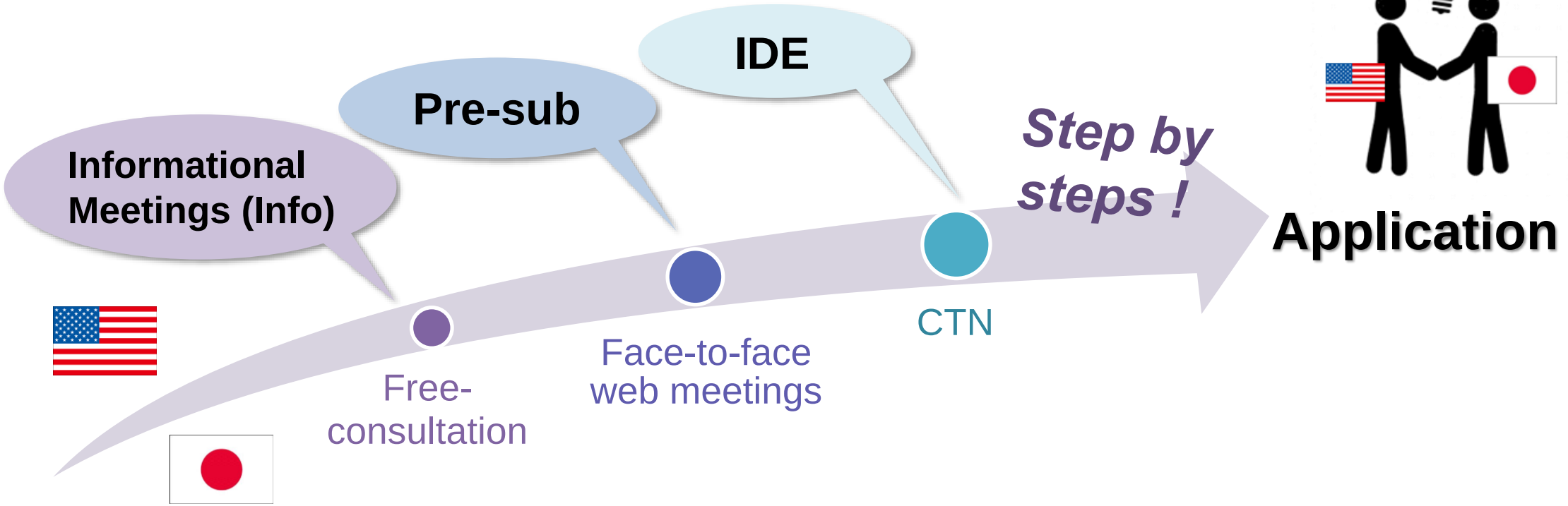
Our activity

- Identify the needs/seeds of medical devices
- Compare the medical environment and target patient in the U.S. and Japan

<u>If it is possible to conduct a global clinical trial…</u>
- Supporting the trial as POC project
- Utilizing consultations of FDA and PMDA

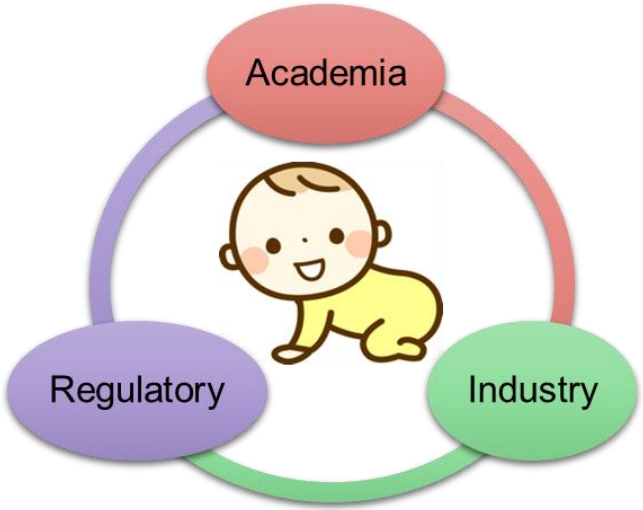
<u>If it is **im**possible to conduct a global clinical trial…</u>
Considering to utilize
- special approval processes in both countries,
- other clinical study data, and/or
- actual data of experience with the product etc.

Proof of Concept (POC) Project



Purpose of “POC” is to promote the convergence from parallel clinical trials in the U.S. and Japan toward **single clinical trial protocol** and to **encourage global development**.

Conclusion



- HBD-for-children activity contributes to the development of pediatric medical devices by supporting the Japan-the U.S. global clinical trial.
- We approach to collaborate with other organizations for accelerating the global development.

We will continue to seek real problems and solutions in Japan and the U.S. It is important to aggressively share the information and discuss between academia, industry and regulatory.

Please join the HBD-for-children activities for the happiness of children!

Thank you for your kind attention.

If you have any questions, please contact us.

HBD_children@pmda.go.jp