CRT 21 Virtual

Overview of the concept paper for global clinical

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pmda

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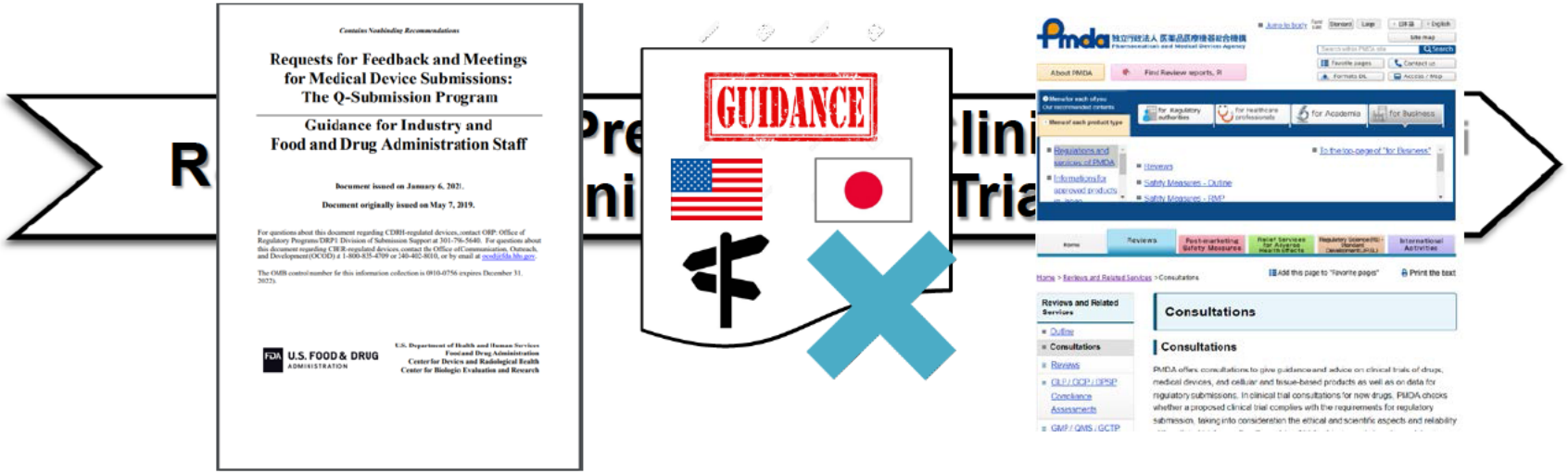
I have no relevant financial relationships

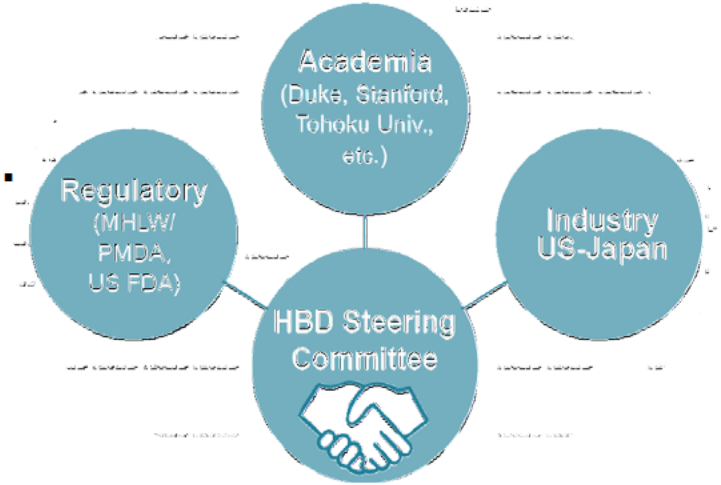
Why need to make “the concept paper"?



There is no guide book/instruction focused on medical devices for a sponsor to conduct a global clinical trial between US and Japan.

Objectives of this presentation

Harmonization By Doing (HBD) activity have several experiences of conducting global (U.S. and Japan joint) clinical trials.

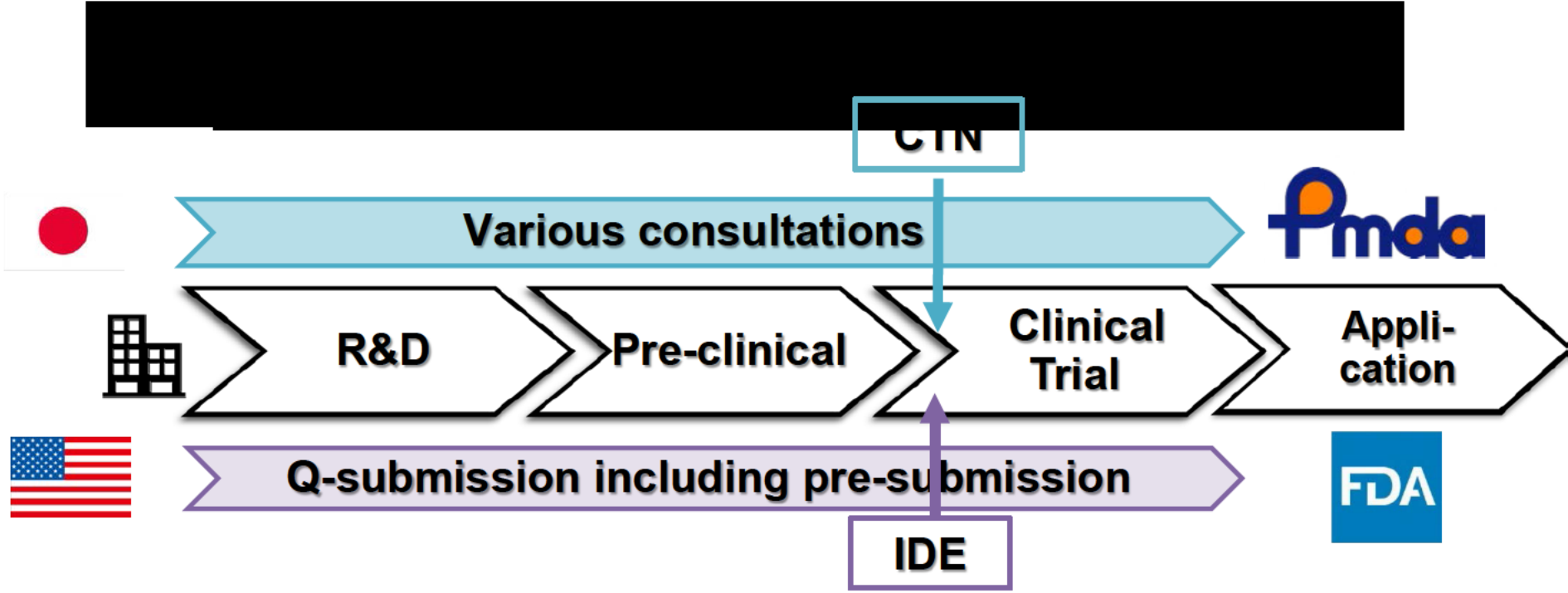


HBD members are trying to make and publish the concept paper to clarify the regulation and/or clinical site related differences between US and Japan.

With the comparison between US and Japan in mind,

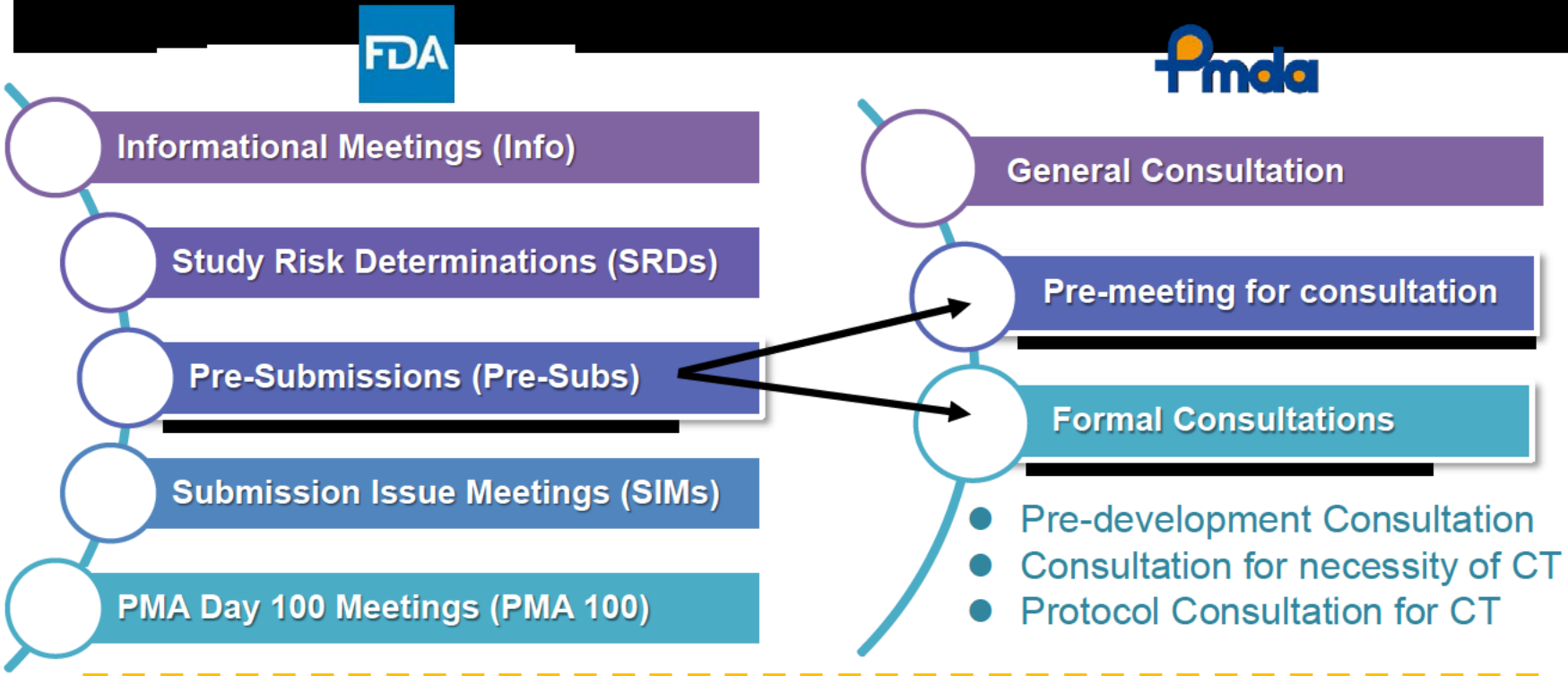
1. Regulatory Pathway for Clinical Trials
2. Q-submission and PMDA's consultation
3. Clinical Trial Notification in Japan
4. Lessons learned from HBD activity

※HBD：Harmonization By Doing
※IDE : Investigational Device Exemption, CTN : Clinical Trial Notification



There are original systems for the pathway for clinical trials in both countries.

※IDE : Investigational Device Exemption, CTN : Clinical Trial Notification



Sponsors can get feedback before starting clinical trials(CT).

Objectives

- ✓ ***Sharing information with PMDA***
- ✓ ***Clarification of the topic we should discuss at consultation.***

Steps

1. **The documents we require for this consultation are as follows:**
   - **Overview of device (intended use, concept, etc)**
   - **Draft of protocol design for clinical trial**
2. **Manufacturer can get the certification within a year from PMDA.**

Schedule

[redacted]

Objective

✓ *To decide the specific evaluation items*

Steps

1. The documents we require for this consultation are as follows:
   a) Device description, b) Clinical trial protocol,
   c) Applicant's opinions, d) Investigator's brochure ,
   e) Draft of Informed Consent

2-3 months for the feedback

2. Sponsors can get the feedback which as follows:

- The validity of the protocol (Study design, Target patients, Primary endpoint and Statistical analysis method ,etc)
- The purpose and the clinical positioning of the medical device

[redacted]rial Notification

Submit the CTN to PMDA → 30 days survey → Report the result to MHLW → Allow to Conduct Clinical trial

pmda reviews in CTN within 30days…

- The safety of Investigation plan
- Protection for patient
- Accordance with GCP

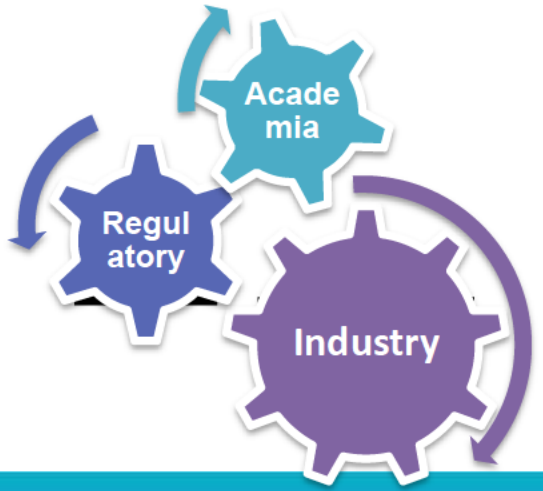
FDA reviews in IDE within 30days…

- The safety and Validity of Investigation plan
- Protection for patient
- Accordance with GCP

Keys to success

- ✓ *Early* interaction with both regulators *at the same time*.
- ✓ Careful consideration of their feedback.
- ✓ *Close communication* with Academia, Industry and Regulator

The concept paper will include
*not only introduction of regulatory systems but also **several case studies**, where global clinical trials were conducted.*



[redacted]

US and Japan have similar systems.
It's important to understand and use each of them.

Informational Meetings (Info)

General consultation

Pre-sub

Consultation

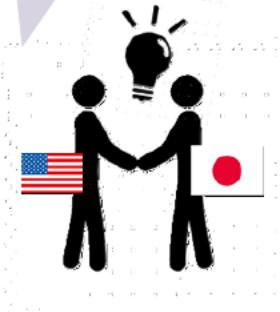
Face-to-face web meetings

- Pre-development Consultation
- Consultation for necessity of CT
- Protocol Consultation for CT etc..

IDE

CTN

Step by steps !



Thank you for listening ! If you have any questions, please contact to us.
*(mail: **hbd.contact@pmda.go.jp**)*