Update on HBD Activities (2020 –2025)

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PMDA Celebrated its *20th Anniversary* in April, 2024

- For the next 20 years, under our newly established purpose and logo, PMDA continues to create
  "Tomorrow's Normal" together with everyone around the world.

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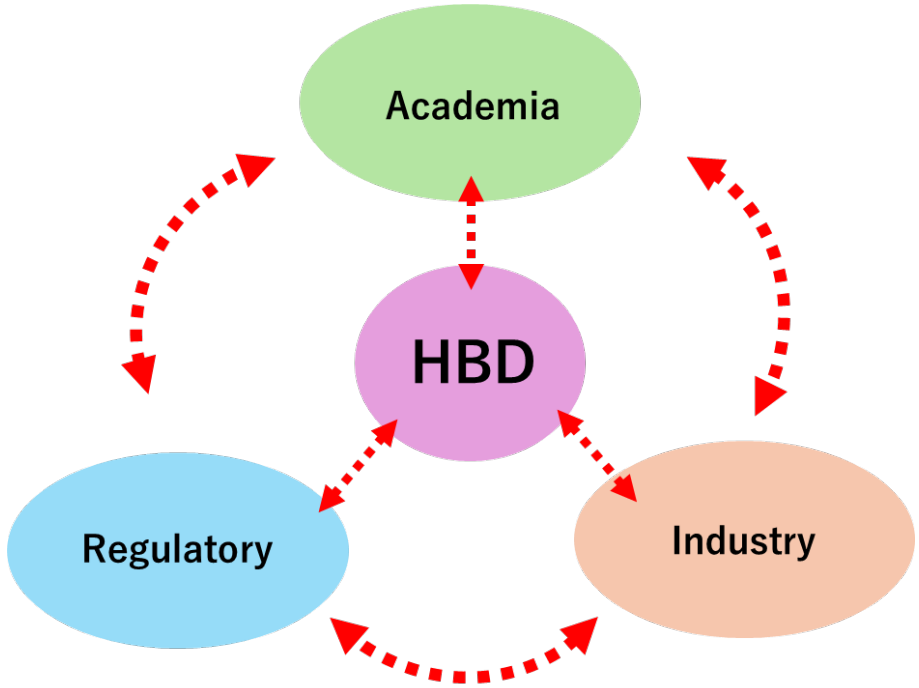
Harmonization By Doing (HBD)

Purpose :

To find more appropriate way for breaking through the developmental barrier (harmonize) between the US and Japan **by taking a real action**, not just discussing hypothetically.



HBD Think Tank Meeting and Scientific Session

The purpose of the meetings is to **share achievements, the ongoing projects and future direction of HBD activities** with stakeholders.

➢ **Topics have been discussed:**

- ✓ Real-world evidence (RWE) ***:Session F***
- ✓ Pediatric medical devices ***:Session D***
- ✓ SaMD ***:Session E***
- ✓ Heart failure disease, Venous disease, Paclitaxel issue, Chronic Limb-Threatening Ischemia (CLTI)
- ✓ Patient involvement
- ✓ GCP inspection of global clinical trial etc…

☐ HBD Think Tank meeting

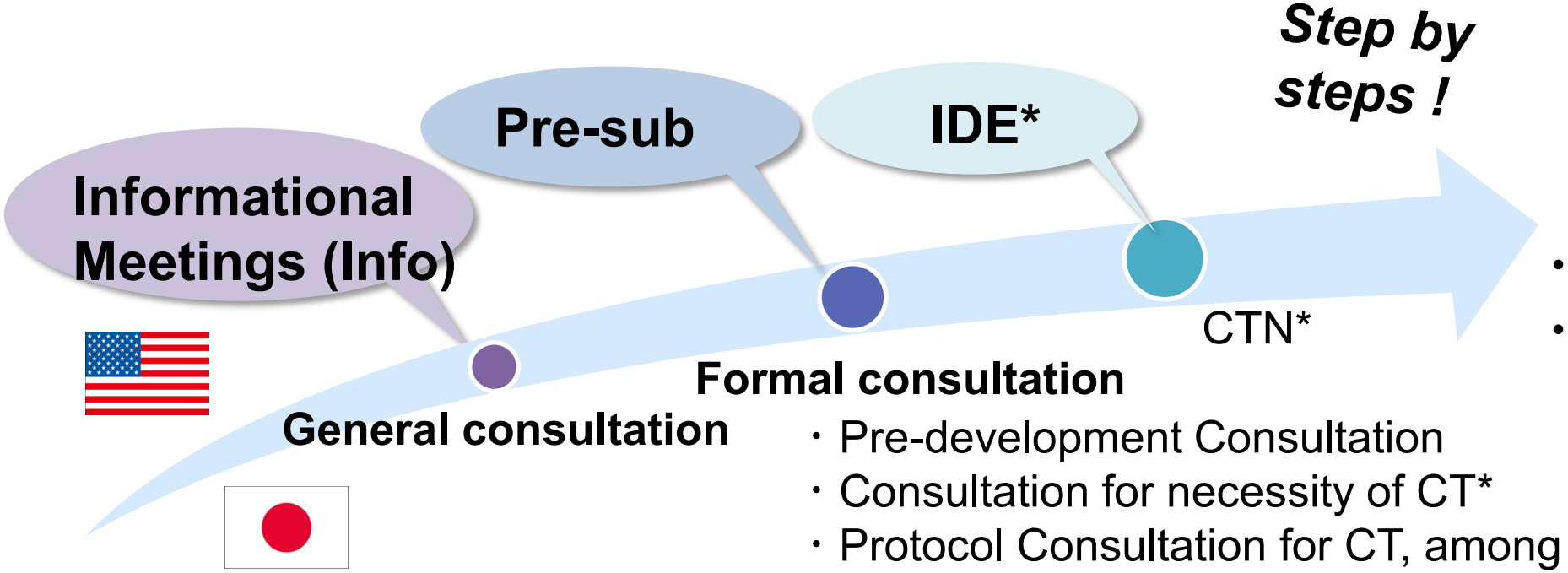
West 2020 (Online)
East 2021(Online)
West 2022 (@CRT2022)
East 2023 (Tokyo)
West 2024 (in FDA campus)
East 2025 (Sapporo)

☐ Scientific Sessions at relevant conferences

CRT, CVIT, TCT, VIVA, RAPS, PICS, JCIC, JSPCCS

Proof Of Concept (POC) Project

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



- Inquiry & Response
- Face-to-face meeting

- Pre-development Consultation
- Consultation for necessity of CT*
- Protocol Consultation for CT, among others.

* CT: Clinical Trial,
CTN: Clinical Trial Notification,
IDE: Investigational Device Exemption

Case Examples of POC Project

<Ongoing projects>

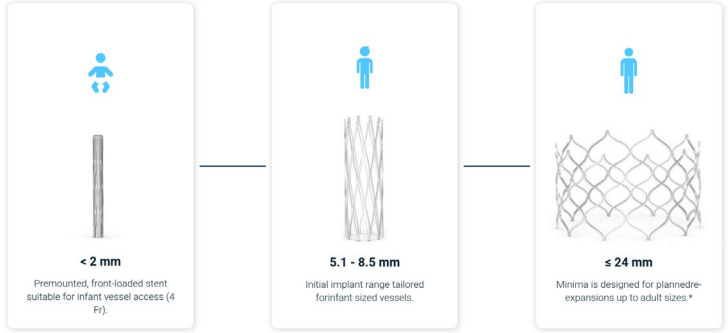
- Atrial Shunt device for heart failure (Corvia Medical)
- Sealded Synthetic Graft (Diaxamed)
- Minima Stent System (Renata Medical)
- TEIJIN‘s Cardiovascular patch（Teijin）, among others.

Atrial Shunt device

https://treatmyheartfailure.com/how-it-works/

Sealed Synthetic Graft

https://www.pmda.go.jp/files/000265740.pdf



Minima Stent System

https://www.renatamedical.com/products

TEIJIN’s Cardiovascular patch

https://www.teijin.com/news/2023/07/12/20230712_01.pdf

Information on How to Join the POC Project

Process for Participation

1. Email to general contact (hbd.contact@pmda.go.jp)
2. Submit **a concept proposal** to HBD SC
3. Introduce the proposed POC project
   in HBD SC teleconference or face to face meeting

Overview of Concept proposal

- An overview of the device description
- The future plan
- How the project relates to HBD activities

We welcome the participation of all stakeholders interested in this initiative!

HBD for Children

This activities focus on identifying problems and solutions for the early development of ***pediatric medical devices*** through the HBD initiative.

- Identify the needs/seeds of pediatric medical devices
- Supporting global trial (POC project, consensus definition)
- Considering to utilize special approval processes in both countries
- Utilizing clinical data except clinical trial (such as RWD) for pre- and post-market evaluation

Effort of pediatric medical device development will be shared at
Session D (11:00～):
HBD activities to advance pediatric device development and access

Publications of Activity Results

1. Key Considerations for US-JP Joint Medical Device Clinical Trials（Published）

- **The concept paper has been published based on our experiences through HBD activity**

< Overview of the concept paper>

- The basic regulatory pathway of US-Japan joint clinical trials
- Lessons learned from previous global trials
- Key Considerations for promoting global clinical trials

Publication: *Cardiovascular Revascularization Medicine* 2023; 52. 67–74.

Global medical device clinical trials involving both the United States and Japan: Key considerations for development, regulatory approval, and conduct

Shin Iwamoto [a], Kenneth Cavanaugh [b,*], Misti Malone [b], Aaron Lottes [c], Robert Thatcher [d], Katherine Kumar [e], Steve Rowland [f], Neal Fearnot [g], Takahiro Uchida [h], Chie Iwaishi [i], Kazuhisa Senshu [j], Ryo Konishi [j], Koji Ikeda [k], Yuka Suzuki [l], Fumiaki Ikeno [m], Atsushi Tamura [n], Mami Ho [o], Moe Ohashi [o], Hiroshi Katayama [p], Mitchell W. Krucoff [q]

2. Comparing the latest regulation systems in the U.S. and Japan（ongoing）

- **Promotion of the utilization of specific programs intended to promote innovation based on points to consider and case studies of those programs.**
- This paper has been drafting with US-JP stakeholders.

3. The experiences of the items presented at the CRT for looking back on **20 years**（ongoing）

- The Pros and Cons of Global Clinical Studies
- HBD’s achievements and future expectations from regulatory perspectives

Conclusion

- **HBD activity** is
  - ✓a US-JP collaborative framework uniting academia, industry and regulators.

    Collaboration
  - ✓paving the way forward through expertise and knowledge.

    By Doing
  - ✓contributing to the early medical device development by fostering U.S.-Japan global development.

    For The Patients

HBD will continue to *address real challenges and solutions* through *collaboration and connections* among the stakeholders!

Thank you for your kind attention!

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