Outcome Statement: HBD East 2025 Think Tank Meeting and face-to-face meetings of the HBD Steering Committee

September 18, 2025; Sapporo, Hokkaido

HBD Steering Committee

HBD (Harmonization By Doing), launched in 2003, is an international regulatory harmonization initiative by regulators (USFDA and MHLW/PMDA), industry, and academia in the US and Japan promoting simultaneous development and approval of medical devices in both countries.

On September 17, 2025, in Sapporo, Hokkaido, the HBD East 2025 Think Tank Meeting was held, hosted by the Ministry of Health, Labour and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency (PMDA), and the Japan Federation of Medical Devices Associations (JFMDA), to present the outcomes of HBD activities to date and to conduct panel discussions. On the 18th, face-to-face meetings of the HBD Steering Committee and HBD for Children were convened among stakeholders to discuss HBD's future operations, activities to be pursued, and related regulatory issues.

The principal outcomes of the series of meetings are as follows.

1. On the main content of the HBD Think Tank discussions and future direction

(1) Utilization of Real-World Evidence (RWE) across multiple countries

Use cases of RWE for label expansion and other purposes, issues identified through examples of RWE infrastructure development, and considerations when utilizing RWE across multiple countries were discussed. Because effective use of RWE for regulatory decision making and other regulatory processes are among the important matters for efficient medical device development, HBD will identify issues that should be addressed—including those related to registry construction (e.g., selection of necessary data elements) and regulatory use—and will further promote the utilization of RWE.

(2) Promotion of pediatric medical device development

After sharing efforts to overcome challenges in pediatric medical device development from the perspectives of industry, academia, and government, the parties discussed directions that should be realized through industry–academia–government collaboration going forward. While considering use of registries and development support measures provided by authorities, HBD for Children—as a Japan–US platform for collaboration among industry, academia, and government—will continue to address challenges specific to pediatric medical devices from a global perspective.

(3) Promotion of development of software as a medical device (SaMD)

Taking into account the respective review approaches in Japan and the US, opportunities and challenges in developing SaMD and approaches to address those challenges were discussed. HBD will continue discussions on issues related to SaMD.

(4) Industry–government–academic collaboration for medical device development over the next ten years

Based on the achievement of HBD activities to date and initiatives of overseas regulatory authorities, a wide-ranging discussion was held on the form of industry–government–academic collaboration over the next decade for promoting efficient medical device development and on developing the next generation of human resources. The discussion identified many remaining issues, such as reimbursement and market size, that can impact US-Japanese alignment but lie outside the traditional scope of medical device regulation. While continuing Japan–US-centered activities, HBD will further examine approaches that may facilitate efficient development and contribute to medical-device development in countries and regions beyond the US and Japan. HBD will also keep under consideration the approaches to workforce development that leverage the cooperative relationship between both countries.

Note: The Proof of Concept (POC) project is a scheme under which HBD participants provide advice on development plans for individual products.

Please refer to the following link for the presentation slides from the Think Tank Meeting.
https://www.pmda.go.jp/english/int-activities/int-harmony/0029.html

2. Future HBD activities

HBD Steering Committee confirmed initiation of the following items as future activities:

(1) Continue to accept applications for POC projects, including pediatric medical devices, and provide development support. In addition, based on HBD's experience, strive to disseminate documents on points to consider when conducting US–Japan joint clinical trials, and continue to promote medical device development.
(2) Submit a paper to a scientific journal comparing the latest regulations in Japan and the US, and, based on that paper, widely publicize—at academic conferences and other fora—points to consider when using each system with practical examples, in order to promote utilization of these systems.
(3) For the purpose of promoting pediatric medical device development, prepare a paper that summarizes points to consider in development based on examples of pediatric device development and review.

(4) Compare Japan–US initiatives to promote RWE utilization and consultation systems, and further promote alignment between Japan and the US on methods to ensure registry quality and to utilize registry data for marketing applications, as well as promote increased utilization of registry data.

3. Plans for HBD meetings in 2026

• The next Think Tank Meeting will be held in the US.

• We are considering holding HBD sessions at the academic conferences listed in the table below (these are current HBD plans and are subject to change).

Conference	Date & Location (2026)
CRT 2026	March 7-10, Washington, D.C.
CVIT 2026	July 16-18, Tokyo
TCT 2026	October 31-November 3, San Diego
VIVA 2026	October 4-7, Las Vegas
JSPCCS 2026*1	July 9-11, Tokyo
PICS 2026*2	August 30-Septmeber 2, San Diego

*1: Japanese Society of Pediatric Cardiology and Cardiac Surgery

*2: Pediatric and Congenital Interventional Cardiovascular Society