Outcome Statement: HBD East 2019

December 12, 2019; Tokyo
HBD Steering Committee

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

On December 11, 2019, HBD East 2019 Think Tank Meeting, hosted by MHLW, PMDA and JFMDA, was held in Tokyo to present the past, current and future progress of HBD activities and conduct panel discussion. On December 12, HBD Steering Committee and HBD Workshop were held to discuss the future HBD activities and the interested issues in regulation.

The major results of the series of meetings are as following:

1. Future direction of topics in HBD

The future directions of topics currently discussed in HBD are confirmed as below:

(1) Utilization of Real World Evidence (RWE): HBD will facilitate further harmonization in US and Japan on the methods of ensuring quality of registries, and of utilizing registry data for pre-market applications, new indications and post-marketing considerations, and increasing interoperability of registry data for encouraging the use of RWE in regulatory decision makings;

(2) HBD for children: HBD will support new approvals and expansions of pediatric indication based on the registry data in US and Japan, and address specific issues on medical devices for pediatric use;

(3) Support for product development: HBD continues to accept further applications for POC projects*. Encouragement of Early Feasibility Studies (EFS), use of new regulatory systems introduced in Japan by the law amendment, and support for global product development were featured in this regard. Also, HBD will develop a concept paper of conducting global clinical trials including in US and Japan, and publish in a scientific journal for better understanding by developers.

* POC (Proof of Concept) project is a scheme to provide instructions on the development

plans of individual products by HBD. By the end of 2019, around ten products have been approved in US and Japan through this scheme.

Please see the materials in URL below for the presentation slides and summary of panel discussion in Think Tank Meeting.

https://www.pmda.go.jp/english/int-activities/int-harmony/0004.html

2. New activities of HBD

The following items were confirmed as the new work items of HBD:

(1) Expansion of the scope of therapeutic area of HBD beyond the cardiovascular area as a pilot program. One product from a new therapeutic area will be considered by inviting relevant academia and industry.

(2) Development of a performance standard or other methods for facilitating a single-arm study paradigm for coronary drug-eluting stents in both the US and Japan. It was recommended to continue the discussion within the HBD Steering Committee and with industry members.

(3) Investigation of more efficient Good Clinical Practice (GCP) inspection processes in US and Japan

3. Plan of HBD meetings in 2020 and beyond

- Next Think Tank Meeting will be held in US.

- HBD sessions are planned to be held in the academic conferences as the table below (tentative plans by HBD: schedule could be changed):

Conference	Date & Location (2020)
CRT 2020	Feb. 22-25 (HBD session on 24), Prince Georges, Maryland
CVIT 2020	June 4-6, Sendai
TCT 2020	Sep. 23-27, Miami
VIVA 2020	Nov. 2-5, Las Vegas
JSPCCS 2020*1	July 9-11, Kyoto
PICS 2020*2 or SCAI*3	PICS-AICS: Sep. 8-11, Boston SCAI: May 13-16, Atlanta

*1: Japanese Society of Pediatric Cardiology and Cardiac Surgery

*2: Pediatric Intensive Care Society

*3: The Society for Cardiovascular Angiography and Interventions