HBD East 2021 Think Tank Meeting

Date: Thursday, January 20th, 2022 (US), Friday, January 21st, 2022 (JP)

Symposium Location: Online (Zoom)

Host: MHLW/PMDA/JFMDA

Language: Japanese and English (Translation from Japanese to English, from English to Japanese)

Day 2: January 20th (US) and 21st (JP)	
Time	Agenda items
3:00 PM (PST), 6:00 PM (EST), 8:00 AM (JST)	Opening remarks (5 min) Mitchell W. Krucoff (DCRI)
3:05 PM (PST), 6:05 PM (EST), 8:05 AM (JST)	(6) Initiatives to improve patient access to new medical devices Chair: Mitchell W. Krucoff (DCRI), Shin IWAMOTO (PMDA), Andrew Farb (FDA) **1) Introduction and Perspective of new regulatory pathways ~ Japanese regulatory view~ (10 min)** Kanako SASAKI (MHLW) **2) Introduction and Perspective of new regulatory pathways ~ US regulatory view~ (10 min)** Hiren Mistry (FDA) **3) Learning from examples of how to utilize a new system for early approval of a new medical device (10 min each)** a. US: Zachary Woodson (LimFlow) b. Japan: Edwards SAPIEN3 (Expand indications for transcatheter pulmonary valve replacement) Aya SAEKI (Edwards) **4) Discussion (20 min)** Panelist: Hiroshi KATAYAMA (PMDA), Koji TODAKA (Kyushu University), Aaron Lottes (Purdue University) Talking point: What are the key considerations when developing an innovative device for multinational regulatory approval?
4:05 PM (PST), 7:05 PM (EST), 9:05 AM (JST)	(7) “Sustainable Development Goals in Real-world data collection” Chair: Kensuke ISHII (PMDA), Kenneth Cavanaugh (FDA), Shigeru SAITO (Shonan Kamakura General Hospital) **1) How to ensure the reliability of registry data ~Experience from PMA approval with registry data~ (10 min)**

4:05 PM (PST), 7:05 PM (EST), 9:05 AM (JST)	Misti Malone (FDA) **2) Introduce the Japanese guidance "To ensure reliability when using registry data for approval applications" (10 min)** Hanako MORIKAWA (PMDA) **3) Real-world considerations for constructing an academic registry for using regulatory decision-making (10 min)** Masahiko FUJIHARA (Kishiwada Tokushukai Hospital) **4) Lessons learned from using registry data for approval applications (10 min)** Yasuhiko MORITA (Nipro) **5) Discussion (20 min)** Panelist: Eric Chen(Abbott) Talking point: What specific quality elements should be established to facilitate multi-national RWE development and acceptance?
5:05 PM (PST), 8:05 PM (EST), 10:05 AM (JST)	(8) Introduction of US – Japan regulatory system for software as a medical device Chair: Madoka MURAKAMI (MHLW), Jessica Paulsen (FDA) and Fumiaki IKENO (Stanford University) **1) Points to consider in the review of the SaMD and action plan of accelerating the review process ~ (10 min each)** a. Japanese regulatory view Takatomo EZURA (PMDA) b. US regulatory view Aneesh Deoras (FDA) **2) The challenge for the development of SaMD in Japan ~ Industry perspective~ (10 min)** Yuki SHIMAHARA (LPIXEL) **3) Discussion (20 min)** Panelist: Yoko TATENO (MHLW) and Teppei SAKANO (Allm Inc.) Talking point: What are the most promising areas of focus for multi-national SaMD approvals?
5:55 PM (PST), 8:55 PM (EST), 10:55 AM (JST)	Closing remarks and next steps (5 min) Mimei Takahashi (PMDA)