HBD East 2021 Think Tank Meeting

Date: Thursday, January 13th, 2022 (US), Friday, January 14th, 2022 (JP)

Symposium Location: Online (Zoom)

Host: MHLW/PMDA/JFMDA

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

Day 1: January 13th (US) and January 14th (JP)	
Time	Agenda items
3:00 PM (PST), 6:00 PM (EST), 8:00 AM (JST)	(1) Welcome speech (5 min each)
	Chair: Masahiro TAKAHATA (MHLW)
	1) MHLW：Fumi YAMAMOTO, Councilor **2) PMDA**：Yasuhiro FUJIWARA, Chief Executive **3) US FDA** : Bram Zuckerman, Office Director **4) JFMDA** : Shugo SUMIYOSHI, Vice Chairman
3:20 PM (PST), 6:20 PM (EST), 8:20 AM (JST)	(2) Keynote Lecture (10 min)
	Chair: Shin IWAMOTO (PMDA)
	Regulatory Innovation for Safe and Early Access to Medical Devices in Japan Hidehito SEKINO (MHLW)
	(3) Update of HBD activity (10 min each)
	1) HBD Steering Committee：Erika NORO (PMDA) **2) HBD for Children**：Kalkidan Molla (FDA)
3:50 PM (PST), 6:50 PM (EST), 8:50 AM (JST)	(4) Rethinking of the New Style of Global Clinical Trial
	Chair: Atsushi TAMURA (PMDA), Yuka SUZUKI (Tohoku University), Neal Fearnot (COOK Medical)
	<Section1: Clinical Design> **1) The outlook for Patient Involvement in Medical Device Development ~Japanese Regulatory View~ (10 min)** Takeshi SHIBA (PMDA) **2) The outlook for Patient Involvement in Medical Device Development ~US Regulatory View~ (10 min)** Michelle Tarver (FDA) **3) Panel Discussion (15 min)**

3:50 PM (PST), 6:50 PM (EST), 8:50 AM (JST)	Panelist: Aaron Lottes (Purdue University), Kate Stohlman (Corvia Medical), Moe OHASHI (PMDA), Takahiro UCHIDA(JOMDD) Talking point: What are the challenges and opportunities for using patient-oriented data for global regulatory purposes?
4:25 PM (PST), 7:25 PM (EST), 9:25 AM (JST)	(4) Rethinking of the New Style of Global Clinical Trial
	Chair: Atsushi TAMURA (PMDA), Yuka SUZUKI (Tohoku University), Neal Fearnot (COOK Medical)
	< Section2: GCP Inspection> **1) Considerations for GCP inspections of global clinical trials (10 min)** Kazuo KAWAHARA (Boston Scientific) **2) Balancing reliability assurance and optimization GCP inspection based on trends of conducting global clinical trial. (10 min)** Takashi YOSHITANI (PMDA) **3) Panel Discussion (15 min)** Panelist: Adam Donat (FDA), US academia, US Industry Talking point: What lessons from conducting clinical studies during the COVID pandemic can be applied to facilitate future global clinical trials?
5:00 PM (PST), 8:00 PM (EST), 10:00 AM (JST)	(5) "How to promote the development of pediatric medical devices." ~HBD for children~ (60min)
	Chair: Satoshi YASUKOCHI (Jisenkai Aizawa Hospital), Nicole Gillette (FDA), Kisaburo SAKAMOTO (Shizuoka Children's Hospital)
	1) Report from Japanese national grant research to promote the efficient development of pediatric medical devices (10 min) Wakako SAKAMOTO (PMDA) **2) Importance of Global development** **~Experience from HBD for children's POC, Harmony valve~ (10min)** Declan Dineen (Medtronic) **3) Importance of Global development ~Standardization of definitions ~ (10min)** Shintaro NEMOTO (Osaka Medical and Pharmaceutical University) **4) Discussion (30 min)** Panelist: Frank Ing (UC Davis Children's Hospital), Hideshi TOMITA (Showa University) and Takeharu KOBAYASHI (DAIKEN MEDICAL) Talking point: What areas of collaboration or standardization would be most beneficial to further encourage pediatric device development?
6:00 PM (PST), 9:00 PM (EST), 11:00 AM (JST)	Closing remarks (5 min)
	Yuka SUZUKI (Tohoku University)