（令和５年10月31日現在）

US-JAPAN
HBD EAST Think Tank Meeting 2023

Date: Thursday, December 14th, 9:30 AM-6:00 PM (JP Time)
Venue: Ariake Central Tower Hall and Conference
Language: English & Japanese (simultaneous interpretation)

Moderator: Tomoyuki Miyasaka (MHLW) & Moe Ohashi (PMDA)

	Agenda items (Draft)	Time	Speakers and Panelists	
			US	JP
Session A：Welcome Speeches (9:30~)				
A-1	From MHLW	5		Yasunori Yoshida
A-2	From PMDA	5		Yasuhiro Fujiwara
A-3	From FDA	5	Jeffrey Shuren	
A-4	From JFMDA	5		Toshiaki Takagi
A-5	From AdvaMed	5	Janet Trunzo	
Session B：20th Anniversary Keynote Speeches (10:00~)				
Chair			Neal Fearnot (MED Institute Incorporated)	Mami Ho (Yumino Heart Clinic)
B-1	HBD history	15	TBD	
B-2	Achievements of HBD activities and future expectations	15		Yuka Suzuki (Clinical Research, Innovation and Education Center, Tohoku University Hospital(CRIETO))
B-3	Q&A	5		
Coffee Break (15min)				
Session C：Learning from HBD activity and recent update (10:50~)				
Chair			Aaron Lottes (Purdue Univ.)	TBD
C-1	Update on HBD activities - Focusing on the last 5 years-	10		Hanako Morikawa (PMDA)
C-2	What we can say now based on our experience in obtaining approval in Japan and the U.S. Case 1: Japanese industry's view	10		Kazuhisa Senshu (Terumo Corporation)
C-3	What we can say now based on our experience in obtaining approval in Japan and the U.S. Case 2: U.S. industry's view	10	Daiki Yasuhara (Medtronic)	
C-4	Role of Academia in HBD Activities	10		Hiroyoshi Yokoi (Fukuoka sanno

				Hospital)
C-5	Q&A	5		
Session D：Evaluating the efficacy and safety of medical devices from pre-market through post-market using RWD (11:40~)				
Chair			Misti Malone (FDA)	Kensuke Ishii (PMDA)
D-1	Basic Approach in utilizing RWD for regulatory decision-making	10	Misti Malone (FDA)	
D-2	Challenges in establishing RWE for pre- and post-market clinical evaluation	10		Masato Nakamura (Toho Univ.)
D-3	Challenges in developing devices using RWD in Japan	10		Kazuo Kawahara (Boston Scientific Japan)
D-4	Panel Discussion Theme: The efficient way of collecting RWD for regulatory decision-making in pre- and post-market to accelerate device development	30	Speakers & Eric Chen (Abbott) & Chie Iwaishi (Edwards Lifesciences) & Aaron Lottes (Purdue Univ.)	Speakers & Takeshi Shiba (PMDA)
Lunch Break (60 min)				
Session E：Approaches of HBD activity to promote the development of SaMD (13:40~)				
Chair			Eric Chen (Abbott)	Yuzuru Okazaki (PMDA)
E-1	Regulation of SaMD in the U.S.	10	Nicole Ibrahim (FDA)	
E-2	Regulation of SaMD in Japan	10		Kentaro Kato (PMDA)
E-3	Learning from “CureApp” :how to develop and get an approval of SaMD	10		Tomoyuki Tanigawa (CureApp)
E-4	Points to consider in the application of AI for medical devices	10		Ryuji Hamamoto (Division of Medical AI Research and Development, National Cancer Center Research Institute)
E-5	Panel Discussion Theme: Strategies to promote the development of SaMD from the standpoints of industry, government, and academia	20	Speakers & Fumiaki Ikeno (Stanford univ.)	Speakers

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Session F：Approaches of HBD activity to promote the development of pediatric devices (14:45~)				
Chair			Nicole Gillette (FDA)	Satoshi Yasukochi (Aizawa hospital)
F-1	Progress and challenges in pediatric medical device development	10		Takanari Fujii (Showa Univ.)
F-2	U.S. Regulatory initiatives to promote pediatric medical device development	10	Nicole Gillette (FDA)	
F-3	The road from development to approval of pediatric medical devices and future approaches.	10		Shintaro Nemoto (Osaka Med. Pharm. Univ.)
F-4	Utilization of RWD in pediatric medical device development	10		Ryo Inuzuka (Tokyo Univ.)
F-5	Panel Discussion Theme: Strategies to promote the development of pediatric medical devices from the standpoints of industry, government, and academia	30	Speakers & TBD	Speakers & Tohru Kobayashi (Department of Data Science, Center for Clinical Research, National Center for Child Health and Development) & Koichi Aizawa (PMDA)
Coffee Break (15 min)				
Session G：What should be considered for global harmonization of medical device development through HBD activity ? (16:10~)				
Chair			TBD	Naoyuki Yabana (PMDA)
G-1	An overview of the global situation surrounding medical devices	10	Fumiaki Ikeno (Stanford univ.)	
G-2	Current situation of medical device regulations outside of Japan and the U.S.	10	Kate Stohlman (Corvia Medical)	
G-3	Comparing clinical practices or consultation processes in the US vs Japan	10	Robert Thatcher (DIAXAMED)	
G-4	Unique points of medical device development and advantages of global development.	10		Koji Ikeda (Clinical Research, Innovation and Education Center, Tohoku

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				University Hospital(CRIETO))
G-5	Post-approval hurdles: Differences and strategies between Japanese and the U.S. insurance systems	10		Makoto Tamura (Healthcare system planning institute (HSPI))
G-6	Panel discussion Theme: Future direction of HBD activity	50	Speakers & Nicole Gillette (FDA) & Janet Trunzo (AdvaMed)	Speakers & Kiyohito Nakai (MHLW) & TBD
Session H：Closing Remarks (17:55~)				
H-1	Closing remarks	5		Tomonori Nakayama (MHLW)