Japan-US HBD East 2019 Think Tank Meeting

Date: Wednesday, December 11, 2019

Venue: Nadao Hall, Zenshakyo

Shin-Kasumigaseki Building 1F, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo, Japan

Host: MHLW/PMDA/JFMDA

Interpreter: English - Japanese simultaneous

Japan-US HBD East 2019 Think Tank Meeting MC: TAKANASHI Fumihito, MHLW	
Time	**Agenda items**
9:00 am- 9:30 am	Registration Speakers Photo Session (9:20-30)
Welcome Speeches	
9:30 am- 9:55 am	JIMI Hanako, Parliamentary Vice-Minister of Health, Labour and Welfare
	TARUMI Hideki, Director General, MHLW
	FUJIWARA Yasuhiro, Chief Executive, PMDA
	Jeffrey Shuren, Director, CDRH, FDA (video letter)
	MIMURA Takayoshi, Vice Chairman, JFMDA
Keynote Speeches Chair: SUZUKI Yuka, Tohoku University & HBD Chair	
9:55 am- 10:30 am	Regulatory Innovation for Safe and Early Access to Medical Devices in Japan MORI Kazuhiko, Councilor for pharmaceuticals, MHLW
	Overview of HBD Activity Mitchell Krucoff, Duke University Medical Center & HBD Chair
Update of HBD Activity Chair: IWAMOTO Shin, PMDA	
10:30 am- 11:00 am	HBD Steering Committee OHASHI Moe, Office of Medical Devices I, PMDA
	HBD for Children Nicole Ibrahim, CDRH, FDA
HBD for Children: Progress and Challenges Moderator: YASUKOCHI Satoshi (Nagano Children's Hospital), Nicole Ibrahim (FDA)	
11:00 am- 12:40 pm	Challenges and Achievement: Japanese Regulatory View MATSUMURA Ryosuke, Office of Medical Devices I, PMDA
	Challenges and Achievement: Japanese Academia View INUZUKA Ryo, University of Tokyo Hospital

	How Should We Develop Medical Devices for a Small Market? Industry Executive's View on What Companies Can Do TSUTSUI Yasuhiro, President, Tokai Medical Products Inc.
	Panel Discussion (speakers and discussants) UCHIDA Takahiro (CEO, JOMDD), Eric Chen (Abbott), MINETA Koji (Office of Medical Devices I, PMDA)
12:40 pm- 1:40 pm	Lunch Break
How Can We Generate Robust Real-World Evidence from Real-World Data? Moderator: Mitchell Krucoff (Duke University Medical Center & HBD Chair), SASE Kazuhiro (Juntendo University)	
1:40 pm- 3:20 pm	Pre and Post-Market Use and Current Consideration of RWE for Regulatory Use Misti Malone, CDRH, FDA
	The Effort of Generating Robust RWE Including Registry and Post-market Survey: Japanese Academia View YOKOI Hiroyoshi, Fukuoka Sanno Hospital
	A Multinational Company's Effort of Utilizing RWE in Japan, the US, and Europe Theodore Lystig, Medtronic
	Panel Discussion (speakers and discussants) Art Sedrakyan, Weill Cornell Medical College IWAMOTO Shin, Office of Medical Devices II, PMDA
3:20 pm- 3:40 pm	Break
Promotion of Early Patient Access to Medical Devices in US and Japan Moderator: NAKAI Kiyohito (MHLW), Neal Fearnot (Cook Medical), IKENO Fumiaki (Stanford University)	
3:40 pm- 5:20 pm	The Approach and Challenges of Entering an Overseas Market INAMURA Kenichi, Kawasumi Laboratories, Inc.
	The Approach and Consideration of Advancing into Overseas Market Eric Chen, Abbott
	Current and Prospective Activities: US Regulatory View Kenneth Cavanaugh, CDRH, FDA
	Panel Discussion (speakers and discussants) HO Mami (PMDA), IWAISHI Chie (Edwards Lifesciences Corporation), IKEDA Koji (Tohoku University), Robert Thatcher (4C Medical Technologies)
Closing Remarks	
5:20 pm- 5:25 pm	NAKAI Kiyohito, Director, Medical Device Evaluation Division, MHLW
Adjourn	