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-	Registration	
9:30 am	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	
7.55 am	Jeffrey Shuren, Director, CDRH, FDA (video letter)	
	MIMURA Takayoshi, Vice Chairman, JFMDA	
	Keynote Speeches	
Chair: SUZUKI Yuka, Tohoku University & HBD Chair		
	Regulatory Innovation for Safe and Early Access to Medical Devices in Japan	
9:55 am-	MORI Kazuhiko, Councilor for pharmaceuticals, MHLW	
10:30 am	Overview of HBD Activity	
	Mitchell Krucoff, Duke University Medical Center & HBD Chair	
Update of HBD Activity		
Chair: IWAMOTO Shin, PMDA		
	HBD Steering Committee	
10:30 am-	OHASHI Moe, Office of Medical Devices I, PMDA	
11:00 am	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	

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) 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 3:20 pm 3:20 pm 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 1WAMOTO Shin, Office of Medical Devices II, PMDA 3:20 pm 3:40 pm Moderator: NAKAI Kiyohito (MHLW), Neal Fearnot (Cook Medical), IKENO Fumiaki (Stanford University) 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		How Should We Develop Medical Devices for a Small Market? Industry Executive's	
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