

Japan-US HBD East 2017 Think Tank Meeting

December 7, 2017

National Center for Global Health and Medicine (NCGM), Tokyo, Japan

Host: MHLW/JFMDA, Auspices: NCGM/PMDA, Support: JCRAC

9:00	Registration
Introduction	
9:30	Mitchell Krucoff Chair, HBD
Welcome Speeches	
9:50	Shinji Miyamoto Director General, MHLW
9:55	Hiroyuki Sasa Vice Chair, JFMDA
Opening Remarks	
10:00	Tatsuya Kondo Chief Executive, PMDA
10:05	Jeffrey Shuren Director, Center for Devices and Radiological Health, FDA
Keynote Speeches Moderators: Kazuhiro Sase, Gary Thompson	
10:10	What Makes HBD So Unique and Significant? Toshiyoshi Tominaga (Associate Executive Director, PMDA)
10:20	Clinical Investigations in Japan then and now Kazuaki Sekiguchi (Chair, JFMDA HBD Sub-committee)
10:30	Changes Brought About by HBD and Future Direction Neal Fearnott (Vice President, Cook Group Inc.)
10:40	Coffee Break
Session1: Update of HBD Activities Moderators: Koji Ikeda, Misti Malone	
11:00	Orbital Atherectomy for Calcific Coronary Lesions Christopher Volker
11:10	Coronary Stent Innovation: EPC Capture Stephen M. Rowland
11:20	Endovascular AV Fistula Noah Bartsch
11:30	HBD for Children: Progress and Challenges Satoshi Yasukochi

11:40	Panel Discussion: Achievements and Lessons Learnt Panelist: Speakers, Yumiko Aoyagi, Neal Fearnot, Fumiaki Ikeno, Shin Iwamoto, Mitchell Krucoff, Katherine Kumar, Seigo Nakano, Kazuhiro Sase, Kazuaki Sekiguchi, Shigeru Saito, Yuka Suzuki, Gary Thompson, Robert Thatcher, Sara Takahashi
12:10	Lunch Break
Session 2: Real World Evidence Moderators: Gary Thompson, Hiroyoshi Yokoi	
13:20	National and International Efforts for Developing Real World Evidence Danica Marinac-Dabic
13:30	View from Japanese Academia Kazuhiro Sase
13:40	Challenges and Efforts; PMDA's View Akihide Konishi
13:50	Use Experience of Real World Evidence in the Actual Review Misti Malone
14:00	Use of Real World Evidence under MDR Andy Crosbie
14:10	Expectation from Medical Device Industry Neal Fearnot
14:20	Panel Discussion: How Can We Develop and Leverage Global Real World Evidence? Panelists: Speakers, Patrick Fandja, Nobuhiro Handa, Ted Heise, Yoji Jokura, David Kong, Hiroshi Ohtsu, Stephen Rowland, Zach Rothstein
Session 3: Early Feasibility Study Moderators: Takahiro Uchida, Mami Ho	
14:50	Expectation from Japanese Physician Shigeru Saito
15:00	Challenges in Development of Innovative Device Robert Thatcher
15:10	Regulations on Clinical Studies in Japan Yumiko Aoyagi
15:20	FDA Considerations for Initiating EFS Ken Cavanaugh
15:30	Experience of First in Human Study in Japan Ken Kozuma
15:40	Panel Discussion: How to Make Japan/US First in the World! Panelists: Speakers, Neal Fearnot, Mitch Krucoff, Katherine Kumar, Aaron Lottes, Gary Thompson, Yuka Suzuki, Christopher Volker
16:10	Coffee Break

Round Table Discussion: Let's Join Forces to Overcome the Challenges in Medical Device Clinical Trials!

Moderators: Mitchell Krucoff, Fumiaki Ikeno

16:30	Issues Brought Up by Japanese Medical Device Industry Seigo Nakano
16:40	Discussion: Where Do We Go From Here? Panelist: Kenneth Cavanaugh, Neal Fearnot, Mami Ho, Chie Iwaishi, Mitchell Krucoff, Kiyohito Nakai, Seigo Nakano, Stephen Rowland, Shigeru Saito, Robert Thatcher, Gary Thompson, Takahiro Uchida, Christopher Volker, Satoshi Yasukochi, Hiroyoshi Yokoi
Closing Remarks	
17:30	Norihiro Kokudo President, NCGM
17:35	Shigeru Saito Vice Director, Shonan Kamakura General Hospital
Adjourn	

Faculty list (in alphabetical order)

AOYAGI, Yumiko	MHLW
BARTSCH, Noah	TVA Medical
CAVANAUGH, Kenneth	FDA CDRH
CROSBIE, Andy	Medicines & Healthcare products Regulatory Agency (MHRA) UK
FANDJA, Patrick	Health Canada
FEARNOT, Neal	Cook Group
HANDA, Nobuhiro	PMDA
HEISE, Ted	MED Institute, Cook Group
HO, Mami	PMDA
IKEDA, Koji	Tohoku U.
IKENO, Fumiaki	Stanford U.
IWAISHI, Chie	Alere Medical
IWAMOTO, Shin	PMDA
JOKURA, Yoji	Cook Japan
KOKUDO, Norihiro	National Center for Global Health and Medicine (NCGM)
KONDO, Tatsuya	PMDA
KONG, David	Duke Clinical Research Institute (DCRI)
KONISHI, Akihide	PMDA
KOZUMA, Ken	Teikyo University Hosp.
KRUCOFF, Mitchell	DCRI
KUMAR, Katherine	4C Medical
LOTTE, Aaron	Cook Medical
MALONE, Misti	FDA CDRH
MARINAC-DABIC, Danica	FDA CDRH
MIYAMOTO, Shinji	MHLW
NAKAI, Kiyohito	MHLW
NAKANO, Seigo	Terumo
OHTSU, Hiroshi	NCGM Joint Center for Researchers, Associates and Clinicians (JCRAC)
ROTHSTEIN, Zach	AdvaMed
ROWLAND, Stephen	OrbusNeich
SAITO, Shigeru	Shonan Kamakura General Hosp.
SASA, Hiroyuki	JFMDA
SASE, Kazuhiro	Juntendo U.
SEKIGUCHI, Kazuaki	SJM/Abbott Japan

SHUREN, Jeffrey	FDA CDRH
SUZUKI, Yuka	Tohoku U.
TAKAHASHI, Sara	PMDA
THATCHER, Robert	4C medical
THOMPSON, Gary	Abbott Vascular
TOMINAGA, Toshiyoshi	PMDA
UCHIDA, Takahiro	Japanese Organization for Medical Device Development, Inc. (JOMDD)
VOLKER, Christopher	Cardiovascular System Inc
YASUKOCHI, Satoshi	Nagano Children's Hosp.
YOKOI, Hiroyoshi	Fukuoka Sanno Hosp.