US-JAPAN
HBD EAST Think Tank Meeting 2025

Date: Wednesday, September 17th, 2025, 9:30 AM- 6:00 PM (JST)
Venue: Sapporo Convention Center (https://www.sora-scc.jp/eng/access.html)
Language: English & Japanese (simultaneous interpretation)

Moderator: **IWAMOTO Shin, NORO Erika** (PMDA)

Session		Chair	Agenda items	Times	Speakers and Panelists
A	Welcome 9:30-9:55		(A-1) From MHLW	5	**NOMURA Yumiko** *Director, Medical Device Evaluation Division, Ministry of Health, Labour and Welfare (MHLW)*
			(A-2) From PMDA	5	**NAKAI Kiyohito** *Chief Safety Officer, Pharmaceuticals and Medical Devices Agency（PMDA）*
			(A-3) From FDA	5	**Michelle Tarver,** *Center Director, the Center for Devices and Radiological Health (CDRH), U.S. Food & Drug Administration (FDA)*
			(A-4) From JFMDA	5	**MIYATA Masahiko** *Vice Chairman, The Japan Federation of Medical Devices Associations (JFMDA)*
			(A-5) From AdvaMed (AMDD)	5	**Janet Trunzo** *Senior Advisor to the President, Senior Executive Vice President, Technology & Regulatory Affairs, AdvaMed*
B	Keynote lecture 9:55-10:30	**Robert Thatcher** (Diaxamed, LLC), **KATAYAMA Hiroshi** (National Cancer Center Hospital)	(B-1) Japanese initiatives to promote medical device development	15	**SUZUKI Yuka** (Clinical Research, Innovation and Education Center, Tohoku Univ. Hospital (CRIETO))
			(B-2) HBD history and global lessons learned	15	**Mitchell Krucoff** (Duke Univ.)
			(B-3) Q&A	5	
C	Update on HBD activities 10:35-10:45	**UCHIDA Takahiro** (Sanamedi, Inc.)	(C-1) Update on HBD activities (2020 – 2025)	10	**NAKAGAWA Makoto** (PMDA)
Break (15min)					
D	HBD activities to advance pediatric device development and access 11:00-12:10	**YASUKOCHI Satoshi** (Aizawa hospital), **Nicole Ibrahim** (Mansfield Fellow)	(D-1) HBD for Children - Achievements and future directions	10	**SASAGAWA Kaoru** (PMDA)
			(D-2) Considerations in Japanese academia in advancing pediatric medical device development: Insight from Japan's Agency for Medical Research and Development	10	**FUJII Takanari** (SHOWA Medical Univ. Hospital)
			(D-3) Japanese research projects and regulatory initiatives to promote pediatric/orphan medical device access	10	**ANDO Mariko** (MHLW)
			(D-4) What else is needed to advance pediatric medical device development? Industry perspective	10	**Dali Alarian** (Renata Medical)
			(D-5) Panel discussion: Breaking barriers: Driving cross-sector collaboration and increased global access	30	**Speakers** & **Sung-Hae Kim** (Shizuoka Children's Hospital) **SUZUKI Yuka** (CRIETO) **Eric Chen** (Abbott Medical) **Nicole Gillette** (FDA) **TAKAHASHI Sara** (MHLW)

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Lunch Break (60 min)					
E	HBD activities to advance smart development of SaMD 13:10-14:20	**IKENO Fumiaki** (Stanford Univ.), **KOIKE Kazuhisa** (PMDA)	(E-1) Regulatory updates: Japan	10	**KOIKE Kazuhisa** (PMDA)
			(E-2) Regulatory updates: US	10	**Ken Cavanaugh** (FDA)
			(E-3) Initiatives to support the expansion of Japanese medical devices into overseas markets: Japanese ministry perspective	10	**TAKAYAMA Masumi** (Ministry of Economy, Trade and Industry)
			(E-4) Considerations in international development of digital health technologies	10	**TADA Tomohiro** (AI Medical Service Inc.)
			(E-5) Panel discussion: Global strategies to accelerate SaMD development: perspectives from industry, academia, and government	30	**Speakers &** **IKEDA Koji** (CRIETO) **OTAKE Masanori** (GE HealthCare Japan)
F	Challenges and solutions when building multi-national registries 14:25-15:35	**IWAMOTO Shin** (PMDA), **Kenneth Cavanaugh** (FDA)	(F-1) The current situation and future direction of utilization of real-world clinical evidence for regulatory decision-making	10	**SHIBA Takeshi** (PMDA)
			(F-2) Experiences with regulatory use of registry data: Industry perspective	10	**IWAISHI Chie** (Edwards Lifesciences)
			(F-3) Consideration and future opportunities identified through the utilization of real-world evidence	10	**Aaron Lottes** (Purdue Univ.)
			(F-4) Deciding whether a registry should go global: Japanese academic perspective	10	**NAKAMURA Masato** (Toho Univ.)
			(F-5) Panel Discussion: Opportunities for further global alignment of real-world evidence collection and application	30	**Speakers &** **YOKOI Hiroyoshi** (Fukuoka Sanno Hospital) **Misti Malone** (FDA) **YASUHARA Daiki** (Medtronic JAPAN)
Break (15min)					
G	Shaping forward-looking collaboration among stakeholders for more efficient global medical device development 15:50-17:10	**Mitchell Krucoff** (Duke Univ.), **YABANA Naoyuki** (PMDA)	(G-1) Addressing key bottlenecks in global medical device development: challenges and strategic solutions	10	**SENSHU Kazuhisa** (Terumo Corporation)
			(G-2) Lessons from success: Rethinking collaboration among stakeholders in medical device innovation	10	**IKEDA Koji** (CRIETO)
			(G-3) Initiatives to accelerate medical device access: US regulatory perspective	10	**Kenneth Cavanaugh** (FDA)
			(G-4) Initiatives to accelerate medical device access: Singapore regulatory perspective	10	**Lai Peng LOW** (Health Sciences Authority, Singapore)
			(G-5) Panel discussion: Envisioning global collaboration in medical device development - a 10-year outlook from industry, academia, and government	40	**Speakers** & **IKENO Fumiaki** (Stanford Univ.) **MORIKAWA Satoshi** (Boston Scientific Japan) **NAKAI Kiyohito** (PMDA) **Rolf Oberlin Hansen** (Danish Medicines Agency)
H	Closing remarks			5	**YABANA Naoyuki** (PMDA)