

**Japan-US HBD East 2013
Think Tank Meeting
HBD: Past Decade, Current and Tomorrow
July 9 – July 10, 2013**

Yayoi Memorial Hall (Tokyo Women's Medical University), Tokyo, Japan

<u>Tuesday, July 9th, 2013 – Yayoi Memorial Hall</u>	
8:30	Registration
Opening Remarks	
9:30 -	Atsushi Tamura, HBD SC co-Chair
Welcome Speech	
9:35 -	Shigekazu Komoto
Keynote Speech	
9:40 -	Shigeru Saito
Update from Working Group 4	
9:50 -	Introduction and Progress Kentaro Azuma
10:00 -	GCP Update and Next Steps Neal Fearnot and Kazuo Yano
10:10 -	Comparative Analysis of Japan and US Data Reliability Assessment Chie Iwaishi and Kazuo Tomida
10:20 -	Summary Technical Documentation (STED) “Harmonizing a Predictable Regulatory Submission” Donna Haire
10:30 -	Orphan Device Comparison Yuka Suzuki and Neal Fearnot
10:40 -	Panel Discussion -What is different in practice as a result of the work of WG 4?- Moderators: Kentaro Azuma, Neal Fearnot Panelists: Kazuo Yano, Chie Iwaishi, Donna Haire, Yuka Suzuki, Koji Ikeda, Kazuo Tomida, Jennifer Kerr
11:00 -	Coffee Break
Update from Working Group 2	
11:15 -	J-MACS Takeshi Nakatani
11:30 -	New Direction of WG2 Masayuki Kawahara
11:40 -	Panel Discussion Moderator: Kazuhiro Sase Panelists Takeshi Nakatani, Koji Todaka, Masayuki Kawahara,
Scientific Session 1	
Valvular Heart Disease in Japan-USA Moderator: Kazuhiro Sase	
11:55-	Experience of PI in Japan Yoshiki Sawa
12:10-	TAVI in the Next Generation Bernard Lyons
12:25-	Panel Discussion Panelists: Bernard Lyons, Mitchell Krucoff, Yoshiki Sawa, Haruki Shirato, Gary Thompson, Shigeru Saito
12:45 -	Lunch

Update from Working Group 3	
14:00 -	Clinical Trial Cost Survey Results in Japan - Lessons Learned from Cost Survey Izumi Fukuzawa
14:10 -	Infrastructure of Translational Research for Medical Devices in Japan Yoshihiro Arakawa
14:20 -	Panel Discussion Moderator: Yoshihiro Arakawa Panelists: Makoto Akabori, Neal Fearnot, Izumi Fukuzawa Allison Handler, Takahiro Uchida
Update from Working Group 1	
14:30 -	Educational Program by HBD WG1 Gary Thompson
14:40 -	Overview of POC Project Hiroyoshi Yokoi
14:50	Overview of WG1 Activity Shin Iwamoto
15:00 -	Panel Discussion Moderators: Gary Thompson, Hiroyoshi Yokoi Panelists: Mitchell Krucoff, Takahiro Uchida, Shigeru Saito, Neal Fearnot, Koji Ikeda, Shin Iwamoto
15:15 -	Coffee Break
Scientific Session 2	
New Coronary Frontiers and Peripheral Intervention in Japan-USA Moderators Shigeru Saito, Gary Thompson	
Topic: New Medical Devices	
15:30-	Combo Stent Steve Rowland
15:40-	Orbital Atherectomy and the Understudied Calcified Coronary Lesion Patient Population Robert Thatcher
15:50-	Experience of BVS in Japan Shigeru Saito
Topic: Critical Limb Ischemia (CLI)	
16:00-	Guidance on the Evaluation of medical devices for CLI treatment in Japan Hiroyoshi Yokoi
16:10-	Regulatory View of Japan-USA Similarities & Differences Kenneth Cavanaugh (Pre-recorded)
16:20-	Peripheral Academic Research Consortium (PARC) Meeting Mitchell Krucoff
Topic: Collaborative Scheme	
16:30-	Overview of Collaborative Scheme Mami Ho
16:40-	Zilver DES and PAD: Japan-USA Clinical Data & Lessons Learned Neal Fearnot
16:50-	MISAGO Seigo Nakano
17:00-	Panel Discussion Panelists: Shigeru Saito, Mami Ho, Hiroyoshi Yokoi, Seigo Nakano, Steve Rowland, Robert Thatcher, Takahiro Uchida, Kentaro Azuma, Neal Fearnot
Medical Device Development during the Past Decade	
17:25 -	Akira Matsumoto, Chairman of the Board, Calbee. Inc
17:35 -	Adjourn

Wednesday, July 10th, 2013 – Yayoi Memorial Hall

8:30 -	Registration
Overview of Day1 and Preview of Day2	
9:00 -	Shigetaka Miura
Regulators' Perspectives for Future Collaboration between Japan & US	
9:10 -	Jeffrey Shuren, Director, FDA CDRH (Pre-recorded)
9:20 -	Tatsuya Kondo, Chief Executive, PMDA
Industry's Perspective for Future Collaboration between Japan & US	
9:35 -	Koji Nakao, Chair, JFMDA
International Collaboration	
9:50 -	Past Decade Mitchell Krucoff
10:00 -	Current Chie Iwaishi
10:10 -	Tomorrow Janet Trunzo
10:20 -	Coffee Break
Total Product Life Cycle Management	
10:40 -	Overview and Recent Efforts in the US Kimberly Trautman
10:55 -	Overview of Japanese Electronic Medical Records Hideto Yokoi
11:10 -	Participation in Post-Market Management of Academia Kazuhiro Sase
11:25 -	Post-Market Surveillance in Japan Tomiko Tawaragi
11:40 -	Panel Discussion Moderators: Mitchell Krucoff, Atsushi Tamura Panelists: Hideto Yokoi, Kimberly Trautman, Kazuhiro Sase, Gary Thompson, Janet Trunzo, Chie Iwaishi, Tomiko Tawaragi
Closing Remarks	
12:05 -	Mitchell Krucoff, HBD SC co-Chair

Speakers

(in alphabetical order)

No.	Name	Affiliation
1	AKABORI, Makoto	U. Tokyo
2	ARAKAWA, Yoshihiro	U. Tokyo
3	AZUMA, Kentaro	MHLW
4	CAVANAUGH, Kenneth	FDA CDRH
5	FEARNOT, Neal	COOK Group, Inc.
6	FUKUZAWA, Izumi	Covidien Japan, Co., Ltd.
7	HAIRE, Donna	The Eriah Group, LLC
8	HANDLER, Allison	Duke Clinical Research Institute
9	HO, Mami	PMDA
10	IKEDA, Koji	Tohoku U.
11	IWAISHI, Chie	Bausch & Lomb Japan, Ltd.
12	IWAMOTO, Shin	PMDA
13	KAWAHARA, Masayuki	PMDA
14	KERR, Jennifer	COOK, MED Institute, Inc.
15	KOMOTO, Shigekazu	MHLW
16	KONDO, Tatsuya	PMDA
17	KRUCOFF, Mitchell	Duke University Medical Center
18	LYONS, Bernard	Direct Flow Medical, Inc
19	MATSUMOTO, Akira	Calbee, Inc.
20	MIURA, Shigetaka	Sakura Seiki, Co., Ltd.
21	NAKANO, Seigo	Terumo Corp.
22	NAKAO, Koji	JFMDA (Terumo Corp.)
23	NAKATANI, Takeshi	National Cerebral and Cardiovascular Center
24	ROWLAND, Steve	OrbusNeich Medical, Inc
25	SAITO, Shigeru	Shonan Kamakura General Hospital
26	SASE, Kazuhiro	Juntendo U.
27	SAWA, Yoshiki	Osaka U.
28	SHIRATO, Haruki	PMDA
29	SHUREN, Jeffrey	FDA CDRH
30	SUZUKI, Yuka	PMDA
31	TAMURA, Atsushi	PMDA
32	TAWARAGI, Tomiko	PMDA
33	THATCHER, Robert	Cardiovascular Systems, Inc.
34	THOMPSON, Gary	Abbott Vascular, Inc
35	TODAKA, Koji	Kyushu U.
36	TOMIDA, Kazuo	Hitachi, Ltd
37	TRAUTMAN, Kimberly	FDA CDRH
38	TRUNZO, Janet	AdvaMed
39	UCHIDA, Takahiro	Tokyo Women's Medical U.
40	YANO, Kazuo	Asahi Kasei Medical Co., Ltd.
41	YOKOI, Hideto	Kagawa U.
42	YOKOI, Hiroyoshi	Kokura Memorial Hospital