Draft Program

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March 16th (Wednesday)

Iron Gate Memorial Hall

13:00-13:40 Introduction of HBD

–Yoshinobu Hirayama(MHLW・Councillor for Pharmaceutical Affairs, Minister's Secretariat), Kazuo Ogino(JFMDA・Chairman) & Mitchell Krucoff(Duke Clinical Research Institute)

13:40-15:25 Advances in Japan-USA regulatory processes (WG4)

Moderator: Carole Carey(FDA) and Kentaro Azuma(MHLW)

Introduction and Progress – Carole Carey(FDA) and Kentaro Azuma(MHLW)

Concept Paper – Gary Thompson(Abbott)

GCP Update and Next Steps: poster board – Neal Fearnot(Cook) and Kazuo Yano(Asahi Kasei Kuraray Medical)

STED POC Progress – Elisabeth George(Philips) and Noriko Yasuda(Toray Medical)

Comparisons of Data Integrity/Reliability Assessment in Japan and the USA – Chie Iwaishi(Cordis, J&J) and Kazuo Tomida(Hitachi)

Results of Future Focus for WG4 Questionnaire – Brad Hossack(Boston Scientific)

Panel Discussion (Modulator: Michael Gropp(Medtronic) and Mime Egami(Tokyo Women's Medical University))

<15:25-15:40 Break>

15:40-16:20 Issues, needs and limitations of Japan-USA research infrastructure (WG3)

Moderator: John Alexander(Duke Clinical Research Institute) and Yoshihiro Arakawa(University of Tokyo)

Top five challenges facing the global clinical research infrastructure – an academic perspective – John Alexander (Duke Clinical Research Institute)

The current Japanese clinical research infrastructure – Lessons from the pharmaceuticals industry – TBA

Initial results from first ever survey on costs of medical devices clinical trials in Japan – Izumi Fukuzawa(BIOMET JAPAN)

Discussion on HBD Working Group 3 (Clinical Research Infrastructure) – Looking forward – John Alexander(Duke Clinical Research Institute) and Yoshihiro Arakawa(University of Tokyo)

16:20-17:00 New Discussion Point

Moderator: Eric Chen(FDA) and Yuka Suzuki(PMDA)

Research proposal regarding orphan device development – Eric Chen(FDA)

Current status of orphan device in Japan – Kentaro Azuma(MHLW) and Kohei Ohtsuki (PMDA)

Panel Discussion – TBA

17:00-17:30 Free time

17:30-19:30 Reception Sanjo Conference Hall

March 17th (Thursday)

Iron Gate Memorial Hall

09:30-10:10 CDRH & PMDA

– Jeffrey Shuren(FDA・CDRH Director: prerecorded) & Hideo Utsumi(PMDA・Executive Director)

10:10-11:10 Post-market directions in Japan-USA (WG2)

Moderator: Eric Chen(FDA) and Kazuhiro Sase(Juntendo University)

Initial Goals of WG2 and INTERMACS – Eric Chen(FDA)

Accomplishments and JMACS – Takeshi Nakatani(National Cerebral and Cardiovascular Center)
Harmonization By Data -Proposed direction for WG2- – John Laschinger (FDA)

<11:10-11:25 Break>

11:25-12:25 Collaborative Scheme
The overview/history of the collaborative Scheme – Carole Carey(FDA)
The experiences/lessons learned from the Scheme – PMDA perspective – Mami Ho(PMDA)
The experiences/lessons learned from the Scheme – FDA perspective – Kenneth Cavanaugh(FDA)
The experiences from Industry side – Neal Fearnot(Cook), Kazuo Kawahara(Terumo), Lucy Tan (Medtronic)
Panel discussion (TBA)

<12:25-13:25 Lunch>

13:25-13:55 Options & Opportunities for Global Clinical Trials: Concept to Proof of Concept (WG1)
Moderator: Mitchell Krucoff(Duke Clinical Research Institute)and Bram Zuckerman(FDA)
Our new mission—educational 'incubator' to facilitate global clinical trials – Koji Ikeda(PMDA)
Update on participation in scientific sessions:US side (TCT, CRT) – Mitchell Krucoff(Duke Clinical Research Institute)
Update on participation in scientific sessions: Japan side (CVIT, Kamakura Live) and future direction of WG1 activities – Shigeru Saito(Shonan Kamakura General Hospital)
Discussion – TBA

13:55-16:10 "Scientific Session"
Part.1 Device Lag & DES: How Far Has Harmonization Come?
Moderator:Shigeru Saito(Shonan Kamakura General Hospital) and Bram Zuckerman(FDA)
- *Introduction: the overview of DES introduction (from Y2004) & Lessons learned/experiences from DES trials/development – Shigeru Saito(Shonan Kamakura General Hospital)*
- *Models of Convergence: From Poolable to Single Protocol to "Japan First" – Mitchell Krucoff(Duke Clinical Research Institute)*
- *Regulatory Convergence and future progress of DES development – Koji Ikeda(PMDA)*
- *Discussion – TBA*

<14:35–14:50 Break>

Part.2 Percutaneous Valves: A New "Device Lag" Challenge
Part 2-I: Mitral Valve
Moderator: Mitchell Krucoff(Duke Clinical Research Institute) and Masato Nakamura(Toho University Ohashi Medical Center)
- *Introduction : current situation facing "device lag" – Fumiaki Ikeno(Stanford University)*
- *Key Patient Descriptors & Endpoints for MV: Same or Different in Japan & USA – John Laschinger(FDA)*
- *Site-Based Research Infrastructure for MV In Japan and USA – Gary Thompson(Abbott)*
- *Medical & Surgical Comparators for Percutaneous Mitral Valves: A Cultural Perspective In Japan and USA – Stanton Rowe(Edwards)*
- *Discussion – TBA*

Part 2-II: Aortic Valve
Moderator:Koji Ikeda(PMDA) and Susan Alpert(Medtronic)
- *Introduction : current situation facing "device lag" – Fumiaki Ikeno(Stanford University)*
- *Key Patient Descriptors & Endpoints for TAVI:Same or Different in Japan & USA – John Laschinger(FDA)*
- *Site-Based Research Infrastructure for TAVI In Japan and USA:A Critical "Partnership" – Jodi*

Akin(Edwards)

- *Comments/expectations from physicians – Yoshiki Sawa (Osaka University)*
- *Discussion – TBA*

16:10 - 16:30 Closing Session –*Toshiyoshi Tominaga(PMDA), Kuniko Shoji(JFMDA)*