

# Japan Safety Biomarker Conference – AGENDA

Day 1: February 20, 2017			
Title	Proposed Presenter	Time (minutes)	Time (hour)
Session 1. Introduction	Dr. John-Michael Sauer (C-Path)	30	13:00-13:30
Session 2. Session on biomarker implementation and public health aspects for novel biomarkers beyond drug development	Session Chairs: Dr. Nishiya Takayoshi (Daiichi Sankyo) and Dr. Piero Carninci	5	13:30-13:35
2.1 Urinary biomarker for drug-induced nephrotoxicity	Dr. Masuda (Kyushu University Hospital)	30	13:35-14:05
2.2 Scientific Validity of Urinary L-FABP for Early Diagnosis of Nephrotoxicity – A case study for the standardization of urinary biomarkers	Dr. Sugaya (St. Marianna Univ. School of Medicine)	30	14:05-14:35
2.3 Utility of KL-6 in the management of interstitial lung diseases	Dr. Hattori (Hiroshima Univ. School of Medicine)	30	14:30-15:05
2.4 CAGE: a useful transcriptome technology for identifying biomarkers	Dr. Carninci (RIKEN Institute)	30	15:05-15:35
2.5 Identification and medical application of the biomarkers based on the transcriptome regulatory network	Dr. Hayashizaki (RIKEN Insititute)	30	15:35-16:05
Break		25	16:05-16:30
2.6 Metabolomics investigation and current issues on safety biomarkers	Dr. Saito (NIHS)	30	16:30-17:00
Session 3. Closing: Ongoing and future safety biomarker qualification projects	Panel consisting of presenters and session chair	60	17:00-18:00
Banquet		90	18:30-20:00

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Day 2: February 21, 2017			
Title	Proposed Presenter	Time (minutes)	Time (hour)
Session 4. PSTC Projects	Session Chair: Dr. Jiri Aubrecht (Pfizer) and Dr. John-Michael Sauer (C-Path)	5	09:00-09:05
4.1 GLDH Clinical Qualification Project	Dr. Jiri Aubrecht (Pfizer)	30	09:05-09:35
4.2 Pancreatic Injury Biomarkers	Dr. Warren Glaab (Merck)	30	09:35-10:05
4.3 Vascular Injury Biomarkers	Dr. Tanja Zabka (Genentech)	30	10:05-10:35
Break		20	10:35-10:55
Session 5. Safety Biomarker Qualification and its importance	Session Chair: Dr. Akihiro Ishiguro (PMDA) and Dr. Shunji Nomura (Pfizer)	5	10:55-11:00
5.1 from the Submitter's perspective	Dr. Elizabeth Walker (C-Path)	30	11:30-12:00
Lunch		60	12:00-13:00
5.2 from the FDA's perspective	Dr. Shashi Amur (FDA)	30	13:00-13:30
5.3 from the EMA's perspective	Dr. Thorsten Vetter (EMA)	30	13:30-14:00
5.4 from the PMDA's perspective	Mr. Yasuto Otsubo (PMDA)	30	14:00-14:30
Session 6. Future Directions	Panel consisting of Session 5 presenters and chairs		14:30-16:00
6.1 Introduction		10	14:00-14:10
6.2 Case Example – Development of Urinary L-FABP, Approved and Reimbursed Renal Biomarker, by The Bridging between The Clinical and Analytical Performance	Dr. Sugaya (St. Marianne Univ. School of Medicine)	30	14:10-14:40
6.3 Case Example – PSTC kidney clinical qualification	Dr. Irene Nunes (Daiichi Sankyo)	30	14:40-15:10

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6.4 Panel Discussion		50	15:10-16:00
Closing Remarks	Dr. John-Michael Sauer (C-Path) and Dr. Nishiya Takayoshi (Daiichi Sankyo)	10	16:00-16:10