



## THE 12<sup>TH</sup> JBF SYMPOSIUM PROGRAM

Date: Tue, 9<sup>th</sup> Mar. – Thu, 11<sup>th</sup> Mar. 2021

Venue: Virtual meeting

### Day 1: Tuesday, 9<sup>th</sup> Mar.

#### 12:30-12:45 Opening Remarks

- Hitoshi UCHIYAMA (The 12<sup>th</sup> JBF Symposium Chair / Towa Pharmaceutical)
- Yoshiro SAITO (JBF Representative / National Institute of Health Sciences)

#### 12:45-14:45 Expectations and Challenges for Bioanalysts in Pharmacokinetic Research

Chair: Nozomu KOSEKI [Kyorin Pharmaceutical]

Junji KOMABA [Ono Pharmaceutical]

- What is the most important role for bioanalysts? [Toshio TERAMURA • Aomori University]
- Expectations for Bioanalysts on ADME-Pharmacokinetic Research [Nobuaki WATANABE • Daiichi Sankyo]
- Case Study of Supporting Drug Development Based on Bioanalytical Platform [Ryosuke IDE • Mitsubishi Tanabe Pharma]
- Applications of LC-MS/MS based absolute protein quantification to the drug development [Yutato HOSHI • Ono Pharmaceutical]

#### 15:00-16:00 Poster Presentation Part 1

#### 15:00-16:00 Sponsored Seminar: SCIEX

#### 16:15-17:55 Hot topics on biomarker analysis for drug development

Chair: Harue IGARASHI [GlaxoSmithKline]

Hisao SHIMIZU [Takeda Pharmaceutical]

- Points to consider document on biomarker assay validation and study sample analysis in Japan [Yoshiro SAITO • National Institute of Health Sciences]
- Validation of Biomarker Quantification in Japan - Context of use for a biomarker assay validation- (DG2020-45) [Yoshitaka HASHIMOTO • Ono Pharmaceutical]
- Antibody Free Approaches to Measuring Protein Biomarkers [Timothy W Sikorski • GlaxoSmithKline]
- Blood-based biomarkers for dementia [Takahiko TOKUDA • National Institutes for Quantum and Radiological Science and Technology]



**Day 2: Wednesday, 10<sup>th</sup> Mar.**

**9:00-10:20 Patient centric sampling and bioanalysis**

Chair: Yosuke KAWAI [Otsuka Pharmaceutical]  
Tomoko ARAKAWA [Pfizer R&D]

- Patient Centric Sampling and Analysis for the Determination of Circulating Concentrations of Drug, Metabolites and Biomarkers [Neil Spooner • Spooner Bioanalytical Solutions]
- Validating and Implementing Bioanalytical Methods for Patient-Centric Sampling [Enaksha Wickremsinhe • Eli Lilly]
- Collaborations in Patient Centric Sampling and Microsampling: Working Together to Reduce Patient Burden and Obtain More Informative Datasets [Melanie Anderson • MSD]

**10:30-12:30 Poster Presentation JBF Discussion Groups (Viewing only)**

- DG2020-46 Bioanalysis of Unstable Analytes
- DG2020-48 Quantitative analysis of oligonucleotide therapeutics by Hybridization assay

The following DG posters will be posted on the JBF website after the symposium.

- DG2019-43 Guide to ADA Analysis: Considerations in Developing Analytical Methods and Conducting Nonclinical/Clinical Studies
- DG2020-45 Validation of Biomarker Quantification in Japan - Context of use for a biomarker assay validation -
- DG2020-49 Neutralizing Antibody Assay: Discussion to Select Assay Format and Improve Assay Performance

**10:30-11:00 Sponsored Seminar: Thermo Fisher Scientific K.K. Sponsored**

**11:00-11:30 Seminar: Toray Research Center**

**12:30-13:00 Sponsored Seminar: Scrum Inc.**

**13:00-13:30 Sponsored Seminar: Gyros**

**13:30-15:00 Hot Topics in Clinical Development (Virtual Clinical Trial)**

Chair: Tomoko ARAKAWA [Pfizer R&D]  
Yoshiaki OHTSU [Kyowa Kirin]

- Towards Realization of Decentralized Clinical Trials in Japan –Recent Status and Perspective learnt from JPMA research– [Soichiro MATSUSHIMA • JPMA]
- Patient-centric Virtual Clinical trial ~ The latest situation in the US ~ [Norikazu EIKI • Eiki Consulting]
- Bioanalysis in Virtual Clinical Trials [Yoshiaki OHTSU • Kyowa Kirin]

**15:15-16:15 Hot Topics in Clinical Development (Gene Therapy)**

Chair: Tomoko ARAKAWA [Pfizer R&D]  
Yoshiaki OHTSU [Kyowa Kirin]

- Bioanalytical Considerations and Strategies in Gene Therapies [Fraser McBlane • Novartis]
- Biodistribution and Immunogenicity Assessments to Support Gene Therapies [Wataru HONMA • Novartis Pharma]

**16:30-17:30 Keynote lecture**

「Development of new cancer antibody drugs」

**Yasuhiro MATSUMURA (National Cancer Center Research Institute / Innovation Center of NanoMedicine / RIN Institute)**



Chair: Noriko KATORI [National Institute of Health Sciences]

**Day 3: Thursday, 11<sup>th</sup> Mar.**

**9:00-10:00 Poster Presentation Part 2**

**9:00-9:30 Sponsored Seminar: Hypha Discovery, Ltd. (BioBridge K.K.)**

**10:15-11:45 Latest Trends in Cancer Genome Medicine**

Chair: Naoaki MURAO [Chugai Pharmaceutical]

Keiko NAKAI [LSIM Safety Institute]

- [Development of companion diagnostic device using gene profiling test and the environment trend of genomic medicine](#) [Yuki KAMIHARA • Chugai Pharmaceutical]
- New horizons of DNA adductome analysis for evaluation of carcinogenesis [Yukari TOTSUKA • National Cancer Center Research Institute]
- Current Status of gene panel testing [Hayato NIIRO • Sysmex]

**12:00-12:30 Sponsored Seminar: ELGA LabWater**

**12:30-13:00 Sponsored Seminar: Agilent Technologies Japan, Ltd.**

**13:00-14:15 Let's Talk to each other about bioanalysis (LBA)**

Additional registration is required to attend this session

**13:00-14:00 Sponsored Seminar: Nihon Waters Co., Ltd.**

**14:30-16:30 Current trends in bioanalytics of therapeutic middle molecules**

Chair: Naoaki MURAO [Chugai Pharmaceutical]

Takahiro NAKAMURA [Shin Nippon Biomedical Laboratories]

- Current status and future perspective of peptide bioanalysis by LC/MS [Ryoya GODA • Daiichi Sankyo]
- [Points to consider on pharmacokinetics of peptide drugs with non-natural structures](#) [Yoshiro SAITO • National Institute of Health Sciences]
- [High-sensitivity analysis of therapeutic oligonucleotides using an LC-MS/MS approach](#) [Naoto SENDA • Shin Nippon Biomedical Laboratories]
- Bioanalysis of oligonucleotide therapeutics: Based on approved cases in Japan [Daisuke IWATA • Pharmaceuticals and Medical Devices Agency]

**16:30-16:45 Closing Remarks**

- Yumi NISHIGUCHI (The 13<sup>th</sup> JBF Symposium Chair / CMIC Pharma Science)
- Takeru YAMAGUCHI (The 13<sup>th</sup> JBF Symposium Chair / Sumika Chemical Analysis Service)

[Note]

All information is subject to change.