DAY 1 | MONDAY, AUGUST 26, 2019

MORNING SHORT COURSE 9:30 – 12:45AM

SC-A Missing Data Analysis in Clinical Trials using SAS®	**SC-B** Confirmatory Adaptive Designs with Multiple Objectives: Methods and Regulatory Experiences	**SC-C** Accelerating drug discovery though Precision Medicine and Innovative Designs: Concepts, Rationale and Case Studies
Room 663, 6F	Room 664, 6F	Room 665, 6F

AFTERNOON SHORT COURSE 1:45 – 5:00PM

SC-D Novel Adaptive Clinical Trial Designs for Immunotherapy and Modern Drug Development	**SC-E** Artificial Intelligence for Medicine and Health **Cancelled**	**SC-F** Hot topics in Clinical Trials: Multiple Outcomes and Befefit:Risk
Room 663, 6F	Room 664, 6F	Room 665, 6F

DAY 2 | TUESDAY, AUGUST 27, 2019

MORNING SESSION 1 8:45 – 10:30AM

Opening & Plenary Session 1
Sakura, 1F

MORNING SESSION 2 10:45AM – 12:15PM

IS01 Enhancing Regulatory Decision-Making to Support Drug Development: US FDA Plot Programs on Complex Innovative Designs and Model-Informed Drug Development	**IS03** Recent Development and Challenges in Bioequivalent or Biosimilar Assessment	**TC16** The Implementation of ICH-E17 in Asian Regions	**TC02** New Developments for Statistical Methods in Personalized Medicine	**CS1** CONTRIBUTED SESSION
Sakura, 1F	ROOM 510, 5F	ROOM 554, 5F	ROOM 555, 5F	ROOM 509, 5F

AFTERNOON SESSION 1 1:30 – 3:00PM

IS06 Use of Machine Learning and AI for Precision Medicine in Drug Development	**IS02** Statistical Designs and Considerations in Early Clinical Development	**TC07** Multiplicity Issues in Complex Clinical Trials	**TC01** Biostatistician Role in Innovative Trial Design in the New Era of Drug Development	**In-Conference Workshop I** Innovative and Flexible Designs for Clinical Trials in the Era of Precision Medicine
Sakura, 1F	ROOM 510, 5F	ROOM 554, 5F	ROOM 555, 5F	ROOM 509, 5F

AFTERNOON SESSION 2 3:30 – 5:00PM

IS19 Industry Leadership Panel Discussion	**IS14** Innovative Approaches for Trial Design and Analysis	**TC11** Advances in Design and Analysis of Clinical Studies that Incorporate Internal and External Data Sources	**TC09** Adverse Events in Clinical Trials and Post-Marketing Pharmacovigilance	**In-Conference Workshop I** Innovative and Flexible Designs for Clinical Trials in the Era of Precision Medicine (cont.)
Sakura, 1F	ROOM 510, 5F	ROOM 554, 5F	ROOM 555, 5F	ROOM 509, 5F

EVEING EVENT 6:00 – 8:00PM

Reception and Poster session
Swan, 1F

DAY 3 | WEDNESDAY, AUGUST 28, 2019

MORNING SESSION 1 8:45 – 10:30AM

Plenary Session 2
Sakura, 1F

MORNING SESSION 2 10:45AM – 12:15PM

IS12 Some Innovative Approaches to Trial Designs and Medical Product Development	**IS09** Statistical Issues and Methods for Vaccine Development	**TC17** Innovative and Strategic Thinking in Pediatric Trials and Early Drug Development based on Bayesian Hierarchical Model	**TC08** Innovative Methods to Support the Development of New Pediatric Medicines	**TC14** Other Way forward for Design, Summary Measures, and Estimands in Survival Clinical Trials
Sakura, 1F	ROOM 510, 5F	ROOM 554, 5F	ROOM 555, 5F	ROOM 509, 5F

AFTERNOON SESSION 1 1:30 – 3:00PM

IS04 Rethinking Estimators within the Estimand Framework	**IS07** Adaptive Designs for Small Population Clinical Trials	**TC05** Machine Learning Methods for Improving Clinical Decision-Making and Precision Health Care	**TC04** Bayesian Approaches for the Utilization of Co-Data for Efficient Drug Development	**In-Conference Workshop II** Adaptive Multi-arm Multi-Stage (MAMS) Designs in Confirmatory Clinical Trials: A Practical Introduction to the Statistical Methodology and its Application
Sakura, 1F	ROOM 510, 5F	ROOM 554, 5F	ROOM 555, 5F	ROOM 509, 5F

AFTERNOON SESSION 2 3:30 – 5:00PM

IS18 Inference and Decision Making for Contemporary Drug Development and Approval	**IS10** Recent Development on Missing Data Issues under ICH E9 (R1) Estimand Framework	**TC13** Data Science for Medicine	**TC10** Designing Clinical Trials with Recurrent Events	**In-Conference Workshop II** Adaptive Multi-arm Multi-Stage (MAMS) Designs in Confirmatory Clinical Trials: A Practical Introduction to the Statistical Methodology and its Application (cont.)
Sakura, 1F	ROOM 510, 5F	ROOM 554, 5F	ROOM 555, 5F	ROOM 509, 5F

DAY 4 | THURSDAY, AUGUST 29, 2019

MORNING SESSION 1 8:45 – 10:30AM

Plenary Session 3
Sakura, 1F

MORNING SESSION 2 10:45AM – 12:15PM

IS05 Demystifying Estimands for Life History Processes	**IS11** Methodology Research for Biopharmaceutical Industry- Panel Discussion	**IS15** Issues in Adaptive and Complex Clinical Trials Designs	**TC03** Regulatory Submissions in Electronic Format	**TC15** Real-Word Data: Implications and Challenges for Medical Product Development
Sakura, 1F	ROOM 510, 5F	ROOM 554, 5F	ROOM 555, 5F	ROOM 509, 5F

AFTERNOON SESSION 1 1:30 – 3:00PM

IS16 Oncology trials with Non-Proportional Hazards	**IS13** Statistical Methods in Drug Development	**IS17** Statistical Methodology for the Comparative Assessment of Quality Attributes	**TC12** Opportunities and Challenges for the Use of Parametric Longitudinal Modelling in Drug Development	**TC06** Utilization of Subgroup and Casual Inference towards Personalized Medicine
Sakura, 1F	ROOM 510, 5F	ROOM 554, 5F	ROOM 555, 5F	ROOM 509, 5F

AFTERNOON SESSION 2 3:30 – 5:00PM

RS03 ICH-E17: How to Implement Multi-Regional Clinical Trials based on the Guidance?	**RS01** Harmonization of Model-Informed Drug Development Approaches in Regulatory Review and Decisions			
Sakura, 1F	ROOM 510, 5F			

EVEING EVENT 7:00 – 9:00PM

Conference Dinner
FUNATSURU KYOTO KAMOGAWA RESORT

DAY 5 | FRIDAY, AUGUST 30, 2019

MORNING SESSION 1 8:45 – 10:15AM

RS04 ICH-E9(R1)- Guidance Concept and Implementation	**CS02** Contributed Session
Sakura, 1F	ROOM 510, 5F

MORNING SESSION 2 10:30AM – 12:00PM

RS02 Estimand, Missing Data and Sensitivity Analysis- Panel Discussion	**CS03** Contributed Session
Sakura, 1F	ROOM 510, 5F

CLOSSING SESSION 12:00 – 12:15PM

Closing Session
Sakura, 1F

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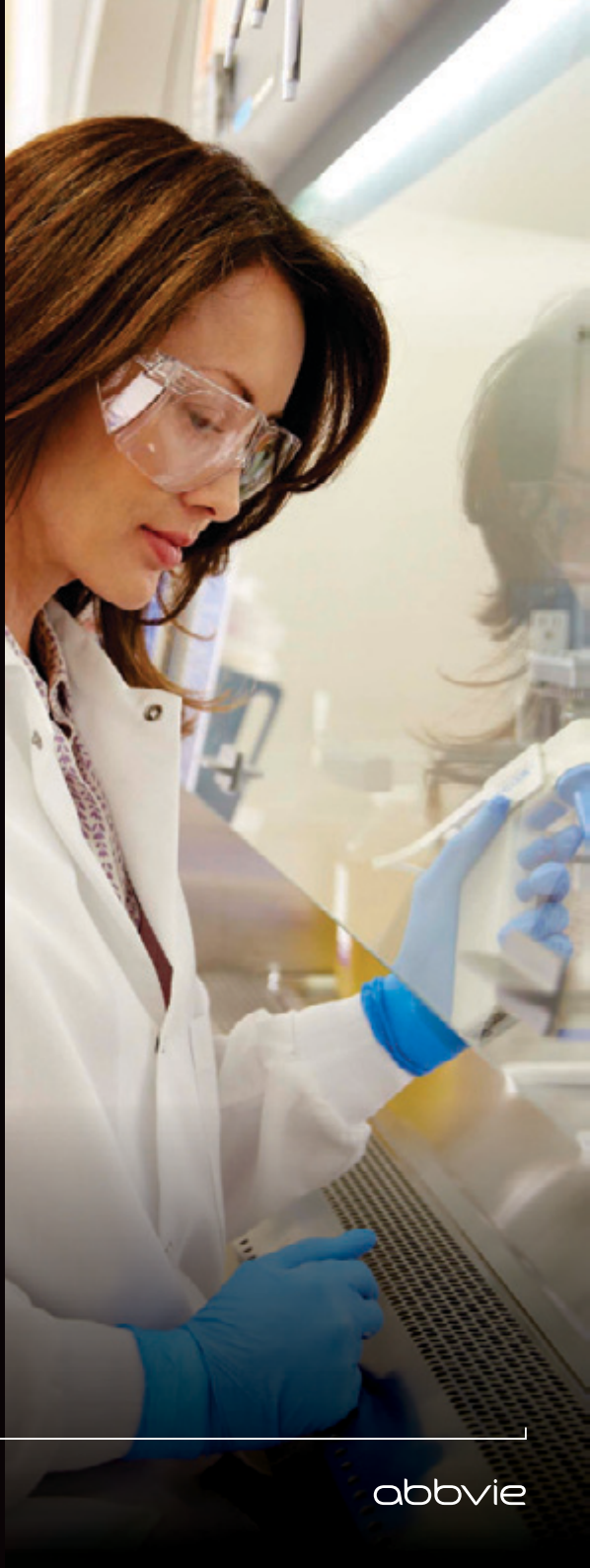

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