**MISSING DATA ANALYSIS IN CLINICAL TRIALS USING SAS®**

**Instructors**
- Frank Liu
  Merck, Sharp & Dohme, Corp.
- Fang Chen
  SAS Institute Inc.

**Overview**
Missing data are inevitable and post many issues and challenge in analysis for clinical trials. Despite a great amount of research has been devoted to this topic, properly handling missing data in clinical trials remains complex. Conventionally, under the missing at random (MAR) assumption, we often use maximum likelihood or multiple imputation based methods for inferences. However, the MAR assumption is unverifiable. More critically, the estimand under MAR is hypothetical as indicated in the recent ICH E9 (R1) addendum and has been considered as overly-simplistic and unrealistic. Both regulatory agencies and industry sponsors have been seeking alternative approaches to handle missing data in clinical trials under missing not at random (MNAR) assumption.

This half-day tutorial is intended to cover issues of missing data in clinical trials including various methods and how to carry out the analyses using SAS software. The tutorial begins with an overview of missing data issues, and concepts and strategies as proposed by ICH E9 (R1) addendum. Then we will review traditional missing data handling methods such as maximum likelihood methods, multiple imputation, generalized estimation equation approaches, and Bayesian methods. The rest of the course is devoted to more recently-developed methods, such as sensitivity analysis to assess robustness, control-based imputation, control-based mean imputation, trimmed mean and tipping point analysis. Real clinical trial examples will be presented for illustration with implementation of the analysis using SAS/STAT software, including PROC MIXED, PROC MI, PROC MIANALYZE, PROC GEE, and PROC MCMC.

**ACCELERATING DRUG DISCOVERY THROUGH PRECISION MEDICINE AND INNOVATIVE DESIGNS: CONCEPTS, RATIONALE, AND CASE STUDIES**

**Instructors**
- Sandeep M Menon
  Pfizer Inc
- Weidong Zhang
  Pfizer Inc

**Overview**
Precision medicine has paved the way for a new era of delivering tailored treatment options to patients according to their biological profiles. Advancement of the biotechnologies such as next generation sequencing technology (NGS) and other omics technologies have enabled us to interrogate a patient’s many molecular biomarkers, and associate them with disease and drug responses. In addition, incorporation of biomarker information in the innovative clinical trial design has presented drug developers unprecedented opportunities to bring a successful drug to
patients in needs.

The first part of this course will focus on the concept of precision medicine, biomarker discovery and its application in clinical trials. Comprehensive review of omics data and major technologies will be presented. Statistical considerations and challenges such as data normalization, dimension reduction and biomarker threshold development and using biomarker for decision making in clinical development will be discussed in details.

The second part of this course will focus on the strategy of the study design that is important to critically determine biomarker performance, reliability and eventually regulatory acceptance. A general overview of the concept and statistical methodologies and designs related to precision medicine will be presented. Specifically, we will discuss various designs including adaptive designs available at our disposal and its merits and limitations.

Overview

1:45-5:00PM SHORT COURSE D
ROOM #663, 6F
NOVEL ADAPTIVE CLINICAL TRIAL DESIGNS FOR IMMUNOTHERAPY AND MODERN DRUG DEVELOPMENT
Instructors
Cong Chen
Merck Sharp & Dohme Corp.
Guosheng Yin
University of Hong Kong
Ying Yuan
University of Texas MD Anderson Cancer Center
Overview Following the success of PD-1 (or PD-L1) inhibitors, a flood of next generation immunotherapies with different mechanisms of action are being developed. While the expectation is high for these new immunotherapies, it is unrealistic to expect all of them to have the same success as their predecessors, especially given the improved standard-of-care. Innovative adaptive clinical trial designs provide a cost-effective and flexible way to improve the success rate of drug development. In this short course, we will present novel Bayesian designs for phase I and II clinical trials (including both single-agent and drug-combination trials), statistical strategies on phase I efficacy screening, adaptive 2-in-1 design for seamless Phase 2/3, Phase 3 adaptive designs for population expansion. We will introduce the freely available software and illustrate the application of the designs using real-world examples. This short course is suitable for statisticians and clinicians from industry, regulatory agencies and academia. Students of this short course are expected to not only apply the new methods learned to their studies but also think out of box when facing unique situations.

1:45-5:00PM SHORT COURSE E
ROOM #664, 6F
ARTIFICIAL INTELLIGENCE FOR MEDICINE AND HEALTH (Cancelled)
Instructor
Mark Chang
Boston University
Overview Artificial intelligence (AI) or machine learning (ML) has been used in drug discovery for many years under name of bioinformatics, such as sequencing, annotating genomes, analysis of gene and protein expression and regulation, linking the biological and disease network to the symptoms and adverse events, identifying structure-activity relationships in discovery and designing new drugable molecules. AI has also been used for the prediction of cancer susceptibility (risk assessment), cancer recurrence/local control, and cancer survival. In analysis of clinical trial data, predicted individual patient outcomes for precision medicine, similarity-based machine learning (SBML) has recently been used in clinical trials for oncology and rare disease without the requirement of big data as most ML methods do. The introductory course will cover supervised, unsupervised, semi-supervised, and reinforcement learning methods, and swarm and evolutionary intelligences. It aims at conceptual clarity and mathematical simplicity. Provide R code for some of the supervised learning methods and discussion case studies.
### DAY 2 | TUESDAY, AUGUST 27, 2019

#### MAIN CONFERENCE

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<td>8:45-9:30AM</td>
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<td>9:30-10:15AM</td>
<td>PLENARY SESSION I</td>
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#### WELCOME REMARKS

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<tr>
<th>Speaker</th>
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<tr>
<td>Jie Chen</td>
<td>Merck Sharp &amp; Dohme Corp.</td>
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<td>Toshimitsu Hamasaki</td>
<td>National Cerebral and Cardiovascular Center</td>
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<td>Satoshi Morita</td>
<td>Kyoto University</td>
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#### OPENING REMARKS

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<tr>
<td>Yasuhiro Fujiwara</td>
<td>Pharmaceutical and Medical Devices Agency</td>
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<td>Yasuo Ohashi</td>
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#### PLENARY SESSION I

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<tr>
<td>Keynote Speaker</td>
<td>Tze Leung Lai, Stanford University</td>
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<tr>
<td>Adaptive Design of Confirmatory Clinical Trials: Regulatory Perspectives and Recent Advances</td>
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#### REFRESHMENT BREAK

10:15-12:15PM

#### INVITED SESSION IS03

**RECENT DEVELOPMENT AND CHALLENGES IN BIOEQUIVALENT OR BIOSIMILAR ASSESSMENT**

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<tr>
<th>Organizer</th>
<th>National Health Research Institutes</th>
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<tr>
<td>Seung-Ho Kang</td>
<td>Yonsei University</td>
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#### INVITED SESSION IS01

**ENHANCING REGULATORY DECISION MAKING TO SUPPORT DRUG DEVELOPMENT: US FDA PILOT PROGRAMS ON COMPLEX INNOVATIVE DESIGNS AND MODEL-INFORMED DRUG DEVELOPMENT**

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<th>Organizer</th>
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<tr>
<td>Olga V. Marchenko</td>
<td>Bayer</td>
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<td>José Pinheiro</td>
<td>Janssen Research &amp; Development</td>
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#### TOPIC-CONTRIBUTED SESSION TC16

**THE IMPLEMENTATION OF ICH E17 IN ASIAN REGIONS**

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<td>Chin-Fu Hsiao</td>
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<tr>
<td>Promoting the Use of Complex Innovative Trial Designs: An Overview</td>
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<tr>
<td>Dionne L. Price</td>
<td>US Food and Drug Administration</td>
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<tr>
<td>Model-Informed Drug Development at the US Food and Drug Administration: A Perspective on Progress</td>
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<td>Issam Zineh</td>
<td>US Food and Drug Administration</td>
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<td>Panelists</td>
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<tr>
<td>Frank Bretz</td>
<td>Novartis Pharma AG</td>
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<td>Norisuke Kawai</td>
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<td>Dionne L. Price</td>
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<tr>
<td>Martin Posch</td>
<td>Medical University of Vienna</td>
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<td>1:30-3:00PM</td>
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**NEW DEVELOPMENTS FOR STATISTICAL METHODS IN PERSONALIZED MEDICINE**

**Organizer**
Menggang Yu  
University of Wisconsin – Madison

**Chair**
Takashi Sozu  
Tokyo University of Science

**Speakers**
*Diagnosis-Group-Specific Translational Care Program Recommendation for Thirty-Day Rehospitalization Reduction*
Menggang Yu  
University of Wisconsin – Madison

*Comparative Intervention Scoring for Assessing Heterogeneity of Long-term Health System Intervention Effects*
Jared Huling  
Ohio State University

*Change-Point Detection for Infinite Horizon Dynamic Treatment Regimes*
Yair Goldberg  
Technion

*Multi-Category Individualized Treatment Regime Using Outcome Weighted Learning*
Jin Xu  
East China Normal University

**Assessing Overall Treatment Effect Based on Robust Estimation in Multi-Regional Clinical Trials**
Shuhei Kaneko  
Novartis Pharma K.K.

*Robust Estimates of Regional Treatment Effects in Multiregional Randomized Clinical Trial with Ordinal Response*
Chongyang Duan  
Southern Medical University

*Using Cure Rate Models to Characterize Survival Data in Oncology*
Kohinoor Dasgupta  
Novartis Healthcare Pvt. Lmt.

*Design and Analysis of Biosimilarity with an Estimated Margin on Interval Estimations*
Chieh Chiang  
National Health Research Institutes

*Introducing the BGLIMM Procedure for Bayesian Generalized Linear Mixed Models*
Fang Chen  
SAS Institute

**USE OF MACHINE LEARNING AND AI FOR PRECISION MEDICINE IN DRUG DEVELOPMENT**

**Organizer**
Ivan SF Chan  
AbbVie Inc.

**Chair**
Ivan SF Chan  
AbbVie Inc.

**Speakers**
*Subgroup Identification in Precision Medicine*
Xin Huang  
AbbVie Inc.

*Ivan SF Chan*
AbbVie Inc.

*How to Use Machine Learning Algorithms in Clinical Development*
Yoshitake Kitanishi  
Shionogi & Co., LTD.

*Masakazu Fujiwara*
Shionogi & Co., LTD.

*The Future Is Now, but Where We Should Focus*
Haoda Fu  
Eli Lilly & Co.

*Estimation and Validation of Regressions for Precision Medicine using Real World Data*
Lu Tian  
Stanford University
1:30-3:00PM INVITED SESSION IS02
ROOM # 510, 5F

STATISTICAL DESIGNS AND CONSIDERATIONS IN EARLY CLINICAL DEVELOPMENT

Organizer
Chin-Fu Hsiao
National Health Research Institutes

Chair
Tong Gao
IQVIA

Speakers
An Adaptive Phase I/II Design
Chin-Fu Hsiao
National Health Research Institutes

Two-stage Phase I/II Designs
Yuh-Ing Chen
National Central University

The Win Ratio: On Interpretation and Handling of Ties
Victoria Chang
AbbVie Stemcentrx

Statistical Design and Analysis of Rare Diseases Clinical Trials
Shein-Chung Chow
Duke University

1:30-3:00PM TOPIC-CONTRIBUTED SESSION TC07
ROOM # 554, 5F

MULTIPlicity ISSUES IN COMPLEX CLINICAL TRIALS

Organizers
Dong Xi
Novartis

Kentaro Sakamaki
Yokohama City University

Chair
Ying Lu
Stanford University

Speakers
An Enhanced Mixture Method for Constructing Gatekeeping Procedures in Clinical Trials
Thomas Brechenmacher
IQVIA Japan

Group Sequential Designs for Clinical Trials with Multiple Survival Endpoints
Kentaro Sakamaki
Yokohama City University

Practical Strategies for Testing Co-primary Endpoints in Group-sequential Clinical Trials
Koko Asakura
National Cerebral and Cardiovascular Center

A Case Study of Refining Testing Strategy Using Graphical Approach
Naoko Kataoka
Novartis Japan K.K.

1:30-3:00PM TOPIC-CONTRIBUTED SESSION TC01
ROOM # 555, 5F

BIOSTATISTICIAN ROLE IN INNOVATIVE TRIAL DESIGN IN THE NEW ERA OF DRUG DEVELOPMENT

Organizer
Summer Xia
Novartis

Chair
Valerie L. Durkalski-Mauldin
Medical University of South Carolina

Speakers
Improving the Assessment of Probability of Success in Late Stage Drug Development
Lisa Hampson
Novartis

A Statistical Framework for Quantitative Decision Making in Early Clinical Development
Weidong Zhang
Pfizer Inc.

Comparison of Frameworks for Tipping Point Analyses
Summer Xia
Novartis

Dynamic Bayesian Decision Making in Early Phase Trials Using Historical Information
Fan Xia
BeiGene Ltd.

1:30-5:00PM IN-CONFERENCE WORKSHOP I
ROOM #509, 5F

INNOVATIVE AND FLEXIBLE DESIGNS FOR CLINICAL TRIALS IN THE ERA OF PRECISION MEDICINE

Organizer
Toshimitsu Hamasaki
National Cerebral and Cardiovascular Center

Moderator
H.M. James Hung
US Food and Drug Administration

Instructors
James Wason
Newcastle University

Florian Klingmüller
Austrian Medicines & Medical Devices Agency

3:30 -5:00PM INVITED SESSION IS19
SAKURA, 1F

INDUSTRY LEADERSHIP PANEL DISCUSSION

Organizers
Jie Chen
Merck Sharp & Dohme Corp

Haiyan Xu
Janssen Research & Development

Chair
Jie Chen
Merck Sharp & Dohme Corp
### INVITED SESSION IS14

**Room #510, 5F**

#### INNOVATIVE APPROACHES FOR TRIAL DESIGN AND ANALYSIS

**Organizer**  
Jie Chen  
Merck Sharp & Dohme Corp.

**Chair**  
Frank Fan  
Novartis

**Speakers**

- **BMA-Mod: A Bayesian Model Averaging Strategy for Determining Dose-Response Relationships in the Presence of Model Uncertainty**  
  A. Lawrence Gould  
  Merck Sharp & Dohme Corp.

- **Practical Considerations of Sequential Analysis of the Restricted Mean Survival Time for Immuno-Oncology Trials**  
  Ying Lu  
  Stanford University

- **BOP2: Bayesian Optimal Design for Phase II Clinical Trials with Binary, Co-primary and Other Complex Endpoints**  
  Ying Yan  
  University of Texas MD Anderson Cancer Center

- **Estimand - An Alternative Implementation of the While on Treatment Strategy**  
  Naitee Ting  
  Boehringer-Ingelheim Pharmaceuticals, Inc.

### TOPIC-CONTRIBUTED SESSION TC09

**Room #555, 5F**

#### ADVERSE EVENTS IN CLINICAL TRIALS AND POST-MARKETING PHARMACOVIGILANCE

**Organizers**  
Tim Friede  
University Medical Center Göttingen  
Brenda Crowe  
Eli Lilly & Co.

**Chair**  
Tim Friede  
University Medical Center Göttingen

**Speakers**

- **Rationale and First Results from the SAVVY Project**  
  Regina Stegherr  
  University of Ulm

- **A Bayesian Meta-analytic Approach for Safety Signal Detection in Randomized Clinical Trials**  
  Motoi Odani  
  Ono Pharmaceutical Co., Ltd.

- **Modified Bayesian Confidence Propagation Neural Network for Signal Detection Analysis**  
  Keisuke Tada  
  Sanofi. K.K.

**Discussant**  
Yuki Ando  
Pharmaceutical and Medical Devices Agency  
Satoshi Hattori  
Osaka University Graduate School of Medicine

### TOPIC-CONTRIBUTED SESSION TC11

**Room #554, 5F**

#### ADVANCES IN DESIGN AND ANALYSIS OF CLINICAL STUDIES THAT INCORPORATE INTERNAL AND EXTERNAL DATA SOURCES

**Organizer**  
Yang Song  
Vertex Pharmaceuticals Incorporated

**Chair**  
Tony Guo  
BeiGene Ltd.
DAY 3 | WEDNESDAY, AUGUST 28, 2019

MAIN CONFERENCE

8:30AM- CONFERENCE REGISTRATION, RECEPTION, MAIN ENTERANCE, 1F

8:45-10:15AM PLENARY SESSION II SAKURA, 1F

Chair
Satoshi Morita
Kyoto University

Keynote Speakers
Open Science, Data Sharing, and Reproducibility: What’s All the Fuss About and Why Should Statisticians Care and Engage in the Journey?
Frank W. Rockhold
Duke University

Recent Advances in Regulatory Statistics in Imaging Diagnostics and Imaging Precision Medicine
Sue-Jane Wang
US Food and Drug Administration

10:15-10:45AM REFRESHMENT BREAK

10:45AM -12:15PM INVITED SESSION IS12

SOME INNOVATIVE APPROACHES TO TRIALS DESIGNS AND MEDICAL PRODUCT DEVELOPMENT

Organizers
Toshimitsu Hamasaki
National Cerebral and Cardiovascular Center
H.M. James Hung
US Food and Drug Administration

Chair
Toshimitsu Hamasaki
National Cerebral and Cardiovascular Center

Speakers
Master Protocol Design Considerations in Settings Where Randomized Controlled Trials Are Not Feasible
Sue-Jane Wang
US Food and Drug Administration

Sequential, Multiple-Assignment, Randomized Trials for COMparing Personalized Antibiotic Strategies (SMART-COMPASS)
Scott R. Evans
George Washington University

Missing data treatment in Sequential Parallel Comparison Design Studies
Gheorghe Doros
Boston University

Discussant
H.M. James Hung
US Food and Drug Administration

10:45AM -12:15PM INVITED SESSION IS09

STATISTICAL ISSUES AND METHODS FOR VACCINE DEVELOPMENT

Organizers
Frank Liu
Merck Sharp & Dohme Corp.
Jie Chen
Merck Sharp & Dohme Corp.

Chair
Frank Liu
Merck Sharp & Dohme Corp.

Speakers
Potential Study Designs for HIV Vaccine Efficacy Trials in the Era of an Expanding Portfolio of Non-Vaccine HIV Prevention Strategies
Holly Janes
Fred Hutchinson Cancer Research Center

Assessment of Correlate of Risk and Protection in Tetravalent Dengue Vaccine Efficacy Trials
Jing Jin
Sanofi R&D Beijing

Quantitative Decision-Making Framework for Phase III Vaccine Efficacy Trial
Wenji Pu
GlaxoSmithKline Plc.

Statistical Challenges of an Immunobridging Approach to Assess Clinical Benefit as the Basis for Licensure of a Prophylactic Ebola Vaccine
Bart Spiessens
Janssen Research & Development

Discussant
Wenquan Wang
Sanofi Pasteur

10:45AM -12:15PM TOPIC-CONTRIBUTED SESSION TC17

INNOVATIVE AND STRATEGIC THINKING IN PEDIATRIC TRIAL AND EARLY DRUG DEVELOPMENT BASED ON BAYESIAN HIERARCHICAL MODEL

Organizer
Binqi Ye
Boehringer Ingelheim, China

Chair
Binqi Ye
Boehringer Ingelheim, China

Speakers
Leveraging Available Information in Pediatric Trial Designs and Analyses using Bayesian Modeling
Susan Wang
Boehringer-Ingelheim Pharmaceuticals, Inc.

A Robust Bayesian Approach for Using Co-data in Phase I Oncology Trials: An Application to Bridging Studies
Haiyan Zheng
Newcastle University
Introduction to the Bayesian Early-Phase Seamless Transformation (BEST) Platform Design
Jiaying Lyu
Fudan University

A Case study: A Bayesian Type Adaptive Dose Finding in a Clinical Trial with Multiple Agents
Wenxiao Zhou
Beigene, Ltd.

10:45AM -12:15PM  TOPIC-CONTRIBUTED SESSION TC08
ROOM #555, 5F

INNOVATIVE METHODS TO SUPPORT THE DEVELOPMENT OF NEW PEDIATRIC MEDICINES

Organizer
Lisa Hampson
Novartis Pharma AG

Chair
Lisa Hampson
Novartis Pharma AG

Speakers
A Clinician’s View of the Importance of Pediatric Extrapolation
Robert M. Nelson
Johnson & Johnson

Extrapolating Information from Adult to Paediatric Studies: a Comparison of Methods
Juan Jose Abellan-Andres
GlaxoSmithKline

Current Situation of Pediatric Drug Development and Evolving Discussion on Extrapolation in Japan
Hidefumi Nakamura
National Center for Child Health and Development

The Challenge of Implementing Bayesian Methods in Paediatric Studies: Our Experience at UCB
Rosalind J. Walley
UCB Pharma

10:45AM -12:15PM  TOPIC-CONTRIBUTED SESSION TC14
ROOM #555, 5F

OTHER WAY FORWARD FOR DESIGN, SUMMARY MEASURES, AND ESTIMANDS IN SURVIVAL CLINICAL TRIALS

Organizers
Shogo Nomura
National Cancer Center
Tomohiro Shinozaki
Tokyo University of Science

Chair
Yuko Y. Palesch
Medical University of South Caronia

Speakers
Hazards of Proportional Hazards Assumption and Small Number of Events: Actual Clinical Problems in Oncology and Alternative Ideas
Shogo Nomura
National Cancer Center

Using Restricted Mean Survival Time in a Non-Inferiority Trial
Isao Yokota
Hokkaido University

Pairwise Pseudolikelihood Estimation of an Average Hazard Ratio under Nonproportional Hazards
Tomohiro Shinozaki
Tokyo University of Science

A Design Consideration on RCTs Assessing Superiority of Immuno-oncology Agents: Sample Size Determination and Monitoring
Takahiro Hasegawa
Shionogi & Co., Ltd.

12:15-1:30PM  LUNCH BREAK
SWAN, 1F

1:30 -3:00PM  INVITED SESSION IS04
SAKURA, 1F

RETHINKING ESTIMATORS WITHIN THE ESTIMAND FRAMEWORK

Organizer
Dong Xi
Novartis

Chair
Frank Bretz
Novartis Pharma AG

Speakers
Semiparametric Copula-based Analysis for Treatment Effects in the Presence of Treatment Switching
Chia-Hui Huang
National Taipei University

What Estimands Do Recurrent Event Data Approaches Estimate When Terminal Event Exists?
Jiawei Wei
Novartis Pharma AG

Mixture of Multivariate t Linear Mixed Models with Missing Information
Tzy-Chy Lin
Taiwan Center for Drug Evaluation

Estimands and Estimation of Population-Averaged Parameters in Randomized Clinical Trials
Tosiya Sato
Kyoto University School of Public Health

1:30 -3:00PM  INVITED SESSION IS07
ROOM #510, 5F

ADAPTIVE DESIGNS FOR SMALL POPULATION CLINICAL TRIALS

Organizer
Frank Bretz
Novartis Pharma AG

Chair
Chin-Fu Hsiao
National Health Research Institutes

Speakers
A Bayesian Nonparametric Utility-Based Design for Comparing Treatments to Resolve Air Leaks After Lung Surgery
Peter Müller
University of Texas at Austin
### Clinical Trial Designs with Data-Driven Selection of Subgroups
Franz König
Medical University of Vienna

### Increasing Evidence Designs in Small Population Clinical Trials
Andreas Faldum
University of Münster

### Experiences with Adaptive Design Clinical Trials for Medical Device Development
Toshimitsu Hamasaki
National Cerebral and Cardiovascular Center

Discussant
Yuki Ando
Pharmaceuticals and Medical Devices Agency

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<td><strong>MACHINE LEARNING METHODS FOR IMPROVING CLINICAL DECISION MAKING AND PRECISION HEALTH CARE</strong></td>
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<td>Organizer</td>
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<td>Chair</td>
<td>Haoda Fu, Eli Lilly &amp; Co.</td>
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<td>Speakers</td>
<td>Learning Optimal Individualized Treatment Strategies from Randomized Trials and Electronic Health Records</td>
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<td>Yuanjia Wang, Columbia University</td>
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<td>Application of Machine Learning to Real World Data</td>
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<td>Joint Variable Screening in Accelerated Failure Time Models</td>
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<td>Jinfeng Xu, University of Hong Kong</td>
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<td>Discussant</td>
<td>Ying Lu, Stanford University</td>
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<td><strong>BAYESIAN APPROACHES FOR THE UTILIZATION OF CO-DATA FOR EFFICIENT DRUG DEVELOPMENT</strong></td>
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<tr>
<td>Organizer</td>
<td>Tomoyuki Kakizume, Novartis Pharma K.K.</td>
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<tr>
<td>Chair</td>
<td>Lisa Hampson, Novartis Pharma AG</td>
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<tr>
<td>Speakers</td>
<td>Bayesian Dose-Finding Phase I Trial Design Incorporating Historical Data from a Preceding Trial</td>
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<td>Kentaro Takeda, Astellas Global Development Inc.</td>
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<tr>
<td>Selection of Robust Meta-Analytic-Predictive Priors based on the Evaluation of Operating Characteristics for Proof-of-Concept Studies</td>
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<tr>
<td>Organizer</td>
<td>Yi Cheng, China Novartis Institutes for Biomedical Research Co., Ltd</td>
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<td>Chair</td>
<td>Akihiro Hirakawa, The University of Tokyo</td>
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<tr>
<td>Speakers</td>
<td>Use of Co-data for Interim Analysis in Clinical Trials</td>
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<td></td>
<td>Tomoyuki Kakizume, Novartis Pharma K.K.</td>
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<tr>
<th>Time</th>
<th>In-Conference Workshop II</th>
<th>Room</th>
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<tr>
<td>3:00-3:30PM</td>
<td><strong>REFRESHMENT BREAK</strong></td>
<td>#509, 5F</td>
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<tr>
<td>3:30 -5:00PM</td>
<td><strong>INVITED SESSION IS18</strong></td>
<td>SAKURA, 1F</td>
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<tr>
<td><strong>INFERENCE AND DECISION MAKING FOR CONTEMPORARY DRUG DEVELOPMENT AND APPROVAL</strong></td>
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<tr>
<td>Organizer</td>
<td>Satoshi Morita, Kyoto University</td>
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<tr>
<td>Chair</td>
<td>Satoshi Morita, Kyoto University</td>
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<tr>
<td>Speakers</td>
<td>J. Jack Lee, University of Texas MD Anderson Cancer Center</td>
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<td>Update Your Prior: Use of Bayesian Methods in Drug Development</td>
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<td>Martin Posch, Medical University of Vienna</td>
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<td>Panelists</td>
<td>Andy Grieve, UCB Pharma</td>
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<td>J. Jack Lee, University of Texas MD Anderson Cancer Center</td>
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<td>Martin Posch, Medical University of Vienna</td>
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### RECENT DEVELOPMENT ON MISSING DATA ISSUES UNDER ICH E9 (R1) ESTIMAND FRAMEWORK

**Organizers**
Frank Liu  
Merck Sharp & Dohme Corp.

Jie Chen  
Merck Sharp & Dohme Corp.

**Chair**
Jie Chen  
Merck Sharp & Dohme Corp.

**Speakers**
- Principal Stratification: A Strategy for Intercurrent Events that Lead to Unascertainable Outcomes or Confounding  
  Bohdana Ratitch  
  Eli Lilly & Co.
- Post E9 (R1) World: Points to Consider from Industry’s Point of View  
  Satoru Tsuchiya  
  Sumitomo Dainippon Pharma, Co., Ltd.
- Implementation of Estimand Concept in Immunology Disease Area  
  Na Hu  
  Boehringer-Ingelheim Inc., Shanghai, China.
- On Statistical Methods for Some Common Hypothetical Estimands in Clinical Trials  
  Frank Liu  
  Merck Sharp & Dohme Corp.

### DATA SCIENCE FOR MEDICINE

**Organizer**
Lisa Hampson  
Novartis Pharma AG

**Chair**
Lisa Hampson  
Novartis Pharma AG

**Speakers**
- Integrative Analysis of Genetic, Transcriptomic and Functional Data in Identification of Potential Driver Genes in Tumors  
  Chen Suo  
  Fudan University
- A Bivariate Shared Parameter Model for Intensive Longitudinal Data Subject to Informative Missing  
  Xiaolei Lin  
  University of Chicago
- Data Processing and Data Analysis with Real World Big Data  
  Kazuo Ishii  
  Kurume University
- Sequential Adaptive Subject and Variable Selection for Generalized Estimating Equation Methods  
  Yuan-Chin Chang  
  Institute of Statistical Science, Academia Sinica
DAY 4 | THURSDAY, AUGUST 29, 2019

MAIN CONFERENCE

8:30AM- CONFERENCE REGISTRATION, RECEPTION, MAIN ENTERANCE, 1F

8:45-10:15AM PLENARY SESSION III SAKURA, 1F

Chair
Jie Chen
Merck Sharp & Dohme Corp.

Keynote Speakers
Statistical Innovation and Contribution Today. Will We Need Statisticians Tomorrow?
Robert J. Hemmings
Consilium Salmonson and Hemmings

Regulatory Reform and Challenges of the Japanese Pharmaceutical Regulations
Daisaku Sato
Pharmaceuticals and Medical Devices Agency

10:15-10:45AM REFRESHMENT BREAK

10:45AM -12:15PM INVITED SESSION IS05 SAKURA, 1F

DEMYSTIFYING ESTIMANDS FOR LIFE HISTORY PROCESSES

Organizer
Jiawei Wei
Novartis

Chair
Jiawei Wei
Novartis

Speakers
Recurrent Event Analysis Yielding Estimands with a Causal Interpretation
Richard J. Cook
University of Waterloo

Assessment of a Treatment Effect for Recurrent Event Data in the Presence of a Terminal Event
Philip Hougaard
Lundbeck

Efficiency Comparison of Time-To-First and Recurrent Event Analyses with A Focus on Heart Failure Trials
Arno Fritsch
Bayer

Causal Mediation of Semi-competing Risks
Yen-Tsung Huang
Institute of Statistical Science, Academia Sinica

Discussant
Mey Wang
Taiwan Center for Drug Evaluation

10:45AM -12:15PM INVITED SESSION IS11 ROOM #510, 5F

METHODOLOGY RESEARCH FOR BIOPHARMACEUTICAL INDUSTRY

Organizers
Frank Liu
Merck Sharp & Dohme Corp.
Jie Chen
Merck Sharp & Dohme Corp.

Chair
Frank Liu
Merck Sharp & Dohme Corp.

Panelists
Frank Bretz
Novartis Pharma AG
Ivan SF Chan
AbbVie Inc.
José Pinheiro
Janssen Research & Development
A. Lawrence Gould
Merck Sharp & Dohme Corp.

10:45AM -12:15PM INVITED SESSION IS15 ROOM #554, 5F

ISSUES IN ADAPTIVE AND COMPLEX CLINICAL TRIAL DESIGNS

Organizer
Franz König
Medical University of Vienna

Chairs
Franz König
Medical University of Vienna
Martin Posch
Medical University of Vienna

Speakers
Patient-Centred Clinical Trial Designs to Support Precision Healthcare
Andrew P. Grieve
UCB Pharma

Bias and Type I Error of Promising Zone Designs Testing One or More Hypotheses
Florian Klingmüeller
Austrian Medicines & Medical Devices Agency

Adapting Study Designs Based on All Available Information from Baseline up to the Primary Endpoint: Is It Worth the Effort?
An Vandebosch
Janssen Research and Development

From Adaptive Designs to Complex Innovative Trials: What Has Changed?
Yannis Jemiai
Cytel

When and How Should Precision Medicine Trials Be Adaptive?
James Wason
Newcastle University
REGULATORY SUBMISSIONS IN ELECTRONIC FORMAT

Organizer
Hong Qi
Merck Sharp & Dohme Corp.

Chair
Mary N. Varughese
Merck Sharp & Dohme Corp.

Speakers
Study Data Technical Rejection Criteria, Validation, and Self-Check Worksheet
Ethan Chen
US Food and Drug Administration

Differences between FDA and PMDA for E-data Submission
Masato Suzuki
MSD K.K.

NMPA Reform and Keytruda Filing in China
Jing Zhang
Merck Sharp & Dohme Corp.

Information Requests during an FDA Review
Hong Qi
Merck Sharp & Dohme Corp.

REAL-WORLD DATA: IMPLICATIONS AND CHALLENGES FOR MEDICAL PRODUCT DEVELOPMENT

Organizers
Shogo Nomura
National Cancer Center

Taro Shibata
National Cancer Center

Hisateru Tachimori
National Center of Neurology and Psychiatry

Chair
Toshimitsu Hamasaki
National Cerebral and Cardiovascular Center

Speakers
Validity and Reliability of Real-World Data for Medical Product Development
Taro Shibata
National Cancer Center

Statistical Methods in Use of Real-world Data in Medical Product Development: Propensity-Based Methods
Hisateru Tachimori
National Center of Neurology and Psychiatry

Instrumental Variable Analysis in Clinical Trials Incorporating Patient Registry Databases as Controls
Yukari Uemura
The University of Tokyo

Discussants
Scott R. Evans
George Washington University

ONCOLOGY TRIALS WITH NON-PROPORTIONAL HAZARDS

Organizers
Franz König
Medical University of Vienna

Martin Posch
Medical University of Vienna

Chairs
Franz König
Medical University of Vienna

Martin Posch
Medical University of Vienna

Speakers
A Modestly Weighted Logrank Test
Carl-Fredrik Burman
AstraZeneca R&D Gothenburg

Design Challenges in the Era beyond Proportional Hazard Assumptions
Armin Schueler
Merck KGaA

The Consideration of Non-Proportional Hazards when Choosing a Randomization Procedure in Survival Studies
Viviane Rückbeil
RWTH Aachen University

Ralf-Dieter Hilgers
RWTH Aachen University

Evaluating the Impact of Delayed Effects in Oncology Confirmatory Clinical Trials
Jose Luis Jimenez
Novartis Pharma AG

STATISTICAL METHODS IN DRUG DEVELOPMENT

Organizer
Hongyuan Cao
Florida State University

Chair
Guosheng Yin
The University of Hong Kong

Speakers
Accounting for Pilot Study Uncertainty in Sample Size Determination of Randomized Controlled Trials
Jie Chen
Merck Sharp & Dohme Corp.

When Convention Meets Practicality: Pooled Analysis Testing under the Two-Study Paradigm
Frank Bretz
Novartis Pharma AG
Roles of Frailty in Modelling Competing-Risks Data: Assessing Treatment Effect
Il Do Ha
Pukyong National University

Accelerating Clinical Development by Incorporating Historical Controls in Proof of Concept Studies
Ivan SF Chan
AbbVie Inc.

1:30 - 3:00 PM INVITED SESSION IS17
ROOM #554, 5F

STATISTICAL METHODOLOGY FOR THE COMPARATIVE ASSESSMENT OF QUALITY ATTRIBUTES
Organizer
Florian Klinglmüeller
Austrian Medicines & Medical Devices Agency
Chair
Florian Klinglmüeller
Austrian Medicines & Medical Devices Agency
Speakers
Can Statistical Inference Improve the (Bio-) Similarity Exercise?
Kit C.B. Roes
UMC Utrecht

Similarity Assessment of Quality Attributes: The Calculation of Operating Characteristics to Compare Different Statistical Approaches
Thomas Stangler
Novartis Pharma AG.

Analytical Similarity and Comparability: What is the Question?
Bruno E. Boulanger
PharmaLex Belgium

Discussant
Shein-Chung Chow
Duke University

1:30 - 3:00 PM TOPIC-CONTRIBUTED SESSION TC12
ROOM #555, 5F

OPPORTUNITIES AND CHALLENGES FOR THE USE OF PARAMETRIC LONGITUDINAL MODELLING IN DRUG DEVELOPMENT
Organizer
Tobias Mielke
Janssen-Cilag GmbH
Chair
José Pinheiro
Janssen Research & Development
Speakers
Opportunities and Pitfalls in the use of Nonlinear Mixed-Effects Models for Leveraging Longitudinal Information in Drug Development
Andrew C. Hooker
Uppsala University

Quantifying and Addressing Model Uncertainty on Longitudinal Data in the Design and Analysis of Clinical Studies
Tobias Mielke
Janssen Pharmaceuticals

Leveraging Parametric Longitudinal Modeling to Improve Drug Development Efficiency
Olga V. Marchenko
Bayer

Calibrated Predictions of Survival based on Tumor Size Dynamics and New Lesions in Lung Cancer via Joint Modeling Approach
Katsuomi Ichikawa
AstraZeneca K.K.

Discussant
Dionne L. Price
US Food and Drug Administration

1:30 - 3:00 PM TOPIC-CONTRIBUTED SESSION TC06
ROOM #509, 5F

UTILIZATION OF SUBGROUP AND CAUSAL INFERENCE TOWARDS PERSONALIZED MEDICINE
Organizer
Ming Tan
Georgetown University
Chair
Chiung-Yu Huang
University of California San Francisco
Speakers
Identifying Targeted Patients Population in Major Depressive Disorder by Enhanced Enrichment Design
Peter Zhang
Otsuka Development & Commercialization Inc.

Double-Robust Inference for Differences in Restricted Mean Lifetimes Using Pseudo-Observations
Sangbum Choi
Korea University

Fortified Robust Estimate of Rx Effects in Nonrandomized External Control Trial, Subgroup and RWD Analysis
Ming Tan
Georgetown University

3:00-3:30PM REFRESHMENT BREAK

REGULATORY SYMPOSIUM

3:30 - 5:00PM REGULATORY SESSION RS03
SAKURA, 1F

ICH-E17: HOW TO IMPLEMENT MULTI-REGIONAL CLINICAL TRIALS BASED ON THE GUIDANCE?
Organizer
Yuki Ando
Pharmaceutical and Medical Devices Agency
Chair
Hideharu Yamamoto
Chugai Pharmaceutical Co., Ltd.
Speakers
Osamu Komiyama
Pfizer Japan Inc.
TBD
William W. Wang
Merck & Co. Inc.
TBD
Hiroyuki Sato
Pharmaceutical and Medical Devices Agency

3:30 - 5:00 PM
REGULATORY SESSION RS01
ROOM #510, 5F

HARMONIZATION OF MODEL-INFORMED DRUG DEVELOPMENT APPROACHES IN REGULATORY REVIEW AND DECISIONS

Organizers
Olga V. Marchenko
Bayer
José Pinheiro
Janssen Research & Development

Chair
Olga V. Marchenko
Bayer

Speaker
Model Informed Drug Development Good Practices: An Industry Perspective
Scott F. Marshall
Pfizer R&D LTD

Panelists
Yuki Ando
Pharmaceutical and Medical Devices Agency
Robert J. Hemmings
Consilium Salmonson and Hemmings
José Pinheiro
Janssen Research & Development
Hiromi Tanii
Janssen
Issam Zineh
US Food and Drug Administration

7:00 - 9:00 PM
CONFERENCE DINNER
FUNATSURU KYOTO KAMOGAWA RESORT
DAY 5 | FRIDAY, AUGUST 30, 2019

8:30AM - CONFERENCE REGISTRATION, RECEPTION, MAIN ENTRANCE, 1F

REGULATORY SYMPOSIUM

8:45-10:15AM REGULATORY SESSION RS04
SAKURA, 1F

ICH-E9(R1)- GUIDANCE CONCEPT AND IMPLEMENTATION

Organizer
Yuki Ando
Pharmaceutical and Medical Devices Agency

Chair
Satoru Tsuchiya
Sumitomo Dainippon Pharma Co., Ltd

Speakers
TBD
Robert J. Hemmings
Consilium Salmonson and Hemmings

TBD
Hideki Suganami
Kowa Pharmaceutical Co.

TBD
Yuki Ando
Pharmaceutical and Medical Devices Agency

10:15-10:30AM STRETCH BREAK

10:30AM - 12:00PM REGULATORY SESSION RS02
SAKURA, 1F

ESTIMAND, MISSING DATA, AND SENSITIVITY ANALYSIS

Organizer
Mey Wang
Taiwan Center for Drug Evaluation

Chairs
Frank Bretz
Novartis Pharma AG

Panelists
Yuki Ando
Pharmaceutical and Medical Devices Agency

Robert J. Hemmings
Consilium Salmonson and Hemmings

Yen-Tsung Huang
Institutes of Statistical Sickness, Academia Sinica

M.H. James Hung
US Food and Drug Administration

Hideki Suganami
Kowa Pharmaceutical Co.

Mey Wang
Taiwan Center for Drug Evaluation

10:15-10:30AM STRETCH BREAK

10:30AM - 12:00PM CONTRIBUTED SESSION CS03
ROOM #510, 5F

Chair
Akira Wakana
MSD K.K.

Speakers
A Novel Bayesian Analysis of Dose-Response Relationship with Dynamic Generalized Linear Models in Oncology Phase I Study Using Power Priors to Incorporate Historical Data

Joji Mori
Eli Lilly Japan K.K.

Adaptive Study Design using Model Based Dose Escalation with Two Pharmacodynamical Endpoints

Dion Chen
Janssen Research and Development

Sample Size and Power Calculations for Reference-Based Imputation

Kimitoshi Ikeda
AbbVie GK
Bayesian Random-Effects Meta-Analysis of Phase I Dose-Finding Studies
Moreno Ursino
INSERM
Blinded Sample Size Re-estimation with Survival Data
Ryuji Uozumi
Kyoto University

<table>
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<th>Time</th>
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<tr>
<td>12:00-12:15PM</td>
<td>CLOSING</td>
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POSTERS

#50005: A Powerful Method to Meta-Analysis for Testing no Treatment Effects (Cancelled)
Kuang Fu Cheng
Asia University

#50029: Concentration-QTc Analysis for Phase 1 Studies without a Placebo Arm
Yasushi Orihashi
Tokai University School of Medicine

#50030: Model Selection for Semiparametric Marginal Mean Regression Accounting for Within-Cluster Subsampling Variability and Informative Cluster Size
Chung Wei Shen
National Chung Cheng University

#50031: Bayesian Flexible Modeling the Odds under Case II Interval-Censored Data
Li-Chu Chien
Kaohsiung Medical University

#50032: Role of Baseline Covariates in ex-Vivo Bioassay for the Assessment of Intrasubject Parallelism
Hideaki Uehara
Tsumura & Co.

#50042: Log-rank Test and Its Handicap Procedure Using Computational Algebraic Statistics
Kotaro Mizuma
Osaka University

#50047: Adaptive Randomization for Multiarm Survival Clinical Trials Using Short-Term Response Information
Yu Mei Chang
Tungnai University

#50049: A Robust Association Test with Multiple Genetic Variants and Covariates
Jen-Yu Lee
Feng Chia University

#50055: Bayesian Model Selection on the Structural Equation Model: An Application to a Longitudinal Myopia Trial
Yi-Fu Wang
National Chung Cheng University

#50056: Statistical Approach with Right-Censored Survival Data for Design and Evaluation in the Multiregional Clinical Trial
Yu-Chieh Zheng
National Health Research Institutes

#50065: Using PMDA Drug Adverse Event Report Database, Study on Collective Background of Adverse Events
Shoko Kamiya
Keio Research Institute at SFC

#50071: The Use of Maximum a Posteriori Estimation for Selecting Dose in Phase I Clinical Trials
Won-Jin Guo
National Health Research Institutes

#50075: Bioequivalence Assessment between Sugar-coated and Film-coated Eperisone Tablets using Reference Replicated Crossover Study for Highly Variable Drug
In-Hwan Baek
Kyungsung University

#50081: Clustering-based Basket Trial Design for Assessing Heterogeneity of Treatment Effect among Strata
Ryo Sadachi
The University of Tokyo

#50087: A Joint Modeling Approach for Predictions of Survival Based on Tumor Dynamics and New Lesions in EGFR Mutation-Positive Non-Small Cell Lung Cancer Patients Treated with Gefitinib or Carboplatin and Paclitaxel
Mario Nagase
AstraZeneca

#50091: Non-Asymptotic Properties and Behaviors for Random-Effects Meta-Analyses When the Number of Studies Is Small
Keisuke Hanada
Kagoshima University

#50098: Comparison of Hazards in Two-Arm Trials with Exponential Distributed Outcomes from the Bayesian Viewpoint
Masaaki Doi
Kyoto University

#50110: Comparison of Bayesian Equivalency Methods for Two Binomial Outcomes Using Bayesian Index
Yohei Kawasaki
Chiba University

#50137: G-estimation of Structural Nested Mean Models for Interval-Censored Data Using Pseudo-Observations
Shiro Tanaka
Kyoto University

#50138: Bayesian Evidence Synthesis and Assessment Techniques across Longitudinal Time Points
Airi Takagi
Tohoku University

#50146: Patient Subtypes Associated with Medication Persistence Using Latent Class Analysis
Shiori Nishimura
Keio University

#50146: A Robust Covariate Selection Method for the Limited Sampling Design in Population Pharmacokinetic Analysis
Asuka Nemoto
Teikyo University Graduate School of Public Health

#50163: Mediation and interaction of age, follicle stimulating hormone(FSH) and anti-müllerian hormone (AMH) on in vitro fertilization pregnancy
Han-Chih Hsieh
Institute of Statistical Science, Academia Sinica

#50164: Semiparametric Causal Mediation Modeling of Semi-Competing Risks
Ju-Sheng Hong
Institute of Statistical Science, Academia Sinica

#50165: A Novel Extension of Keyboard Design: MT-Keyboard with Multiple Toxicity Constraints
Fangrong Yan
China Pharmaceutical University

#50166: Causal Mediation of Chronic Hepatitis B or C on Mortality through Liver Cancer Incidence
Yi-Ting Huang
Institute of Statistical Science, Academia Sinica