The 6th International Symposium on Biopharmaceutical Statistics

Statistical Innovation and Contribution in the Era of Precision Healthcare

Program Book
August 19, 2019

Kyoto International Conference Center, Kyoto, Japan
Short course: August 26 | Main Conference: August 27-29, 2019

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ISBS2019 | Kyoto International Conference Center | August 26-30, 2019
Overview Missing data are inevitable and post many issues and challenges 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 methods, here we often call it as data imputation methods based on the MAR assumption. 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, 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.

CONFIRMATORY ADAPTIVE DESIGNS WITH MULTIPLE OBJECTIVES: METHODS AND REGULATORY EXPERIENCES
PRE-REGISTRATION REQUIRED

Sponsored by

Instructors Franz König, Medical University of Vienna; Martin Posch, Medical University of Vienna; H.M. James Hung, US Food and Drug Administration; Sue-Jane Wang, US Food and Drug Administration; Frank Bretz, Novartis Pharma AG

Overview Adaptive (flexible) designs allow for mid-course design adaptations based on interim data without compromising the overall type I error rate. Examples of design adaptations are the adjustment of sample sizes or the number and timing of interim analyses. These design parameters may be adapted depending on interim estimates of the variance, the treatment effect and safety parameters. An important field of application of the adaptive design methodology are clinical trials with several treatment arms, where promising treatments can be selected at an interim analysis. Using adaptive multiple test procedures the type I error rate can be controlled even if the selection rule, the number of selected treatments or the final sample sizes are not prefixed. Adaptive multiple testing procedures can also be used in adaptive designs with the option of population enrichment. In such designs a sub population may be selected in an interim analysis and further recruitment of patients is restricted to the selected subgroup. In the past few years adaptations proposed in regulatory applications may involve a hybrid or a complex form of various design features, such as reasonably likely surrogate or predictive biomarker, external control. This short course will share with some regulatory experiences in such adaptive designs in cardiovascular, renal, CNS and imaging drug trials.

PRE-REGISTRATION REQUIRED

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 need. 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.

NOVEL ADAPTIVE CLINICAL TRIAL DESIGNS FOR IMMUNOTHERAPY AND MODERN DRUG DEVELOPMENT

Instructors Cong Chen, Merck Sharp & Dohme Corp.; Guosheng Yin, The 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 1 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.

PART I: The effects of interventions are multidimensional. Use of more than one outcome offers an attractive design feature in clinical trials as they capture more complete characterization of the benefit and risk of an intervention and provide more informative intervention comparisons. The first part of the tutorial will focus on design and analysis of clinical trials with such multiple outcomes. The part I of the tutorial will focus on methods for clinical trial designs evaluating efficacy of two interventions with multiple primary endpoints, especially co-primary endpoints. “Co-primary” means that a trial is designed to evaluate if the test intervention is superior (or noninferior) to the control on all primary endpoints. We describe methods for power and sample size calculations in clinical trials with multiple endpoints including recently developed approaches. We include real clinical trial examples to illustrate the concepts and to help participants apply the methods in practice, and illustrate how to implement the methods using standard statistical software including R and SAS.

PART 2: In the future, clinical trials will have an increased emphasis on pragmatism, providing a practical description of the effects of new treatments in realistic clinical settings. Accomplishing pragmatism requires better summaries of the totality of the evidence that allow for informed benefit:risk decision-making and in a way that clinical trials consumers—patients, physicians, insurers—find transparent. The current approach to the analysis of clinical trials is to analyze efficacy and safety separately and then combine these analyses into a benefit:risk assessment. Many assume that this will effectively describe the impact on patients. But this approach is suboptimal for evaluating the totality of effects on patients. In part II of the tutorial, we will describe a broad vision for the future of clinical trials consistent with increased pragmatism. Greater focus on using outcomes to analyze patients rather than patients to analyze outcomes particularly in late-phase/stage clinical trials is an important part of this vision. We discuss the desirability of outcome ranking (DOOR) and the partial credit strategy for design and analysis of clinical trials based on benefit:risk assessment. These strategies involve utilizing composite benefit:risk endpoints with a goal of understanding how to analyze one patient before trying to figure out how to analyze many. With a desire to measure and weigh outcomes that are most important from the patient’s perspective, we discuss using patients as a resource to inform analyses.

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.

1:45-5:00PM SHORT COURSE F
ROOM 665, 6F

HOT TOPICS IN CLINICAL TRIALS: MULTIPLE OUTCOMES AND BENEFIT:RISK
PRE-REGISTRATION REQUIRED
Sponsored by National Cerebral and Cardiovascular Center
Instructors Scott R. Evans, George Washington University; Toshimitsu Hamasaki, National Cerebral and Cardiovascular Center
Overview We discuss two hot topics in clinical trials. In Part I we discuss the design and analysis of clinical trials with multiple outcomes. In Part II, we discuss benefit:risk evaluation in clinical trials by using outcomes to analyze patient rather than patients to analyze outcomes.

PART I: The effects of interventions are multidimensional. Use of more than one outcome offers an attractive design feature in clinical trials as they capture more complete characterization of the benefit and risk of an intervention and provide more informative intervention comparisons. The tutorial will focus on design and analysis of clinical trials with such multiple outcomes. The first part of the tutorial will focus on methods for clinical trial
DAY 2 | TUESDAY, AUGUST 27, 2019

MAIN CONFERENCE

8:30AM-4:30PM REGISTRATION
RECEPTION, MAIN ENTRANCE, 1F

8:45-9:30AM OPENING SESSION
SAKURA, 1F

WELCOME REMARKS
Jie Chen
Merck Sharp & Dohme Corp.
Toshimitsu Hamasaki
National Cerebral and Cardiovascular Center
Satoshi Morita
Kyoto University

OPENING REMARKS
Yasuhiro Fujiwara
Pharmaceutical and Medical Devices Agency
Yasuo Ohashi
Chuo University

9:30-10:15AM PLENARY SESSION I
SAKURA, 1F

Chair
Toshimitsu Hamasaki
National Cerebral and Cardiovascular Center

Keynote Speaker
Adaptive Design of Confirmatory Clinical Trials: Regulatory Perspectives and Recent Advances
Tze Leung Lai
Stanford University

10:15-10:45AM REFRESHMENT BREAK

10:45AM -12:15PM INVITED SESSION IS01
SAKURA, 1F

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

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

Chair
Jeff Maca
Bayer

Speakers
Promoting the Use of Complex Innovative Trial Designs: An Overview
Dionne L. Price
US Food and Drug Administration

Model-Informed Drug Development at the US Food and Drug Administration: A Perspective on Progress
Issam Zineh
US Food and Drug Administration

Panelists
Frank Bretz
Novartis Pharma AG
Norisuke Kawai
Pfizer Japan Inc.
Olga V. Marchenko
Bayer
José Pinheiro
Janssen Research & Development
Martin Posch
Medical University of Vienna
Dionne L. Price
US Food and Drug Administration
Issam Zineh
US Food and Drug Administration

10:45AM-12:15PM INVITED SESSION IS03
ROOM 510, 5F

RECENT DEVELOPMENT AND CHALLENGES IN BIOEQUIVALENT OR BIOSIMILAR ASSESSMENT

Organizers
Hsiao-Hui Tsou
National Health Research Institutes
Seung-Ho Kang
Yonsei University

Chair
Victoria Chang
BeiGene

Speakers
Statistical Considerations for Demonstration of Analytical Similarity
Harry Yang
Astra Zeneca
Recent Development Strategies and Challenges in Biosimilarity Assessment
Heike Woehling
Sandoz Biopharmaceuticals
Effects of Between-Batch Variability on the Type I Error Rate in Biosimilar Development
Seung-Ho Kang
Yonsei University
Statistical Quality Control for Biosimilar Assessment
Hsiao-Hui Tsou
National Health Research Institutes

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THE IMPLEMENTATION OF ICH E17 IN ASIAN REGIONS

Organizers
Chin-Fu Hsiao
National Health Research Institutes
Toshimitsu Hamasaki
National Cerebral and Cardiovascular Center

Chair
Chin-Fu Hsiao
National Health Research Institutes

Speakers
Taiwan CDE's Experience to Review MRCT Results
I-Chun Lai
Taiwan Center for Drug Evaluation

Key Principles of the ICH E17 and Their Implementation
William W. Wang
Merck Sharp & Dohme Corp.

Panelists
Tony Guo
BeiGene Ltd.
I-Chun Lai
Taiwan Center for Drug Evaluation
Nobushige Matsuoka
Pfizer Japan Inc.
Mey Wang
Taiwan Center for Drug Evaluation
William W. Wang
Merck Sharp & Dohme Corp.

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

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
BeiGene

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

MULTIPLECTY 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

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

INNOVATIVE AND FLEXIBLE DESIGNS FOR CLINICAL TRIALS IN THE ERA OF PRECISION MEDICINE
Sponsored by
Toshimitsu Hamaasaki
National Cerebral and Cardiovascular Center

Organizer
Toshimitsu Hamaasaki
National Cerebral and Cardiovascular Center

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

Instructors
James Wason
Newcastle University
3:00-3:30AM  REFRESHMENT BREAK

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
Panelists
Francois Beckers
Merck Serono
Ivan SF Chan
AbbVie Inc.
Pandu Kulkarni
Eli Lilly & Co.
Kannan Natarajan
Pfizer Inc.
Akiko Okamoto
Janssen Research & Development
Susan Wang
Boehringer-Ingelheim Pharmaceuticals, Inc.
William W. Wang
Merck Sharp & Dohme Corp.
Sherry Zhao
Allergan

3:30-5:00PM  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.
Speakers
Target Population Statistical Inference with Data Integration across Multiple Sources: An Approach to Mitigate Information Shortage in Rare Disease Clinical Trials
Yang Song
Vertex Pharmaceuticals Inc.
Estimation of the Effect of the NSAID Celecoxib on the Risk of Cancer using Electronic Healthcare Record Data
Tasuku Okui
Kyushu University Hospital
Biomarker-integrated Clinical Trials with Threshold Selection and Enrichment
Xiaofei Wang
Duke University
Discussant
Jie Ding
MSD R&D (China) Ltd.

3:30 -5:00PM  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

6:00-8:00PM
RECEPTION AND POSTER SESSION
SWAN, 1F
# ISBS2019 | Kyoto International Conference Center | August 26-30, 2019

## DAY 3 | WEDNESDAY, AUGUST 28, 2019

### MAIN CONFERENCE

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30AM-4:30PM</td>
<td>REGISTRATION</td>
<td>RECEPTION, MAIN ENTERANCE, 1F</td>
</tr>
<tr>
<td>8:45-10:15AM</td>
<td>PLENARY SESSION II</td>
<td>SAKURA, 1F</td>
</tr>
</tbody>
</table>

**Chair**  
Satoshi Morita  
Kyoto University

**Keynote Speakers**

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

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

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10:15-10:45AM   REFRESHMENT BREAK

10:45AM -12:15PM INVITED SESSION IS12  
SAKURA, 1F

**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

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10:45AM -12:15PM INVITED SESSION IS09  
ROOM 510, 5F

**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.

**Discussant**  
Wenquan Wang  
Sanofi Pasteur

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10:45AM -12:15PM TOPIC-CONTRIBUTED SESSION TC17  
ROOM 554, 5F

**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 Carolina

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
ROOM E, 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 Taiwan 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

1:30 - 3:00PM  TOPIC-CONTRIBUTED SESSION TC05
ROOM 554, 5F

MACHINE LEARNING METHODS FOR IMPROVING CLINICAL DECISION MAKING AND PRECISION HEALTH CARE

Organizer
Yuanjia Wang
Columbia University

Chair
Haoda Fu
Eli Lilly & Co.

Speakers

Learning Optimal Individualized Treatment Strategies from Randomized Trials and Electronic Health Records
Yuanjia Wang
Columbia University

Application of Machine Learning to Real World Data
Shintaro Hiro
Pfizer R&D Japan

Joint Variable Screening in Accelerated Failure Time Models
Jinfeng Xu
The University of Hong Kong

Discussant
Ying Lu
Stanford University

1:30 - 3:00PM  TOPIC-CONTRIBUTED SESSION TC04
ROOM 555, 5F

BAYESIAN APPROACHES FOR THE UTILIZATION OF CO-DATA FOR EFFICIENT DRUG DEVELOPMENT

Organizer
Tomoyuki Kakizume
Novartis Pharma K.K.

Chair
Lisa Hampson
Novartis Pharma AG

Speakers

Bayesian Dose-Finding Phase I Trial Design Incorporating Historical Data from a Preceding Trial
Kentaro Takeda
Astellas Global Development Inc.

Selection of Robust Meta-Analytic-Predictive Priors based on the Evaluation of Operating Characteristics for Proof-of-Concept Studies
Yi Cheng
China Novartis Institutes for Biomedical Research Co., Ltd

Utility of Bayesian Single-Arm Design in New Drug Application for Rare Cancers in Japan
Akihiro Hirakawa
The University of Tokyo
Use of Co-data for Interim Analysis in Clinical Trials
Tomoyuki Kakizume
Novartis Pharma K.K.

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

ADAPTIVE MULTI-ARM MULTI-STAGE (MAMS) DESIGNS IN CONFIRMATORY CLINICAL TRIALS: A PRACTICAL INTRODUCTION TO THE STATISTICAL METHODOLOGY AND ITS APPLICATION

Sponsored by

Organizer
Yannis Jemiai
Cytel Inc.

Instructors
Yannis Jemiai
Cytel Inc.
Lingyun Liu
Cytel Inc.
Hrishikesh Kulkarni
Cytel Inc.

3:00-3:30PM REFRESHMENT BREAK

3:30 -5:00PM INVITED SESSION IS18
SAKURA, 1F

INFERENCE AND DECISION MAKING FOR CONTEMPORARY DRUG DEVELOPMENT AND APPROVAL

Organizer
Satoshi Morita
Kyoto University

Chair
Satoshi Morita
Kyoto University

Speakers
Journey of Bayesian Inference and Decision Making on Drug Development and Approval
J. Jack Lee
University of Texas MD Anderson Cancer Center

Update Your Prior: Use of Bayesian Methods in Drug Development
Martin Posch
Medical University of Vienna

3:30 -5:00PM INVITED SESSION IS10
ROOM 510, 5F

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.

3:30 -5:00PM TOPIC-CONTRIBUTED SESSION TC13
ROOM 554, 5F

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

3:30 -5:00PM  TOPIC-CONTRIBUTED SESSION TC10
ROOM 555, 5F

DESIGNING CLINICAL TRIALS WITH RECURRENT EVENTS

Organizers
Tim Friede
University Medical Center Göttingen
Satoshi Hattori
Osaka University

Chair
Satoshi Hattori
Osaka University

Speakers
Designing a Trial in Multiple Sclerosis with Relapses as Endpoint
Isao Tsumiyama
Novartis Pharma K.K.

Introducing a Clinical Trial Sample Size Calculation: Experiences in Hemophilia A using recurrent events
Wataru Ohtsuka
Chugai Pharmaceutical Co., Ltd.

Incorporating Variance Miss-Specification in Designing Comparative Clinical Trials with Over-Dispersed Count Data
Masataka Igeta
Hyogo College of Medicine

Adaptive Designs for Clinical Trials with Recurrent Events
Tim Friede
University Medical Center Göttingen

Discussant
Tzy-Chy Lin
Taiwan Center for Drug Evaluation
### Day 4 | Thursday, August 29, 2019

#### Main Conference

**8:30am-4:30pm**
- **Registration**
  - Reception, Main Entrance, 1F

**8:45am-10:15am**
- **Plenary Session III**
  - Sakura, 1F
  - **Chair**: Jie Chen  
  - **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

**10:15am-10:45am**
- **Refreshment Break**

**10:45am-12:15pm**
- **Invited Session IS05**
  - Sakura, 1F
  - **Organizer**: Jiawei Wei  
  - **Chair**: Jiawei Wei  
  - **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

- **Invited Session IS11**
  - Room 510, 5F
  - **Organizers**: Frank Liu, Jie Chen  
  - **Chair**: Frank Liu  
  - **Panelists**
    - Frank Bretz  
    - Novartis Pharma AG
    - Ivan SF Chan  
    - AbbVie Inc.
    - José Pinheiro  
    - Janssen Research & Development
    - A. Lawrence Gould  
    - Merck Sharp & Dohme Corp.

- **Invited Session IS15**
  - Room 554, 5F
  - **Organizer**: Franz König  
  - **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 Klingmüller  
      - Austrian Medicines & Medical Devices Agency

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**For more information, visit ISBS2019 official website.**
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

Sponsored by AMED-funded Project “Regulatory Science Research to Achieve Efficiency of Clinical Research and Development with Utilization of Patient Registry”

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
Kit C.B. Roes
Radboud University Medical Centre
### 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**

Jiawei Wei  
Novartis Institutes for BioMedical Research

**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

### STATISTICAL METHODOLOGY FOR THE COMPARATIVE ASSESSMENT OF QUALITY ATTRIBUTES

**Organizer**

Florian Klingmüller  
Austrian Medicines & Medical Devices Agency

**Chair**

Florian Klingmüller  
Austrian Medicines & Medical Devices Agency

**Speakers**

- **Can Statistical Inference Improve the (Bio-) Similarity Exercise?**  
  Kit C.B. Roes  
  Radboud University Medical Centre

- **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

### 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 - 3:00PM  
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  
TBD  
Osamu Komiyama  
Pfizer Japan Inc.

TBD  
William W. Wang  
Merck, Sharp & Dohme, Corp.

TBD  
Hiroyuki Sato  
Pharmaceutical and Medical Devices Agency

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

8:30AM-11:30PM  REGISTRATION
RECEPTION, MAIN ENTERANCE, 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

MAIN CONFERENCE

8:45-10:15AM  CONTRIBUTED SESSION CS02
ROOM 510, 5F

Chair
Tomokazu Inomata
IQVIA

Speakers
Multiple Imputation with Auxiliary Variables in Longitudinal Clinical Trials: Imputation Models Using Bayesian Lasso and Tree-Based Approaches
Yusuke Yamaguchi
Astellas Pharma Inc.

Efficient, Doubly Robust Estimation of the Effect of Dose Switching for Switchers in a Randomised Clinical Trial
Kelly Van Lancker
Ghent University

A Variable Selection Criterion for Competing Risk Data with Pseudo-Observations
Kenichi Hayashi
Keio University

The Impact of Heterogeneity and Outliers on Flexible Shrinkage Estimators for Local Treatment Effects in Multi-Regional Clinical Trials
Naoki Isogawa
Pfizer R&D Japan

Meta-Analysis and Matrix Decomposition for Pattern Extraction and Patient-Level Prediction of Adverse Events
Kentaro Matsuura
Johnson & Johnson

Adaptive Power Prior for Sequential Clinical Trials - Application to Bringing Studies
Adrien Nigel Ollier
INSERM

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

12:00-12:15PM  CLOSING
SAKURA, 1F
POSTER PRESENTATIONS

#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
Tunghai University

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

#5005: 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
Wen-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

#50150: 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

#50167: Enterprise Investment Selection for the Kickstarter Projects
Yu-Jie, Huang
National Sun Yat-sen University
Japan’s Largest Claims Database.

☐ Payer-based DB
Data source: claim, enrollment information and health checkup from 130 + payers
Data period: January 2005 – the latest
Data volume: about 7 million enrollments

☐ Hospital-based DB
Data source: claim + DPC survey data from 190 + hospitals
Data period: April 2014 – the latest
Data volume: about 8 million patients
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