2022 Orange County
Biostatistics Symposium

Day 2 — Track 1: Clinical/Statistics (AbbVie Auditorium)

Session 1 (13:30 – 15:00) Chair: Kathy Chi-Burris, Acadia Pharmaceuticals Inc

13:30 - 13:50 Design and Inference in a RCT when Treatment Observations Follow a Two-Component Mixture Model
- ***Daniel R Jeske***, *University of California, Riverside*

13:50 - 14:10 Our Experience with Real World Evidence (RWE) in Rare Disease Drug Development – A Sequel
- ***Larry Shen***, *Wuxi AppTec*

14:10 - 14:30 A one-shot Deep Learning Framework for Psoriasis Area and Severity Prediction
- ***Yunzhao Xing***, *AbbVie*

14:30 - 14:50 Orthogonal Array Composite Designs for Drug Combination Experiments with Applications for Tuberculosis
- ***Jessica Jaynes***, *California State University, Fullerton*

14:50 - 15:00 Q&A

Days 1: Student Poster Session

- A Comparison of Statistical Methods for Evaluation of Slope-based Estimated Glomerular Filtration Rate in Chronic Kidney Disease Randomized Controlled Clinical Trials
  - ***Navneet Hakhu***, *UC Irvine*
- Statistical Inference for Method of Moments Estimators of a Semi-Supervised Two-Component Mixture Model
  - ***Bradley Lubich***, *UC Riverside*
- Multivariate spatiotemporal functional principal component analysis for modeling hospitalization and mortality rates in the dialysis population
  - ***Qi Qian***, *UC Los Angeles*
- Multivariate functional modeling of multiple dependent regions in eye-tracking experiments for school-age children with autism spectrum disorder and typical development
  - ***Brian Kwan***, *UC Los Angeles*
- Unknown System Migration under Correct Model Specification in Indian Health Services Data
  - ***Kyle Richard Conniff***, *UC Irvine*
- A Functional Model for Studying Common Trends Across Trial Time in Eye Tracking Experiments
  - ***Mingfei Dong***, *UC Los Angeles*
- *Single-cell Hi-C Statistical Simulator*
  - ***Huiling Liu and Rui Ma***, *UC Riverside*

AbbVie Auditorium and Theater

Committee

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Gajanan Bhat (Chair) | Thomas Lin (Co-Chair) | Xinping Cui (Co-Chair) | Pamela Hsu | Jihao Zhou | Kitty Guo | Weixin Yao

Clinical and Statistics Committee
Jihao Zhou (Lead) | Kitty Guo (Co-Lead) | Judy Li | Weixin Yao | Esra Kurum | Kathy Burris

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Pamela Hsu (Lead) | Xingyu Gao (Co-Lead) | Liang Li | Dwight Wynne | Francis Lai

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Orange County Biostatistics Symposium 2022

Leveraging Data to Shape the Future of Clinical Development

ORANGE COUNTY BIOSTATISTICS SYMPOSIUM 2022
ASA ORANGE COUNTY/ LONG BEACH CHAPTER

Organized by
OCLB Chapter of ASA
https://community.amstat.org/oclb/home

When | 14-15 October 2022
Where | AbbVie Auditorium and Theater
2525 Dupont Drive, Irvine, CA 92612

Day 1 Keynote Session (AbbVie Auditorium)

07:30 - 08:30 Registration / Breakfast
08:30 - 12:00 Keynote Session Chair: *Gajanan Bhat PhD,* *Spectrum Pharmaceuticals*
08:30 - 08:45 Welcome and Introduction
08:45 - 09:35 **Keynote address 1**
Convergence of Big-Data and Artificial Intelligence In Augmenting Drug Discovery And Development
- ***Prasun Mishra PhD***, *Founder & CEO American Association for Precision Medicine (AAPM)*

09:35 - 10:25 **Keynote speaker 2**
Statistical Innovations in Bayesian Adaptive Clinical Trials
- ***Donald Berry PhD***, *Professor, Department of Biostatistics, MD Anderson Cancer Center, Houston, TX*

10:25 - 10:45 Q&A
10:45 - 11:00 Break
11:00 - 12:00 **Q&A/Panel Discussion:** Moderated by ***Gajanan Bhat***, Spectrum Pharmaceuticals
Discussants: ***Prasun Mishra,*** AAPM**;** ***Donald Berry,*** *MDACC;* ***Li Wang,*** *AbbVie;* ***Larry Shen,*** *Wuxi AppTec*

12:00 - 13:00 Lunch/ Round Table Discussions

Topics for Tables:

- Clinical development in rare diseases and unmet medical needs
- Real-world data backed clinical development
- Usage of synthetic control in trial design
- Accelerated approval pathways
- Master protocols in clinical development
- Regulatory submission data preparation – challenges
- Estimands in Clinical Trials
- Use of AI and machine learning in clinical development
- Data visualization techniques for clinical trials
- Use of R, python and other software tools in clinical trial data analysis
- Importance of Medical Imaging in Clinical Research

Track 1: Clinical and Statistics (AbbVie Auditorium)

Session 1 (13:00 - 14:40) Chair: *Jihao Zhou MD PhD,* *AnaptysBio*

13:00 - 13:20 How do we talk about the Estimands?
- ***Natasa Rajicic***, *Cytel*

13:20 - 13:40 Comparison of Estimand Strategies and Analysis Methods on Patient-Reported Outcome (PRO) Endpoint
- ***Sandra Zhang***, *BMS*

13:40 - 14:00 Design and Analysis of Dose-finding Study with a Binary Efficacy Endpoint; A permutation Testing-Modeling Approach
- ***Andrew Yan***, *Evive Biotech*

14:00 - 14:20 Seamless Phase 2/3 Clinical Trials with Covariate Adaptive Randomization
- ***Hongjian Zhu***, *AbbVie*

14:20 - 14:40 Q&A
14:40 - 15:00 Afternoon Break

Session 2 (15:00 - 16:40) Chair: Esra Kurum PhD, *University of California, Riverside*

15:00 - 15:20 A Bayesian Approach for Benefit-Risk Assessment in Clinical Studies with Longitudinal Data
- ***Charlie Ahn***, *Edwards Lifesciences*

15:20 - 15:40 AI/Machine Learning (ML) for Pharmaceutical Research and Development (R&D)
- ***Junshi Ma***, *Merck*

15:40 - 16:00 Complex Innovative Design Pilot Program and a Potential Proposal
- ***Li Wang***, *AbbVie*

16:00 - 16:20 Exploratory Subgroup Identification for Censored Data: A Relatively Simple Procedure
- ***Larry Leon***, *Merck*

16:20 - 16:40 Q&A

17:00 - 18:30 Reception and Networking

Track 2: Data Science and Analytics (AbbVie Theater)

Session 1 (13:00 - 14:40) Chair: *Pamela Hsu,* *Spectrum Pharmaceuticals*

13:00 - 13:20 Quality of Life Evaluations for Outside US Submissions and Publications
- ***Xiao Yu***, *Edwards Lifesciences*

13:20 - 13:40 Automatic Endpoint Adjudication Using Artificial Intelligence
- ***Saman Parvaneh***, *Edwards Lifesciences*

13:40 - 14:00 Evaluating the Effect of Sugar Sweetened Beverage Tax in California by Electronic Health Record Data
- ***Bing Han***, *Kaiser Permanente*

14:00 - 14:20 A Comparison of MarketScan Research Database between Source and Agile Data Model
- ***Kaiding Zhu***, *Horizon Therapeutics*

14:20 - 14:40 Q&A
14:40 - 15:00 Afternoon Break

Session 2 (15:00 - 16:40) Chair: Xingyu Gao, *Edwards Lifesciences*

15:00 - 15:20 Interactive Data Review Platform Applied in Clinical Trial
- ***Kun Liang***, *LLX Solutions*

15:20 - 15:40 Open-Source TFL Designer
- ***Bhavin Busa***, *Clinical Data SME*

15:40 - 16:00 Various Aspects of Using R for Regulatory Reporting
- ***Tomas Hovorka***, *Edwards LiveSciences*

16:00 - 16:20 How to Get Your BIMO Listings Ready for NDA/BLA Submissions
- ***Anil Hiteshi/Pamela Hsu***, *Spectrum Pharmaceuticals*

16:20 - 16:40 Q&A
17:00 - 18:30 Reception and Networking

Day 2 Morning Session (AbbVie Auditorium)

08:00 - 08:30 Light Breakfast (AbbVie Auditorium)
08:30 - 12:30 Workshop on Clinical Trials Using Master Protocol and Its Applications Chair: Weixin Yao PhD, *University of California, Riverside*

08:30 - 09:55 Workshop 1 - ***Jingjing Ye***, *BeiGene*
09:55 - 11:20 Workshop 2 - ***Nicole Li***, BeiGene
11:20 - 12:30 Workshop 3 - ***Cindy Lu***, *AstraZeneca*