Adaptive Design – Online Short Course

Instructors: Dr. Frank Bretz, Novartis; Dr. Dong Xi, Gilead Sciences

About the Course

Clinical trials play a critical role in pharmaceutical drug development. New trial designs often depend on historical data, which, however, may not be accurate for the current study due to changes in study populations, patient heterogeneity, or different medical facilities. As a result, the original plan and study design may need to be adjusted or even altered to accommodate new findings and unexpected interim results. Through carefully thought-out and planned adaptation, the right dose can be identified faster, patients can be treated more effectively, and treatment effects evaluated more efficiently.

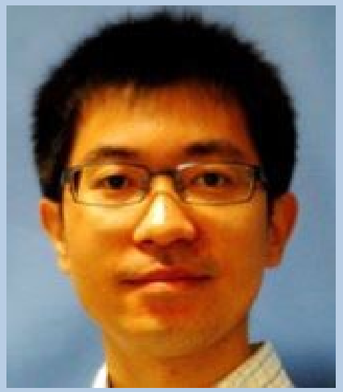
This one-day short course will introduce different types of adaptive designs tailored for adaptive dose finding and confirmatory clinical trials. Practical considerations will be illustrated with case studies. Types of adaptive clinical trial designs covered in this course include adaptive dose finding studies using optimal designs to allocate new cohorts of patients based on the accumulated evidence, group sequential designs, blinded and unblinded sample size re-estimation as well as adaptive designs for confirmatory trials with treatment or population selection at interim.

Registration Link: https://forms.gle/y7H1uk1uLyKsux1KA

Wednesday, May 25, 2022
9:00 am - 4:00 pm CDT

About the Instructors

Dr. Frank Bretz is a Distinguished Quantitative Research Scientist at Novartis. He has supported the methodological development in various areas of pharmaceutical statistics, including dose finding, multiple comparisons, estimands, and adaptive designs. Frank is an Adjunct Professor at the Hannover Medical School (Germany) and the Medical University of Vienna (Austria). He was a member of the ICH E9(R1) Expert Working Group on 'Estimands and sensitivity analysis in clinical trials' and currently serves on the ICH E20 Expert Working Group on 'Adaptive clinical trials'. Frank is a Fellow of the American Statistical Association.



Dr. Dong Xi is a Director in the Center for Statistical Excellence at Gilead Sciences. Previously, he was a member in the Advanced Methodology and Data Science group at Novartis. He has supported development and implementation of innovative statistical methodologies in multiple comparisons, dose finding, group sequential designs, estimands and causal inference. He has co-authored four book chapters on multiplicity and many publications in peer-reviewed journals. Dong is an associate editor of Statistics in Biopharmaceutical Research and Contemporary Clinical Trials, and he is a committee member of the International Conference of Multiple Comparison Procedures. His work won the biennial (2019-2020) “Best Paper Award” for manuscripts published in Statistics in Biopharmaceutical Research.

ASA AMERICAN STATISTICAL ASSOCIATION
Promoting the Practice and Profession of Statistics
Central Arkansas Chapter

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Course Outline

This one-day short course will include four lectures (1.5 hours for each).

Lectures 1: Definition and concepts; overview of adaptive clinical trial designs; advantages and limitations; key principles and considerations.

Lectures 2: Interim analyses; group sequential designs; efficacy stopping; futility stopping; adaptive-flavored group sequential design.

Lectures 3: Adaptive designs for confirmatory trials; sources and impact of multiplicity; p-value combination methods; conditional error rates.

Lectures 4: Examples of adaptive designs for confirmatory trials; sample size adaptation based on nuisance parameter estimates; adaptive treatment selection; population enrichment designs.

Course Learning Objectives

(1) To understand the fundamentals of clinical trials, e.g., blinding, randomization, different development phases.

(2) To learn how to apply tailored statistical techniques at different stages of clinical development.

(3) To understand how different adaptations can take place in clinical trials in order to achieve the study goals.

$25 - Students
$45 - Members of CASA or ASA
$50 - Non-Members of CASA or ASA

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