ASA 18TH ANNUAL CT CHAPTER MINI-CONFERENCE

Note: This has been changed to a **WEBCAST ONLY EVENT**. Please register to receive the webcast link.

Webcast Event
Wednesday, April 22, 2020
9:00 am – 2:30 pm

REGISTRATION

This is a **free event** sponsored by the Connecticut Chapter of the American Statistical Association

Register here:

https://www.123signup.com/register?id=rnvns

Registration closes at **noon** on **Friday, April 17th**

WEBCAST

Note that this conference has been changed to a **webcast event**.
The Zoom link will be sent to registered participants before the meeting.

SCHEDULE

9-10 

Demissie Alemayehu, PhD, Head, Statistical Research and Data Science Center, Pfizer Inc. "*Trending topics in enhanced clinical research and drug development*"

10:15-11:45 

John Preisser, PhD, Professor, Department of Biostatistics, University of North Carolina at Chapel Hill. "*Design and analysis of stepped wedge and other cluster randomized trials based upon generalized estimating equations*"

12-1 

Max Kuhn, PhD, Software Engineer, RStudio, PBC. "*What inferential statistics can utilize from predictive models*"

1:15-2:15 

Naitee Ting, PhD, Director, Biostatistics and Data Science, Boehringer-Ingelheim. "*Subgroup analysis in clinical development of new drugs*"

Questions? Contact ctchapterasa@gmail.com

Demissie Alemayehu, PhD, Head, Statistical Research and Data Science Center, Pfizer Inc.

"Trending topics in enhanced clinical research and drug development"

Abstract. With the growing cost and complexity of drug development, novel approaches for the design and analysis of trials and data sources are increasingly proposed to enhance efficiency and optimize sample size requirements. These approaches may especially be attractive options in situations where traditional randomized controlled trials are impractical or not feasible for operational or ethical reasons. Examples of trending approaches that are specifically intended to optimize subject allocation include use of external control groups and the so-called multi-armed bandit designs. However, the validity of the evidence generated from such trials is dependent on several factors, including research trial objectives, data quality and disease natural history. In this talk, we highlight common issues that arise in the implementation of selected approaches, and provide examples of applications in regulatory settings, where appropriate.

John Preisser, PhD, Professor, Department of Biostatistics, University of North Carolina at Chapel Hill

"Design and analysis of stepped wedge and other cluster randomized trials based upon generalized estimating equations"

Abstract. While mixed effects models for cluster randomized trials (CRTs) are widely used, less attention has been given to population-averaged models for CRTs, particularly stepped wedge (SW) trials and binary outcomes. Starting with a brief review of the primary statistical issues, this talk describes the design and analysis of longitudinal CRTs based on generalized estimating equations (GEE). Topics include (i) accurate formulae for sample size determination; (ii) joint models for the marginal mean outcome, as a function of the treatment indicator and time trend, and within-cluster correlation structure; and (iii) estimation procedures with finite-sample bias adjustments for model parameters and standard errors. The methods are applied to published cross-sectional SW-CRT data for evaluation of the effectiveness of patient-delivered partner therapy to reduce chlamydial infection among heterosexual individuals in 22 local health jurisdictions in Washington State. Ongoing and future work is summarized for the design of incomplete SW-CRTs and computationally fast GEE-type analysis of cluster-period means for SW-CRTs with large clusters.

Max Kuhn, PhD, Software Engineer, RStudio, PBC

"What inferential statistics can utilize from predictive models"

Abstract. In practice, the main objective function for models built for inference is only a function of statistical significance. This can lead to problems. Predictive models tend to focus on empirical validation to evaluate models. Can these techniques be applied to inferential techniques and how could they benefit? A few examples are used as illustration.

Naitee Ting, PhD, Director, Biostatistics and Data Science, Boehringer-Ingelheim

"Subgroup analysis in clinical development of new drugs"

Abstract. In clinical development of new medicinal products, it is common to perform subgroup analysis after trial results are available. There are many reasons for performing subgroup analyses. However, most of these analyses are post hoc in nature and hence clinical findings simply from these analyses may not be thought of as confirmatory evidence. In this presentation, a few case studies are used to clarify some of the considerations in performing subgroup analysis.