DEPARTMENT of BIOSTATISTICS EPIDEMIOLOGY & INFORMATICS

14th Annual Conference on
Statistical Issues in Clinical Trials
UPenn Perelman School of Medicine
Philadelphia, PA 19104

April 12, 2022
REGISTRATION OPEN
THIS WILL BE A VIRTUAL CONFERENCE
TOPIC: Subgroup Analysis in Clinical Trials: Opportunities and Challenges

MORNING SESSION
David Kent, MD (Tufts University) *Overview:* Overall average treatment effects and one-variable-at-a-time subgroup analysis: The Scylla and Charybdis of Evidence Based Medicine
Ellis Unger, MD (Consultant) *An "unofficial" US Regulatory Perspective*
Tom Fleming, PhD (University of Washington) *Pitfalls of subgroup analysis*
Lisa McShane, PhD (NCI) *Finding the subgroup of patients who benefit from a novel therapy: no time for a game of hide and seek*
AFTERNOON SESSION
Noah Simon, PhD (University of Washington) *Adaptive Enrichment Trials: Identifying the 'right' subgroup*
Anastasia Ivanova, PhD (UNC) *Methodological challenges in PrecISE (Precision Interventions for SEvere asthma)*
Ilya Lipkovich, PhD (Eli Lilly) *Comparison of recent approaches for subgroup identification from clinical and observational data*
Patrick Schnell, PhD (Ohio State) *Multiplicity considerations for analyses of non-exchangeable subgroups*
PANELISTS
Mark Rothmann (FDA) Kosuke Imai (Harvard) Kit Roes (European Regulatory Perspective) Michael Rosenblum (Johns Hopkins) Janet Wittes (Statistics Collaborative, Inc.)