Kansas Western-Missouri Chapter of the ASA and KU Dept of Biostatistics invites you to attend an ASA Council of Chapters Traveling Short-Course and chapter meeting.

Please join us for an exciting day of networking and continuing education events in Kansas City. The Kansas-Western Missouri Chapter of ASA and the University of Kansas Medical Center Department of Biostatistics are co-sponsoring an American Statistical Association Council of Chapters Traveling Short Course, and the annual Fall Chapter Meeting will be held 30 minutes after conclusion of the short course. The short course will be given by Dr. Devan Mehrotra from Merck and keynote address of the following chapter meeting will be given by Dr. Jeffrey Thompson from the University of Kansas Medical Center, Department of Biostatistics.

ASA Traveling Short Course: ***Randomized Clinical Trials – Replacing Traditional Analyses with Better Alternatives***

Presenter: Devan Mehrotra, Ph.D. (Merck Research Laboratories, Associate Vice-President, Clinical Biostatistics)
Date: Friday October 26th 2018, 9:00 AM to 3:30 PM, on-site registration opens at 8:30 AM.
Location: University of Kansas, Edwards Campus (Regents Center 110)
12600 Quivira Rd., Overland Park, KS 66213
Registration Fee: $50 for ASA members, $25 for students, $75 for non-ASA members

Abstract:

Increased efficiency in the clinical drug development process can deliver downstream benefits to multiple stakeholders in the healthcare ecosystem including patients, prescribers, and payers. Value-added statistical contributions on that front can be made, in part, by developing and implementing analyses of randomized clinical trials that are notably better than their traditional counterparts. In this 1-day course, I will present examples of efficiency-boosting statistical approaches across all phases of clinical drug development. To appeal to a broad audience, the following six diverse topics will be covered: (i) crossover trials with baseline measurements, (ii) trials with unequally powered primary endpoints, (iii) analyses of time-to-event endpoints with small sample sizes, (iv) pharmacogenomics to enable personalized medicine, (v) analyses of stratified trials with binary or time-to-event endpoints, and (vi) estimand-aligned primary and sensitivity analyses. For each topic, the key points will be amplified using real examples and simulations. All the methods discussed can be easily implemented using SAS and/or R code.

Biographical Sketch:

Dr. Devan V. Mehrotra is Associate Vice President, Clinical Biostatistics, and a Presidential Fellow at Merck Research Laboratories. Over the past 25+ years, he has made scientific and strategic contributions towards the research, development and regulatory approval of medical drugs and vaccines across a broad spectrum of therapeutic areas. He is an Adjunct Associate Professor of Biostatistics at the University of Pennsylvania, an Associate Editor for *The American Statistician* and *Pharmaceutical Statistics*, an elected Fellow of the American Statistical Association, and a 7-time winner of the best biopharmaceutical paper award at the annual Joint Statistical Meetings. Dr. Mehrotra has served as a subject matter expert for the Bill and Melinda Gates Foundation and for the US National Academy of Sciences, and he is a member of the ICH E9/R1 expert working group that has developed draft guidance on estimands and sensitivity analyses for clinical trials. His current

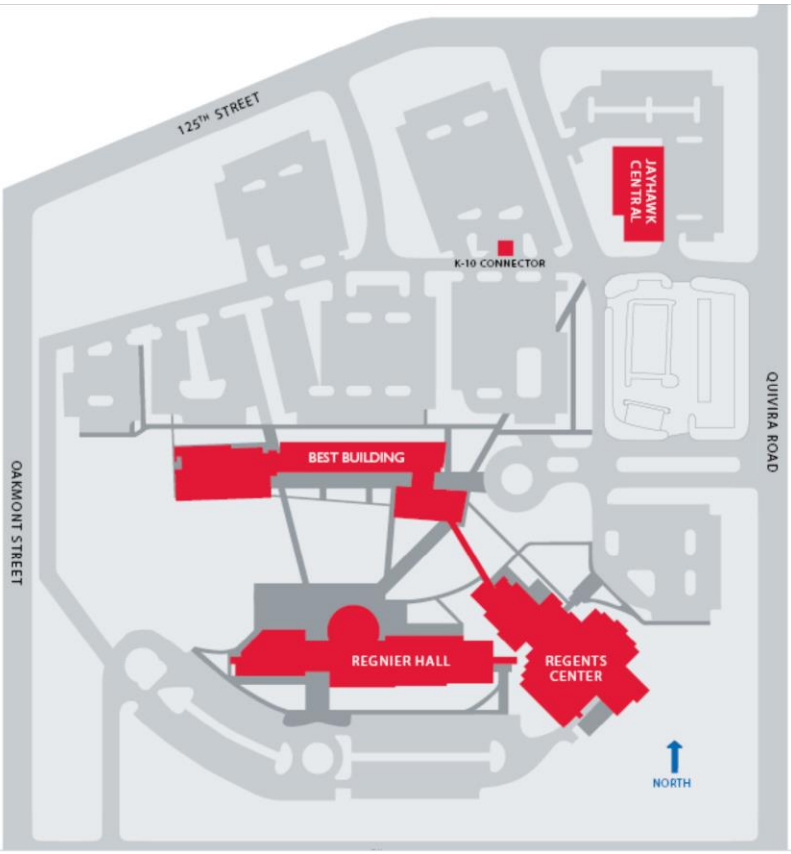
focus areas include the use of statistical/machine learning tools and pharmacogenomics for enabling personalized/precision medicine.

Course Agenda

8:30 – 9:00 am	On-site Registration
9:00 – 9:10 am	Introduction
9:10 – 9:35 am	Crossover trials with baseline measurements
9:35 – 10:30 am	Trials with unequally powered primary endpoints
10:30 – 10:45 am	Break
10:45 – 11:15 am	Small trials with time-to-event endpoints
11:15 – 12:15 pm	Pharmacogenomics in phase 2-3 trials
12:15 – 1:15 pm	LUNCH (Box Lunch Included in Registration)
1:15 – 2:30 pm	Stratified trials: binary and time-to-event endpoints
2:30 – 2:45 pm	Break
2:45 – 3:25 pm	Estimand-aligned primary and sensitivity analyses
3:25 – 3:30 pm	Wrap-up

Campus Map
12600 Quivira Road
Overland Park, KS 66213

Conference Center is in the West end of the BEST Building. Park in the lot north of the building



Chapter Meeting (KU-Edwards Regents Center 110), same room as short course
Non-student $25 until 10/22/2018, $30 after 10/22/2018
Student $15 until 10/22/2018, $20 after 10/22/2018

4 PM Social Mixer with appetizers
4:15 PM Chapter Business
4:30 PM Keynote
5:30 Dismissal

Keynote Speaker at Chapter Meeting

Jeffrey A. Thompson, PhD
Assistant Professor, Department of Biostatistics
Co-director of C3OD for the University of Kansas Cancer Center
University of Kansas Medical Center

Abstract:

In silico functional genomics have become a driving force in the way we interpret and use gene expression data, enabling researchers to understand which biological pathways or molecular functions are likely to be affected by the treatments or conditions being studied. There are many approaches, but a number of popular methods determine if a set of modified genes has a higher than expected overlap with genes known to function as part of a pathway (functional enrichment testing). Recently, researchers have started to apply such analyses in a new way: to ask if the data they are collecting show similar disruptions to biological functions as some reference data. Examples include studying whether or not similar genes are perturbed in smokers vs. users of e-cigarettes, or whether a new mouse model of schizophrenia is justified, based on its similarity in cytokine expression to a previously published model. However, there is a dearth of robust statistical methods for testing hypotheses related to these questions. This work proposes a novel statistical approach to testing if the observed perturbances in two biological datasets cause equivalent biological functional changes.

Biographical Sketch:

Dr. Thompson’s work focuses on developing methods of integrating and understanding biological data that provide a more holistic view of disease outcomes and etiology. In part, this involves building predictive models leveraging data from multiple sources, such ‘omic and clinical data, to better support predictions. He also works on methods of functional analysis that identify biological processes that are similarly disrupted across multiple experiments. This work has the potential to support the use of model organisms to study disease, make the case for drug repositioning, and show that a new chemical might present similar risks to existing chemicals, among other uses. He is a strong proponent of the role of biostatistics and bioinformatics in supporting biomedical research. As co-director of the Curated Cancer Clinical Outcomes database at the University of Kansas Cancer Center, he leads an initiative to provide informatics solutions that facilitates recruitment to clinical trials and supports research into cancer prevention and risk prediction. Dr. Thompson also brings his integrative view of analysis to a number of collaborative projects and teaches graduate courses in statistical learning.

The Online registration links:

Short Course: https://www.123signup.com/register?id=hkrps
Chapter Meeting: https://www.123signup.com/register?id=hkrnq

For questions, please contact John Keighley at jkeighle@kumc.edu