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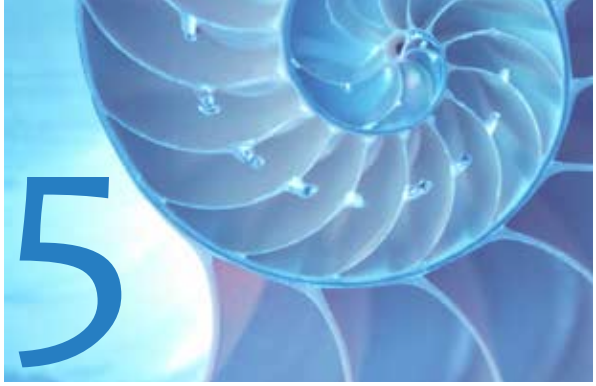

Short Courses

	REGISTRATION PAYMENT RECEIVED					
	BY February 8			AFTER February 8		
	HALF DAY	SECOND HALF DAY	FULL DAY	HALF DAY	SECOND HALF DAY	FULL DAY
Member	$ 225	$ 190	$ 325	$ 250	$ 215	$ 350
Nonmember	$ 275	$ 240	$ 375	$ 300	$ 265	$ 400

SC1: Bayesian Clinical Trials

FULL DAY | 8:00 am to 5:00 pm

David Draper

University of California, Santa Cruz

Overview

Experiments that would today be recognized as clinical trials have been performed at least since the 1740s (with James Lind's demonstration that citrus fruits cure scurvy). From the late 19th century through the 1990s, sound inferential design and analysis of clinical trials has largely been based on the frequentist probability paradigm, but there has been a recent recognition that Bayesian methods can offer significant advantages in both design and analysis.

The course

– Optimal Bayesian design of clinical trials: sequential designs, adaptive designs; the use of Bayesian decision theory for optimal design

– Optimal Bayesian analysis of clinical trial outcomes: what optimal analysis is, when it can be achieved, and how to achieve it when it's possible

– Well-calibrated Bayesian clinical trial analyses; appropriate use of prior distributions

– Drawing valid causal conclusions with Bayesian analyses of observational clinical studies

– Bayesian meta-analysis for combining information

SC2: Statistical Methods for fMRI and EEG Data Analysis

FULL DAY | 8:00 am to 5:00 pm

Martin Lindquist

Johns Hopkins School of Public Health

Hernando Ombao

University of California, Irvine

Overview

This course will cover the state-of-the-art techniques and statistical approaches for analyzing fMRI and EEG data. Though there are many types of brain imaging modalities, these two are the most common. This course will be scheduled for 4 hours and will be divided into 2 parts: the first devoted to analyzing fMRI data and the second to EEG data.

The topics in the fMRI section include:

(a) an overview of the acquisition and reconstruction of fMRI data

(b) overview of the physiological basis of the fMRI signal

(c) common experimental designs

(d) pre-processing steps

(e) methods for localizing areas activated by a task

(f) connectivity analysis

(g) prediction and brain decoding.

The topics for the EEG section are:

(a) overview of the physiological basis of the EEG signal

(b) common experimental designs

(c) pre-processing steps including artifact rejection and filtering

(d) spectral analysis

(e) coherence and connectivity analysis

(f) statistical approaches to modeling variation across trials and subjects

(g) source localization.

SC3: Design Considerations in Early Phase Clinical Trials: Phase I, Phase I/II Trials

FULL DAY | 8:00 am to 5:00 pm

John O'Quigley
University Pierre and Marie Curie, Paris, France

Alexia Iasonos
Memorial Sloan Kettering Cancer Center

Overview

This course will cover design considerations specific to Phase I and Phase I/II clinical trials, dose finding studies in humans (not in healthy volunteers), in various disease settings. The topic is receiving increased attention in the statistical literature and as a result there exist several new designs that can be made use of in any given situation. The workshop will start with a review of the aims of Phase I trials, Phase I trials with expansion cohorts, Ph I/II trials and provide a link between the aims, designs, and methods of analysis. The workshop will focus on more advanced statistical topics such as studies involving more than one drug or schedule, patient heterogeneity, and bridging studies. Monitoring safety and efficacy simultaneously in dose expansion cohorts or as part of a Phase I/II trial will also be discussed as Phase I trials are increasingly including aiming to further characterize the toxicity and efficacy profile. Illustrations on how to use model based designs, implement and carry out a model based Phase I trial in practice will be provided based on actual studies from oncology. Computational considerations and available software will also be discussed.

The course

– Overview of Phase I designs

– Basic theory of model based designs

– How good can a design be? Defining optimal performance

– Approaches to non-binary outcomes

– More complex problems: drug combinations, patient heterogeneity

– Dose expansion cohorts

– Phase I/II; estimating toxicity and efficacy in the presence of bivariate endpoints

– Statistical Theory (retrospective vs. prospective analysis, convergence, model robustness)

– Protocol development, review of available software

SC4: Personalized Medicine and Dynamic Treatment Regimes

HALF DAY | 8:00 am to 12:00 noon

Marie Davidian
North Carolina State University

Butch Tsiatis
North Carolina State University

Overview

Personalized medicine is focused on making treatment decisions for an individual patient based on his/her genetic/genomic, clinical, and other characteristics. Traditional approaches to this goal seek to develop new treatments that are tailored to specific subgroups of patients with unique characteristics. An alternative objective is to determine the best treatment for each patient, not only those in a small subgroup, to the benefit of the entire patient population.

This course will take this point of view and introduce basic concepts and methods for discovery of dynamic treatment regimes based on data. In the simplest case of a single treatment decision, a dynamic treatment regime

is a rule that assigns treatment to patients based on their own characteristics, and the goal is to find the optimal regime, that leading to the greatest benefit if followed by all patients. In chronic diseases and disorders such as cancer, treatment decisions may be made at multiple time points. In this setting, a dynamic treatment regime is a set of sequential such decision rules corresponding to each decision point, and the optimal regime is the set of rules that would lead to greatest benefit if followed over the entire course of decision making by all patients.

SC5: Data Science and High-Performance Statistical Computing

HALF DAY | 1:00 pm to 5:00 pm

Marc A. Suchard
UCLA School of Public Health

Martijn J. Schmuemie
Johnson & Johnson

Overview

Healthcare data are a prime research target for the Data Sciences because most databases are not only massive in size, but also very highly complex due to issues in sampling, the recording process, dependency through time and across individuals, and privacy in biomedicine. The size and complexity of these data present challenges to traditional statistical analysis that require novel method development and high-performance computing for scalability.

This course explores recent advances in large-scale statistical inference in healthcare as an example of Big Data in the Data Sciences. The course takes 4 hours and is divided into didactic lectures and hands-on, computing tutorials. Topics include massive observational healthcare databasing and wrangling, scaling inference tools that incorporate complex data structure, and high-performance implementation using emerging computing technology. To this end, participants will use and develop open-source R packages, learn important design patterns for statistical computing, and discuss delegation of performance dependent hot-spots to C/C++ with multi-core and many-core parallelization (including on graphics processing units).

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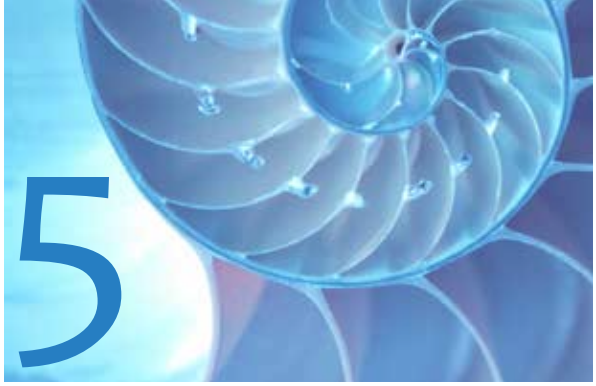

Tutorials

	REGISTRATION PAYMENT RECEIVED	
	BY February 8	AFTER February 8
	T1–T6	T1–T6
Member	$ 75	$ 85
Nonmember	$ 85	$ 95
Student	$ 40	$ 50

Monday, March 16

T1:
Group Sequential Designs Using the gsDesign R Package and Web Interface

8:30 am – 10:15 am

Keaven Anderson
Merck Research Laboratories

Description

Group sequential design is the most widely-used and well-accepted form of adaptive design for confirmatory clinical trials. It controls Type I error for multiple analyses of a primary endpoint during the course of a clinical trial and allows early, well-controlled evaluation of stopping for strong efficacy results or futility. This tutorial will review the basics of group sequential theory and demonstrate common applications of the method. The R package gsDesign and its graphical user interface will be demonstrated to provide the user with an easy-to-use, open source option for designing group sequential clinical trials. The user should leave the tutorial with an ability to propose effective group sequential design solutions to confirmatory clinical trial design. Topics covered include: application of spending functions for selection of appropriate timing and levels of evidence for early stopping; confidence intervals; conditional power, predictive power and prediction intervals; time-to-event endpoints, including stratified populations and power for meta-analyses; binomial endpoints; superiority and non-inferiority designs; information-based sample size re-estimation and conditional power designs for sample size re-estimation; generation of publication-quality tables, figures and documents describing designs.

T2:
Graphics for Clinical Trials

10:30 am to 12:15 pm

Frank E. Harrell Jr.
Vanderbilt University School of Medicine

Description

This tutorial deals with some of the graphical displays that are useful for reporting clinical trial results and for data monitoring committee reports. Emphasis is placed on replacing tables with graphics, new graphical displays for adverse events, longitudinal data, subject enrollment and exclusions, and reproducible

reporting using R, LaTeX, and knitr. The philosophy of the approach is that tables should only support graphics, and they should be hyperlinked to graphics rather than appearing in the main report. Information that supports graphics such as definitions and sample sizes are pop-ups in the pdf report. More details are available at biostat.mc.vanderbilt.edu/Greport.

T3:
Statistical Leadership in Research and the Important Role of Influence

1:45 pm – 3:30 pm

Bill Sollecito
University of North Carolina, Chapel Hill

Lisa LaVange
Food and Drug Administration

Description
This tutorial will first define leadership and its importance for statisticians; various leadership styles and skills will be introduced. The concept of emergent leadership will be illustrated using the research team environment as an example of how statisticians can develop leadership skills. The important role of influence as a leadership skill will be given special emphasis as a way to develop leadership abilities and as a way to have a greater impact on the teams and organizations in which statisticians work.

T4:
A Tutorial for Multisequence Clinical Structural Brain MRI

3:45 pm – 5:30 pm

Ciprian Crainiceanu, Ani Eloyan, Elizabeth Sweeney, and John Muschelli
Johns Hopkins University

Description
High resolution structural magnetic resonance imaging (sMRI) is used extensively in clinical practice, as it provides detailed anatomical information of the living organism, is sensitive to many pathologies, and assists in the diagnosis of disease. Applications of sMRI cover essentially every part of the human body from toes to brain and a wide variety of diseases from stroke, cancer, and multiple sclerosis (MS), to internal bleeding and torn ligaments. Since the introduction of MRI in the 1980s, the noninvasive nature of the technique, the continuously improving resolution of images, and the wide availability of MRI scanners have made sMRI instantly recognizable in the popular literature. Indeed, when one is asked to have an MRI in a clinical context it is almost certainly an sMRI. These images are fundamentally different from functional MRI (fMRI) in size, complexity, measurement target, type of measurement, and intended use. While fMRI aims to study brain activity, sMRI reveals anatomical information. This distinction is important as the scientific problems and statistical techniques for fMRI and sMRI analysis differ greatly, yet confusion between the two continues to exist in the statistical literature and among reviewers. Despite the enormous practical importance of sMRI, few biostatisticians have made research contributions in this field. This may be due to the subtle aspects of sMRI, the relatively flat learning curve, and the lack of contact between biostatisticians and the scientists working in clinical neuroimaging. Our goal is reduce the price of entry, accelerate learning, and provide the information required to progress from novice to initiated sMRI researcher. This tutorial will provide a gentle introduction to high resolution multisequence structural MRI (sMRI) using several data sets. The tutorial will provide hands-on training in a variety of image processing techniques including: data structure and visualization, data storage and management, inhomogeneity correction, spatial interpolation, skull stripping, spatial registration, intensity normalization, lesion segmentation and mapping, and cross-sectional and longitudinal analysis of images. The tutorial will use R and several other free specialized brain imaging software.

Tuesday, March 17

T5:
Bayesian Computation using PROC MCMC

1:45 pm – 3:30 pm

Fang Chen
SAS Institute Inc.

Description

The MCMC procedure is a general purpose Markov chain Monte Carlo simulation tool designed to fit a wide range of Bayesian models, including linear or nonlinear models, multi-level hierarchical models, models with nonstandard likelihood function or prior distributions, and missing data problems. This tutorial provides a quick and gentle introduction to PROC MCMC and demonstrates its use with a series of applications, such as Monte Carlo simulation, various regression models, sensitivity analysis, random-effects models, and predictions.

Increasingly, Bayesian methods are being used by statisticians in the pharmaceutical field to handle industry-specific problems. This tutorial will also present a number of pharma-related data analysis examples and case studies, including network meta-analysis, power prior, and missing data analysis. This tutorial is intended for statisticians who are interested in Bayesian computation. Attendees should have a basic understanding of Bayesian methods (the tutorial does not allocate time covering basic concepts of Bayesian inference) and experience using the SAS language. This tutorial is based on SAS/STAT 13.2.

T6:
Graphical Approaches to Multiple Test Problems

3:45 pm – 5:30 pm

Dong Xi
Novartis Pharmaceuticals

Description

Methods for addressing multiplicity are becoming increasingly more important in clinical trials and other applications. In the recent past, several multiple test procedures have been developed that allow one to map the relative importance of different study objectives as well as their relation onto an appropriately tailored multiple test procedure, such as fixed-sequence, fallback, and gate keeping procedures. In this tutorial we focus on graphical approaches that can be applied to common multiple test problems, such as comparing several treatments with a control, assessing the benefit of a new drug for more than one endpoint, and combined non-inferiority and superiority testing. Using graphical approaches, one can easily construct and explore different test strategies and thus tailor the test procedure to the given study objectives. The resulting multiple test procedures are represented by directed, weighted graphs, where each node corresponds to an elementary hypothesis, together with a simple algorithm to generate such graphs while sequentially testing the individual hypotheses. We also present several case studies to illustrate how the approach can be used in clinical practice. In addition, we briefly consider power and sample size calculation to optimize a multiple test procedure for given study objectives. The presented methods will be illustrated using the graphical user interface from the gMCP package in R, which is freely available on CRAN.

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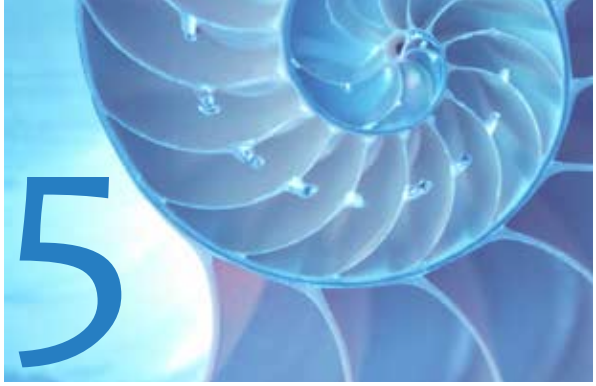

Roundtables

Monday, March 16 | 12:15pm – 1:30pm

Registration Is Required: $40

R1: Survival Strategies for Junior Researchers: Can You Have It All?

Bhramar Mukherjee
University of Michigan School of Public Health

Description

As soon as you get a "real job" after completing your doctoral or post-doctoral training, the expectations and responsibilities from your employer increase dramatically. Unfortunately, this critical time window of establishing yourself in the profession also coincides with the phase when demands from your personal life escalate. We will share some useful strategies for time management, carefully selecting research problems as a junior researcher, establishing independence from your advisor, prioritizing in terms of teaching, research, collaboration and professional service opportunities and ultimately for trying to strike a work-life balance.

It is a complex multi-dimensional optimization problem with non-linear constraints, and while there is no uniform and obvious solution that works for everybody, we can take advantage of shared experiences and existing resources to maximize our chance of success, in both personal and professional terms. This discussion will be relevant for senior graduate students, post-doctoral researchers, junior researchers in both industry and academia who are planning to enter/have recently entered the work force.

SOLD OUT

R2: New Trends and Innovations in Science and Practice of Clinical Trials

Olga Marchenko
Quintiles

Description

The intent of this roundtable discussion is to highlight, share, and discuss the views on some new trends and innovations in science and practice of clinical trials. Specific topics of this discussion will include:

- Innovative designs (e.g., adaptive designs, biomarker-driven designs) where we are today
- Statistical and IT applications on smart phones to collect data (e.g., patient diary), to adjust doses (e.g., a dose for diabetes patients), to analyze data (e.g., simple summaries and graphics) just an idea or the reality?
- Statistical and operational simulations why do we need them?
- Predictive analytics to improve operational support should we statisticians step up?

SOLD OUT

R3:
The Role of Statisticians at the FDA

Dionne L. Price
Food and Drug Administration

Description
The Food and Drug Administration (FDA) is composed of seven centers which collectively employ over 250 statisticians. Statisticians at the FDA are an integral part of multidisciplinary teams dedicated to assuring the safety and efficacy of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. Statisticians analyze and evaluate data, provide leadership, promote innovation in study designs and statistical techniques, and conduct methodological research aimed at addressing the many complex issues that arise in a regulatory environment. FDA statisticians utilize their statistical training and knowledge to directly impact the public health. Roundtable participants will learn the role of statisticians at the FDA and potential paths to successful careers with the Agency.

R4:
Applying Bayesian Evidence Synthesis in Comparative Effectiveness Research

David Ohlssen
Novartis Pharmaceuticals

Description
Motivated by the use of evidence based medicine to evaluate health technology, there has been an enormous increase in the use of quantitative techniques that allow data to be combined from a variety of sources. In a drug development setting, there have been a number of recent key works: The recommendations on the use and application of network meta-analysis were recently presented by the ISPOR task force; from a regulatory perspective, the work of the Canadian Agency (Indirect Evidence: Indirect Treatment Comparisons in Meta-Analysis) and the UK NICE Evidence synthesis series have recently been published; Further, the FDA also started a number of recent projects on comparative effectiveness research as part of a plan to enhance regulatory science. By drawing on examples from a drug development setting, this roundtable aims to discuss these recent advances.

SOLD OUT

R5:
Survival Skills for Biostatisticians in Academic Medical Centers

Mithat Gönen
Memorial Sloan-Kettering Cancer Center

Description
Biostatisticians in academic medical centers face different challenges than their counterparts in universities and academia. This will be an interactive discussion of these challenges. Possible topics to be covered include the double-edged nature of collaborative work, managing the collaborations to sustain funding, find intellectual fulfillment in formulating one's own methodological work, avoiding being overwhelmed and demotivated by the amount and nature of collaborations, gaining acceptance as an intellectual contributor (as opposed to being a p-value generator) from one's collaborators and striking work-life balance.

SOLD OUT

R6:
Working as a Statistician at the Center for Devices at the FDA

Telba Irony
Food and Drug Administration

Description
In this round table, I will discuss the life of statistician at the Center for Devices and Radiological Health, highlighting the fact that the statistician is a problem solver, who must be interested in science and teaching, and could aspire to leadership positions.

R7:
Writing Collaborative Grant Applications: Tips and Strategies

Brisa Sánchez
University of Michigan School of Public Health

Description
One of the key aspects of a biostatistics career in academia or university is participation in collaborative research and writing grant proposals to support that research. In this round table we will discuss the range of contributions statisticians make to the grant writing process, share tips and strategies to make the process more efficient, and discuss how participation in collaborative grant proposals can enhance the biostatistician's methodological research.

SOLD OUT

R8:
Interplay Between Adaptive Design Features and Complex Study Subjectives, Case Studies and Tools

Yevgen Tymofyeyev
Janssen Research & Development

Description

The current state of available commercial implementations of adaptive designs software covers substantial practical needs. On the other hand, there are also practical situations where a need exists for custom-made programming to satisfy requirements and special features of a particular study or program. Such cases are hard to envision up-front in order to warrant a commercial off-the-shelf tool. An example could be a study with multiple doses of the active drug, multiple comparators and several primary endpoints, where the corresponding multiple tests can be organized into some logical structure resolved by the application of a gatekeeping- type procedure, to address the multiple testing problem. This roundtable is intended to share experiences of interesting case studies addressing not only statistical design and simulation components, but also logistical implementation issues and interactions with regulatory agencies.

R9:
Publishing Without Perishing: Strategies for Success in Publishing in (Bio)statistical Journals

Marie Davidian
North Carolina State University

Description

Contributing to the advance of our discipline through publication of articles in peer-reviewed journals is a fundamental expectation for both junior and not-so junior biostatistical researchers alike. Success in publishing one's work ensures that it will be widely disseminated to researchers and practitioners who stand to benefit. In addition, funding agencies and academic institutions place considerable importance on a successful record of publication. Accordingly, understanding the peer review and publication process, knowing journals and mastering the art of writing an effective journal article are keys to success in publishing. How does one determine the best outlet for one's work? What are the essential elements of a successful journal article? How does one maximize the chance of acceptance? What strategies can ensure that a published paper is read and cited? How does one make optimal use of limited space and additional supplementary material in conveying the message? What are the roles of the editor, associate editor, and referees? What considerations do editors use when evaluating a paper? This roundtable will provide a forum for candid discussion of these and other questions.

SOLD OUT