American Statistical Association Kansas-Western Missouri Chapter

Please join us for our fall Chapter meeting on Thursday, October 29th, 2015 at Edwards Campus - University of Kansas. The dinner and the Chapter meeting will be held in the BEST 120 Conference room after the conclusion of the Short Course *Introduction to Clinical Trials* (see below). The directions to KU Edwards Campus and a map of the facilities are provided. You may also visit their website at http://edwardscampus.drupal.ku.edu/campus-map for more information.

Keynote Address: Susanne May, PhD, Associate Professor, Department of Biostatistics, University of Washington, Seattle

Title: *The rise and fall of hypertonic saline (with sugar on top)*

Abstract: In the US traumatic injury is the leading cause of death between the ages of 1 and 44 and results in almost 150,000 deaths per year. Early deaths are typically the result of hypovolemic shock or severe traumatic brain injury. Late deaths typically result from multiple organ dysfunction or nosocomial infection. Hypertonic saline (HS, 7.5% saline solution) and hypertonic saline coupled with 6% dextran-70 (HSD) were expected to aid in rapid restoration of cerebral perfusion and to reduce subsequent organ injury. There were promising results from animal studies, but early clinical trials had mixed results. This talk will focus on a phase II and a phase III clinical trial which investigated HS and/or HSD and their impact on survival for patients with hypovolemic shock and/or traumatic brain injury (TBI). The phase III study in TBI was stopped because it was determined that the hypertonic saline solutions were no better than the standard treatment of normal saline and that it was unlikely that continuing to enroll new patients would change the outcome of the study. The phase III study in shock patients was stopped because patients who received the concentrated saline solutions were no more likely to survive than those who received a normal saline solution and had earlier, although not increased mortality. While presenting further details regarding the rise and fall of HS(D) questions such as the following will be discussed: Do you know that visiting San Diego puts you "at risk" of being enrolled into a study without being asked whether you want to? What does (bio)statistics have to do with the rise and fall of HS(D)? Why was a government agency disappointed with modification of the sequential monitoring boundaries before they stopped? Could a statistician be accused of killing patients?

Registration for this event can be done online at https://www.123signup.com/register?id=pmnxf
Please contact Wei-Wen Hsu at KSU (wwhsu@k-state.edu) or John Keighley (jkeighle@kumc.edu) if you have any questions.

Cost: The cost to attend the Chapter meeting is $30.00 ($20.00 for students), and includes dinner. Vegetarian options will be available.

Location: University of Kansas, Edwards Campus (BEST 120)
                12600 Quivira Rd., Overland Park, KS 66213

We look forward to seeing you at the Chapter meeting!

Chapter Meeting Agenda:

> 6:00 – 6:30 p.m. Social time
>
> 6:30 – 7:15 p.m. Dinner
>
> 7:15 – 7:30 p.m. Chapter business
>
> 7:30 – 8:30 p.m. Keynote Address

Short Course:

Time: 9:00AM-5:00PM on October 29, 2015

Location: University of Kansas, Edwards Campus (BEST 120)
                   12600 Quivira Rd., Overland Park, KS 66213

Title: *Introduction to Clinical Trials*

Presented by: Susanne May, Ph.D.

Course summary:

Primary Design Issues
– Introduction / Background
– Screening Studies
– Fundamentals of Trial Design
– Statistical Tasks in Trial Design

Conduct and Implementation
– Randomization strategies
– Blinding
– Handling of missing data
– Conduct and monitoring of the study
– Reporting of result

The course does not assume prior knowledge of clinical trial design or analysis, but familiarity with basic statistical concepts and study designs is assumed. Mathematical details are kept to a minimum. Approaches, challenges and issues will be illustrated with examples.

After this short course you should be able to

- Critique some of the aspects of the design, conduct and analysis of a randomized clinical trial
- Design the fundamental characteristics of a clinical trial to address an important scientific problem

- Understand the challenges related to selected topics regarding the conduct and implementation of a clinical trial

Registration for this event is now open: https://www.123signup.com/register?id=pmhbr

Cost: $100 for ASA members, $50 for students, $150 for non-ASA members
Boxed lunch included in registration, limited number of vegetarian options available

About the Instructor:
Dr. May is Associate Professor of Biostatistics at the University of Washington, Seattle. She has twenty years of experience in providing statistical support for research projects. She has taught on the subjects of introductory statistics, survival analysis and clinical trials. She is the principal investigator of a large data coordinating center for a multisite North American Resuscitation Outcomes Consortium.

Directions to Edwards Campus – University of Kansas:
12600 Quivira Rd., Overland Park, KS 66213

Free parking is available to visitors and students except for designated faculty/staff parking located on the South side of Regnier Hall marked with signage. Please refer to the campus map for more details.

From the West:
Via **I-70 East**
- From I-435, take Exit 411A to merge onto I-435 S
- Take Exit 82 for Quivira Rd and turn right
- Campus is approximately 2.5 miles South on your right

Via **K-10 East**
- From K-10 E, merge onto I-435 E
- Take Exit 82 for Quivira Rd. and turn right
- Campus is approximately 2.5 miles South on your right

From the East:
Via **I-470 South**
- Merge onto I-435 West
- Take Exit 82 for Quivira Rd. and turn left
- Campus is approximately 2.5 miles South on your right

Via **I-435 South/East**
- From I-435, take Exit 82 for Quivira Rd and turn left
- Campus is approximately 2.5 miles South on your right

From the South:

Via **I-35 North**
- From I-35 N, take Exit 222A for I-435 E
- Take Exit 82 for Quivira Rd. and turn right
- Campus is approximately 2.5 miles South on your right

From the North:
Via **I-35 South**
- From I-35 S, take Exit 222A for I-435 E
- Take Exit 82 for Quivira Rd. and turn right
- Campus is approximately 2.5 miles South on your right