

Statfax

Fall Meeting Presentations

Please join us for the Fall Meeting on Thursday, October 15, at the Renaissance Hotel, 933 Skokie Blvd., Northbrook IL 60062. Lunch is at 11:30 with presentations starting at 12:30. There will be two sessions featuring three speakers discussing practical issues on adaptive design in drug development.

If you think adaptive design is just an academic game that is played by Assistant Professors in order to get tenured or the tenured professors to get famous and rich, think again. It is actually much closer to applied biostatisticians than you might think. In this Fall meeting of NIC-ASA, we will feature three speakers from Takeda and Abbott who are going to discuss REAL life examples that involve the adaptive design.

The titles, abstracts, and biographies for the speakers are:

Title: Adaptive Design Considerations for Evaluating Cardiovascular Risk among Patients with Type-2 Diabetes

Speaker: Craig Wilson, PhD

Abstract: In December 2008, the FDA released a final Guidance for Industry for evaluating Cardiovascular Risk (CV) risk in subjects with Type-2 Diabetes (T2DM). This guidance established criteria for assessing the risk ratio of an investigational drug relative to

control in premarketing applications. In particular, if sufficient data are available to rule out a risk ratio of 1.8, then an investigational drug may be approved with a postmarketing commitment; if a risk ratio of 1.3 may also be ruled out, then a postmarketing requirement to assess CV risk may not be required.

For sponsors with investigational drugs for treatment of T2DM currently under development, one approach to satisfy this guidance is to design a single stand-alone CV trial which may sequentially rule out risk ratios of 1.8 and 1.3.

This presentation will focus on design considerations for such a trial, including adaptive design issues. Discussion of the pros/cons of Bayesian vs. group sequential design will be provided.

Speaker's Bio: Dr. Craig Wilson is a Principal Statistician at Takeda Global R&D in Lake Forest, Illinois. Since receiving his PhD from Oklahoma State University in 1998, Craig has served as study statistician and lead statistician on a variety of drugs for treatment of T1DM and T2DM. During his time in industry, Craig has had extensive discussions with the FDA regarding the design and analysis of diabetes trials, including trial requirements for satisfying the CV guidance.



Title: Bayesian Adaptive Randomization Design- A Case Study & More

Speakers: Yili Pritchett, PhD & Shu Han, PhD

Abstract: In recent years, Bayesian adaptive randomization design has been increasingly applied to clinical trials. In this presentation, a real case study will be used as an example of the three major mathematical components of the design: the modeling of dose-response relationship, the algorithm of computing updated randomization ratio, and the longitudinal model that predicts endpoint using partial observations.

Additionally the decision rules that allow the study to stop early due to efficacy or futility will be explained, and the operating characteristics of the design and the results of sensitivity analyses for the key parameters will be illustrated. Simulation procedures via MCMC (Markov Chain Monte Carlo) method will also be described.

Lastly, other real clinical trial cases where Bayesian adaptive designs were used to gain efficiency and effectiveness in drug and medical device developments will be shared.

Speakers' Bio:

Yili L. Pritchett is a Research Fellow and a Director of Clinical Statistics in Global Pharmaceutical R&D at Abbott Laboratories. She is responsible for statistical aspects of Phase II – IV drug development in Neuroscience, Pain Care, and Renal Care therapeutic areas. Before joining Abbott in April 2006, Dr. Pritchett was a Research Advisor at Eli Lilly and Company where she provided statistical leadership at various levels for the development and approval of several brands. Dr. Pritchett obtained her Ph.D. in Statistics from the University of Wisconsin–Madison in 1994.

Dr. Pritchett is an active member of PhRMA Adaptive Trial Design Working Group. She has championed the use of adaptive design in Abbott, and led the efforts of delivering a number of protocols with different types of adaptive design. Dr. Pritchett authored or co-authored 46 peer-reviewed manuscripts or book chapters, and made over 100 presentations at statistical or medical conferences.

Shu Han, Ph.D. is currently a research statistician at Abbott Laboratories, where he played active role in the designs and implementations of multiple clinical trials using Bayesian adaptive designs. Before joining Abbott in 2006, Shu worked for Guidant/Boston Scientific Corporation, where he designed an adaptive seamless exploratory-confirmatory clinical trial evaluating heart failure diagnostic medical devices, and got FDA's agreement on the design. Shu also worked for the Quantitative Science Division of M. D. Anderson Cancer Center as a Research Assistant to Dr. Donald A. Berry from 2003 to 2005. Shu received his Ph.D. in statistics from a joint doctoral program at M.D. Anderson Cancer Center and Rice University, and received a Masters degree in statistics from Columbia University. He is currently pursuing a MBA at the University of Chicago.

President's Report

Dear Fellow Members,

It has been a great pleasure and honor for me to serve as the President of the NICASA this year. Despite tighter budget control by the employers of our members, we still managed to hold our Spring and Summer meetings successfully. Thanks to savings from previous years, I am glad to report that our chapter has

a positive balance to move forward with future meetings.

Although we have talked about adaptive designs in previous meetings, this Fall we will feature three speakers who are statisticians among our members with their hands “dirty” in the practice of adaptive design. I hope this seminar will provide some unique perspectives on the challenges and issues we are facing. Rumor has it that FDA has been working on a draft guidance for the industry on adaptive designs in drug development and is planning to issue it to the public in the near future, so this is gaining momentum for the industry. Regardless of whether you are trained as a Frequentist or as a Bayesian Statistician, you may benefit from this seminar. So please mark your calendar on October 15th and “beg” your supervisor for half day off. (I personally think that our seminars are the most cost-effective learning venues for statisticians in this region and would encourage our members to take advantage of them whenever possible.)

Since all of our committee members serve the chapter on a voluntary basis, I would like to thank each and every one for contributing time and effort to keep our chapter active in pursuing scientific discussions and continuing education. While every chapter officer deserves a pat on the back when you see them in the meetings, my special thanks go to Sandra Sinisi who has been a wonderful Chapter Secretary in keeping us organized and Zhen Zhao who has served us for the past three years to make sure we are not running on subprime loans or money borrowed from China. So please give each of them at least two pats on the back if you get a chance.

As the country and the world have witnessed economic roller coasters lately, I am glad that our members have been able to keep our jobs.

In fact, there was a recent report by New York Times advertising Statistics to students (<http://www.nytimes.com/2009/08/06/technology/06stats.html>). So the future seems to be bright for our profession and I wish every member of our chapter job security and prosperity. Zhu Ni Hao Yun!



Upcoming Meetings

Joint Statistical Meeting, ASA (Vancouver, July 31 - August 5 2010)



SAS Global Forum April 11-14, 2010 in Seattle



PharmaSUG May 23 to 26, 2010 in Orlando



The Chicago ASA usually has a Statistical Lunch each month. For details see the Chicago ASA web site (<http://www.chicagoasa.org/>).



Stats Seminars at UIC: The Mathematics, Statistics, and Computer Science Department of the University of Illinois at Chicago hosts statistical seminars throughout the year. For more information, see the seminars website (<http://www.math.uic.edu/seminars/>).

Volunteers Opportunities

Please see the chapter website for any opportunities.

Getting Involved

Volunteers are needed to help with registration at the Fall Meeting. Registration volunteers will be expected to arrive about a half-hour prior to the start of the registration period and will work at the registration desk as directed by the Chapter Treasurer, Zhen Zhao. This is a great way to connect faces

with names and get to know other Chapter members.

Election of the Chapter Officers for 2010 will take place at the start of the Fall Meeting. If you would like to run for office or become a Chapter Committee Member or registration volunteer, please contact the Chapter Secretary, Sandra Sinisi.

~ Sandra Sinisi

Job Opportunities

Please see the chapter website for any opportunities.

Chapter Website

Our Chapter's website is getting a new look. Please check it out at:
<http://www.amstat.org/chapters/NortheasternIllinois>.

The website contains lots of information about our Chapter, including events, program information, and contact information for Chapter officers and committee members. You can also peruse current and past Chapter newsletters. Finally, if the speaker provides them, slides/notes from previous presentations are available to view or download.

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Statfax is published three times a year (Spring, Summer, and Fall), by the Northeastern Illinois Chapter of the American Statistical Association.

Statfax welcomes letters and material for articles from its readers. Address correspondence to: The Editor, Statfax, c/o Carl Slenk, Abbott Molecular, 1300 E. Touhy Ave., Des Plaines IL 60018

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The Chapter's purpose, as stated in its Constitution, is "to foster statistics and its applications and promote the interests of the statistical profession...". Accordingly, diverse views are presented. They do not necessarily reflect the opinions of the officers or the policies of the Chapter.