
Statfax

Fall 2023 Newsletter

Northeastern Illinois Chapter of the American Statistical Association

From the Editor's Desk



Welcome to the second newsletter of 2023. This newsletter looks at chapter activity during 2023, and it provides brief summaries as appropriate.

The end of this year marks the end of Jamie Myles' 2-year term as the Chapter's Past President. I would like to thank him for the many (uncountably infinite) contributions that he has made to the Chapter and wish him the best as he continues his professional career. Next January will also mark Saurabh Mukhopadhyay's transition from President to Past President and Jung Wook Park's transition from President-Elect to President.

Chapter Election

An important remaining activity for this year is the election of Chapter officers and the possible associated reconstruction of the Executive Committee.

Currently the Executive Committee has received nominations for the three elected offices of President-Elect, Secretary, and Treasurer. The President-Elect will serve a 6-year term – 2 years in that position, followed by 2 years as President, followed by 2 years as Past President. In addition to those positions, nominations are also being received for positions on the Executive Committee (Scientific Outreach, Webmaster, Newsletter Editor, Mailing List Administrator, Arrangements Coordinator, and Community Officer). The new officers will assume their positions on January 1, next year.

Nominations will remain open until October 5. If you would like to nominate someone, please notify us by sending an email to the Chapter address (northeasternchapterasa@gmail.com). New officers will be announced at the annual business meeting.

Spring Course

In June, the chapter sponsored and organized a successful ASA Council of Chapters traveling course entitled 'Fundamentals of Causal Inference: With R'. The all-day course was taught by Dr. Babette Brumback, Professor Emerita of the Department of Biostatistics at the University of Florida. Dr. Brumback is well known for her research on causal inference and is the author of a recently published textbook 'Fundamentals of Causal Inference: with R'. The course focused on explaining and relating different methods for disentangling causation from confounding in clinical trials and observational studies.

The course was held at Astellas Pharma Global Development and was attended by approximately forty statisticians.

President: Saurabh Mukhopadhyay,
AbbVie

Past President: Jamie Myles,
Immunix Therapeutics

President-Elect: Jung Wook Park,
Astellas

Secretary: Lei Shu, AbbVie

Treasurer: Mengqi (Maggie) Xiao,
J&J

Scientific Outreach: Julia Lee,
Northwestern University

Webmaster: Jiewei Zeng, AbbVie

Newsletter Editor: John Schoenfelder,
AbbVie (retired)

**Mailing List Administrator
& Arrangements Coordinator:**
Yunzhao Xing,
AbbVie

Community Officer: Xiaotian Chen,
AbbVie

Fall Conference

Each fall, the NIC-ASA and the Midwest Chapter of the ICSA (International Chinese Statistical Association) hold a Joint Meeting. The responsibility for organizing that meeting alternates between the two groups yearly. This year, the ICSA Midwest Chapter is taking the lead in organizing the meeting, and multiple members of the NIC-ASA are actively involved in the organizing committee. The two-day event will be held at the Hilton Chicago/Northbrook hotel on October 12 and 13.

The first day will consist of two short courses. The morning course is 'Randomization in Clinical Trials: Theory and Practice' and will be taught by Dr. William F. Rosenberger, Distinguished University Professor, George Mason University. The afternoon course is 'Defining Causal Estimands and Handling Missing Values in Clinical Trials' and will be taught by Dr. Ilya Lipkovich, an Executive Director at Eli Lilly and Company, and Dr. Yongming Qu, a Vice President at Eli Lilly and Company.

The second day will begin with the Keynote address given by Dr. Claude Petit, Vice President, Statistical and Real World Data Science at Astellas. Her address is entitled 'Will AI Change the Future of Biostatistician'. The keynote address will be followed by 9 scientific sessions, a student roundtable, and a student poster session.

More information is available via the announcement on the landing page of our NIC-ASA website (see the link below). Individual registration will be open until October 5 and is being handled by Eventbrite (a link to Eventbrite is included on the NIC-ASA website).

Website

Information about the Chapter and its activities can be found on the chapter's Website. The link to the website is given below:

<https://community.amstat.org/northeasternillinoischapter>

We are continuing to update and modernize the website with the general goal of making it more complete and easier to navigate. We recently incorporated a generic

landing page that introduces the chapter and provides space for general announcements. The next update will be a modernization of the history link. That is scheduled to be completed later this year.

The following are snapshots of the two Chapter Chatter articles that have been published to date.

Chapter Chatter

We recently submitted our second Chapter Chatter of 2023. The current schedule is that it will be published on the ASA Portal in mid-October.

Update on FDA Guidance Documents**FDA Issues Draft Guidance Regarding Confirmatory Evidence of Clinical Trials.**

Recently (September 2023), CDER, along with FDA's Center for Biologics Evaluation and Research and the Oncology Center of Excellence, issued the draft guidance [Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence](#).

This guidance (the Confirmatory Evidence guidance) complements the draft guidance for industry [Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products](#) (December 2019) and the guidance for industry [Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products](#) (May 1998).