12th Statistics Workshop:

From Data to Patients – CMC Statisticians Contributions to Quality, Safety, and Efficacy of Pharmaceutical Products

October 20-22, 2026

Rockville, MD, U.S.A.

IABS
International Alliance for Biological Standardization
www.iabs.org

Every analysis, model, and decision in Chemistry, Manufacturing, and Controls (CMC) ultimately serves one goal—improving patient outcomes. CMC statisticians are at the forefront of this mission, ensuring that pharmaceutical products meet the highest standards of quality, safety, and efficacy.

Like chefs transforming ingredients into a finished dish, statisticians transform data using their knowledge, methodologies, and software, into insights that support sound decision making. In a regulated environment, our work is rigorously evaluated by health authorities, much like critics assessing whether a Michelin star is deserved. As Dr. Ji Hyun Lee, former ASA President, remarked: "I truly value every data point in my hand, because each one represents a patient's story, struggle and journey." This mindset reflects the broader reality across CMC: behind every data point is a patient, and our analytical rigor directly contributes to ensuring their safety and well being.

This conference will highlight the critical role of statisticians across the CMC lifecycle through four core sessions:

1. Data – The early role statisticians can play in shaping data systems, improving data quality, as well as managing and leveraging increasingly complex datasets.

2. Software – The importance of reliable software—both point and click and code based—, and their appropriate use, in producing sound statistical analyses in a regulated environment.

3. Methodologies – Three mini-keynotes highlighting the evolving landscape of statistical methodologies within CMC:

- The fundamental role of **frequentist statistics** in CMC decision-making
- The growing influence of **Bayesian methods** in uncertainty quantification, inference, and modeling
- The potential of **AI and machine learning** for predictive modeling and process optimization

4. Regulatory Review – Perspectives from global health authorities on key statistical considerations in regulatory submissions.

Additionally, a **workshop** will provide practical overviews of the role SAS, JMP and R have in helping us transform data into insights.

This program reflects the Big Tent vision of statisticians' contributions to healthcare and reinforces the vital connection between statistical rigor and patient well-being.

Scientific Committee

Ruojia Li – BMS (Co-Chair)
Jia Liu – Pfizer (Co-Chair)
José Ramírez – Kite Pharma, a Gilead Company (Co-Chair)
Timo Bailer – Boehringer Ingelheim
Fang Chen – SAS
Catherine Cheng – Novartis
Madinina Cox – Events Manager, IABS/MC'Com
Irina Gershgorin – Legend Biotech
Ashley Giambrone – Regeneron
Jennifer Kirk – FDA
Brooke Marshall – Eli Lilly & Co.
Cristian M. Oliva-Aviles – Genentech
Oluyemi Oyeniran – Johnson & Johnson
Laura Pack – Moderna
Jayda Siggers – Health Canada
Christopher Thompson – AstraZeneca
Travis Wolter – Amgen
Jie Zhao – Merck

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Further information