



**IABS 12th Annual Statistics Workshop:
From Data to Patients – CMC Statisticians Contributions to
Quality, Safety, and Efficacy of Pharmaceutical Products**

October 20-22, 2026

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 / Organizing Committee

Ruojia **Li** – BMS (Co-Chair)
Jia **Liu** – Pfizer (Co-Chair)
José **Ramírez** - Kite Pharma, a Gilead Company (Co-Chair)
Timo **Bailer** - Boehringer Ingelheim
Madinina **Cox**, Events Manager, IABS/MC'Com
Fang **Chen** – SAS
Catherine **Cheng** – Novartis
Jennifer **Kirk** – FDA
Irina **Gershgorin** – Legend Biotech

Ashley **Giambrone** – Regeneron
Brooke **Marshall** - Eli Lilly & Co.
Cristian **M. Oliva-Aviles** – Genentech
Oluyemi **Oyeniran** – Johnson & Johnson
Laura **Pack** – Moderna
Christopher **Thompson** – AstraZeneca
Travis **Wolter** – Amgen
Jie **Zhao** – Merck

Provisional Workshop Program

Day 1: Tuesday, October 20, 2026

8.30am *Registration & Welcome Coffee*

9.00 am *Introduction to IABS*

Welcome to Workshop
Ruojia LI – Co-Chair, BMS
Jia Liu – Co-Chair, Pfizer
José **Ramírez** - Co-Chair, Kite Pharma, a Gilead Company

Keynote Session

9.15 am More Than Numbers: How Everyday Statisticians Shape Science
Prof. Ji-Hyun **Lee** – University of Florida

Session I: Data

Session Chairs: Brooke Marshall & Ashley Giambrone

10.15 am *Session introduction*
TBC

10.20 am TBC
Dan (Cassie) **Liu**, Ruojia **Li** – BMS

10.50 am Kite From Data to Insight: Enabling Scalable, GxP-Compliant Analytics Through an Integrated Data Lake
Brenda **Ramirez** – Kite Pharma, a Gilead Company

11.20-11.35 am Break

- 11.35 am** Beyond the Spreadsheet: Strengthening CMC Data Governance as the Foundation for Advanced Analytics and Regulatory Compliance
Sara **Cook**- IliaCool Consulting
- 12.05 pm** TBC
- 12.35 am** Panel Discussion
All speakers
- 1.15-2.15 pm** *Lunch Break*

Session II: Software
Session Chairs: Travis Wolter & Fang Chen

- 2.15 pm** *Session Introduction*
TBC
- TBD** Keynote
- 2.45 pm** TBC
- 3.15 pm** TBC
- 3.45 pm** TBC
- 4.15-4.30 pm** Break
- 4.30 pm** TBC
- 5.00 pm** Panel Discussion
All speakers
- 6.00 pm** *End of Day 1*

Day 2: Wednesday, October 21, 2026

8.30am *Registration & Welcome Coffee*

Session III: Methodologies
Session Chairs: Laura Pack, Timo Bailer & Cristian M. Oliva-Aviles

9.00 am *Session introduction*
TBC

9.05 am	The fundamental role of frequentist statistics in CMC decision making Rick Burdick , Burdick Statistical Consulting, LLC
9.35 am	Role of Bayesian statistics in CMC Stan Altan , Johnson&Johnson
10.05 am	Role of ML/AI in CMC TBC
10.35-11.00 am	Break
11.00 am	TBC
11.30 am	Panel Discussion All speakers
12.30-1.30 pm	<i>Lunch Break</i>

Session IV: Regulatory Review

Session Chairs: Jennifer Kirk

1.30 pm	<i>Session Introduction</i> TBC
1.35 pm	TBC
2.05 pm	TBC
2.35 pm	TBC
3.05 pm	Break
3.35 pm	TBC
4.05pm	Panel Discussion All speakers
5.05pm	<i>End of Day 2</i>

Day 3: Thursday, October 22, 2025

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| 8.30 am | <i>Registration & Welcome Coffee</i> |
| 9.00 am | Workshop 1 - JMP |
| 10.00 am | Workshop 2 by R: AI Tooling for Data Analysis
Max Kuhn - Posit PBC |
| 11.00 am | Workshop 3 - SAS |
| 12.00 pm | <i>Workshop Summary</i> |
| 12.15 pm | <i>End of Workshop and Invitation to 2027 Workshop</i> |