



**IABS 11<sup>th</sup> Annual Statistics Workshop:  
Big Tent Statistics - Conveying the Importance of Statistical Contributions**

*October 20-23, 2025*

*Virtual Meeting*

As president of the American Statistical Association (ASA), Dr. Robert Rodriguez envisioned the association as a “big tent” for statistics—one that welcomes diverse statisticians, supports their growth, and amplifies their impact. In his 2012 presidential address, he emphasized that “Statistics improves human welfare. Statistics improves human welfare not by its own ends, but by its contributions in all fields.”

The theme of this year’s workshop highlights the collaborative and contributory nature of our profession. Statisticians play a crucial role as strategic partners not only in science, engineering, and business, but in society at large. Through four key sessions:

- Contribution & Differentiation,
- Experimentation & Investigation,
- Collaboration and Recognition, and
- Innovation & Acceleration

We will explore the breadth and depth of these contributions and how our collaborative efforts with scientists, regulators and other stakeholders drive innovation and efficiency. By fostering strong cross-functional collaborations, we can ensure that our collective efforts lead to meaningful advancements in science, engineering, and business, ultimately improving human welfare and accelerating the delivery of medicines to patients.

Drawing inspiration from Dr. Rodriguez’s charge— “Regardless of whom we serve, whether they call themselves statisticians, scientists, or business analysts, we must convey the importance of statistical contributions. We must have the ability to explain, demonstrate, and prove that importance to students, to the media—and most of all—to society.” — We will discuss strategies for effectively communicating our impact and demonstrating the value of statistics across disciplines.

Join us in affirming the ‘Big Tent’ vision and shaping a future where statistics continues to enrich every domain it touches.

## 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  
Stan **Broskey** – Merck  
Madinina **Cox**, Events Manager, IABS/MC'Com  
Fang **Chen** - SAS  
Catherine Cheng – Novartis  
Jennifer **Kirk** – FDA

Irina **Gershgorin** – Legend Biotech  
Ashley **Giambrone** – Regeneron  
Kristi **Griffiths** - 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

## Workshop Program

Times are indicated Eastern Daylight Time

### Day 1: Monday, October 20, 2025

- 9.15 am      **Opening of the meeting – Welcome and introduction to the meeting and IABS**  
                 **Ruojia LI** – Co-Chair, BMS  
                 **Jia LIU** – Co-Chair, Pfizer  
                 **José RAMIREZ** – Co-Chair, Kite Pharma, a Gilead Company
- 9.25 am      *Keynote: Conveying the Value of Statistical Contributions*  
                 Dr. Robert **Rodriguez**

### Session I: Contribution & Differentiation

*Session Chairs: Oyeniran Oluyemi & Fang Chen*

The contribution of CMC (Chemistry, Manufacturing, and Controls) statistics in the pharmaceutical industry is fundamental to establishing and maintaining high standards of drug quality, safety, and efficacy throughout the product lifecycle. Additionally, CMC statisticians play a crucial role in facilitating regulatory compliance and optimizing manufacturing processes. However, as the pharmaceutical industry advances into the era of Industry 4.0, automation, and digital transformation, CMC statisticians encounter the complex challenge of clearly articulating their vital contributions amid the increasing prominence of other data-centric roles. Compounding this challenge is the fact that these roles often employ similar statistical techniques, advanced algorithms, and large datasets to derive insights, and decision-making.

In this evolving landscape, CMC statisticians must strategically navigate these challenges to assert their distinct and critical contributions to drug development and manufacturing excellence. This session aims to explore strategies for regaining recognition and maximizing the value delivered to our respective organizations. Esteemed speakers, collectively possessing over a century of experience, will share insights into the unique value statisticians bring to the table, effective methods of advocacy within leadership, and approaches to strengthening statistical practices in the industry.

- 10.10 am      *Session introduction*  
                 Oluyemi **Oyeniran** – Johnson & Johnson  
                 Fang **Chen**, SAS

- 10.15 am Expanding Our Reach by Reviewing Our Roots  
Jim **Garrett**, Replicate! Statistical Planning and Analysis
- 10.45 am Collaborating with Impact: Differentiating CMC Statistics in a Data-Driven Industry  
Stan **Altan**, JJIM
- 11.15 am CMC Statistics in a Data Science World  
Mark **DiMartino**, Amgen
- 11.45 am **Break**
- 12.00 pm **Panel Discussion**  
**All speakers**
- 1.00 pm **Parallel Breakout Sessions**  
#1 – The Statisticians’ Seat at the Table – Strategies for building effective, cross-functional collaborations  
Moderator: Fang Chen, SAS  
#2 - How can AI be leveraged to advance CMC statistics?  
Moderator: Ruoja Li, BMS
- 1.40 pm Conclusion & End of Day 1

## Day 2: Tuesday, October 21, 2025

### Session II: Experimentation & Investigation

*Session Chairs: Kristi Griffiths & Travis Wolter*

Effective experimentation and investigation hinge on the ability to formulate pertinent questions, fostering deeper understanding and impactful discoveries. This session will spotlight case studies showcasing vital collaborations between statisticians and scientists/engineers. Topics may include experimental design, statistical insights, quality by design principles, applications of statistics to QbD (Quality by Design), and industry guidelines.

- 10.00 am *Session introduction*  
Kristi **Griffiths** - Eli Lilly & Co.  
Travis **Wolter** – Amgen
- 10.05 am Bayesian Hierarchical Models for Enhanced Experimental Design  
Adam **Rauk** - Eli Lilly & Co.
- 10.35 am DoE as a process discovery tool in compositional systems  
Rick **Kramer**, Ferring Microbiome Inc.
- 11.05 am Statistical Empowerment through Collaboration with Method SMEs  
David **Ciciora**, Regeneron
- 11.35 am **Break**
- 11.50 am **Panel Discussion**  
**All Speakers**

- 12.50 pm **Parallel Breakout Sessions**  
#1 – How CMC statistics and data science collaborate to support emerging modalities and technologies  
Moderator: Travis Wolter, Amgen  
#2 – Statisticians as Agents of Change – Real-world examples of how statistical collaboration has led to meaningful change in drug development  
Moderator: Ashley Giambrone, Regeneron
- 1.30 pm  
Conclusion & End of Day 2

## Day 3: Wednesday, October 22, 2025

### Session III: Collaboration & Recognition

*Session Chairs: Timo Bailer & Laura Pack*

Statisticians are tackling some of the toughest problems in the pharmaceutical industry — not just through technical expertise, but through strategic partnerships. Yet too often, they are brought in too late, after key decisions have been made. To maximize their impact, statisticians must be involved from the start — helping to frame the right questions, not just analyze data.

This session examines how organizational structure, visibility, and early engagement can elevate statistical contributions. We'll consider how collaboration across disciplines can influence outcomes — from solving technical challenges and shaping regulatory strategies to learning from setbacks.

Through selected examples and discussion, we'll highlight practical and cultural levers that make a difference: team setup, leadership positioning, and how we communicate our value. We'll also reflect on the behaviors and mindsets that enable statisticians to take on pivotal roles.

**The goal:** to provide insights on fostering collaboration, shifting perceptions, and establishing statisticians as strategic partners — from the moment problems are defined.

- 10.00 am *Session introduction*  
Timo **Bailer** – Boehringer Ingelheim  
Laura **Pack** – Moderna
- 10.05 am CMC Statisticians – the backbone from Development to Lifecycle Management  
Bianca **Teodorescu**, UCB
- 10.35 am Recognition & Collaboration: A Customer's Perspective  
John **Farris**, Kyverna Therapeutics
- 11.05 am The Stability Scientist and the Statistician – An Essential Partnership that Delivers  
Lori **McCaig**, Stability Strategist & Expert (former Seagen/Pfizer)
- 11.35 am **Break**
- 11.50 am **Panel Discussion**  
**All Speakers, Catherine Njue, BRDD / DMBR and Andreas Brandt**

- 12.50 pm     **Parallel Breakout Sessions**  
#1 – Beyond the Numbers – How to tell compelling stories about statistical contributions to non-statistical audiences  
Moderator: Jia Liu, Pfizer  
#2 - Accelerated Stability Modeling: Applying ICH Q1 to Predict Long-Term Degradation  
Moderator: Cristian Oliva-Aviles, Genentech
- 1.30 pm     Conclusion & End of Day 3

## Day 4: Thursday, October 23, 2025

### Session IV: Innovation & Acceleration

*Session Chairs: Jayda Siggers, Chris Thompson & Cristian Oliva Aviles*

The critical need for faster patient access to innovative medical treatments has accelerated the development of biologic drugs. In response, the CMC statistical community has increasingly focused on adopting advance approaches (e.g., Bayesian methods, mechanistic models and AI technologies) that incorporate prior knowledge to improve modeling efficiency and strengthen decision-making. While these methods offer significant potential, they also raise challenges related to methodological appropriateness and regulatory acceptance. This session will feature case studies highlighting practical applications of advanced statistical techniques in biologic drug development. Speakers will share insights on implementation, benefits, and lessons learned, with a focus on balancing innovation with the need for transparent, robust evidence to support regulatory decision-making.

- 10.00 am     *Session introduction*  
Jayda **Siggers** – Health Canada  
Christopher **Thompson** – AstraZeneca  
Cristian **M. Oliva-Aviles** – Genentech
- 10.05 am     Enhancing Yield Investigations through Interpretable Machine Learning  
Shu **Yang**, Pfizer
- 10.35 am     Applying Bayesian Methods to Flow Cytometry in Cell Therapy  
Christopher **Kot**, AstraZeneca
- 11.05 am     Shelf-Life Estimation and Internal Release Limits accounting for a Series of Storage Excursions through Bayesian Kinetic Hierarchical Model  
Ji Young **Kim**, Takeda
- 11.35 am     **Break**
- 11.50 am     **Panel Discussion**  
**All Speakers, Paula Russell, Health Canada & Bernard Francq, GSK**

- 12.50 pm **Parallel Breakout Sessions**  
#1 – Accelerating Innovation through Statistical Leadership – How innovative statistical methods are shaping science, business, and policy  
Moderators: Jose Ramirez, Kite Pharma, a Gilead Company & Timo Bailer, Boehringer Ingelheim  
#2 - Lessons from Regulatory Reviews of Statistical Analyses  
Moderators: Laura Pack, Moderna & Jayda Siggers, Health Canada
- 1.30 pm **Workshop Summary**
- 1.40 pm **Closing of the Workshop and Invitation to 2026 Workshop**