

SCIENTIFIC Conference e-book



International Alliance for
Biological Standardization

IABS 11th Annual Statistics Workshop

Big Tent Statistics
Conveying the Importance
of Statistical Contributions

October 20-23, 2025

www.iabs.org

**VIRTUAL
MEETING**





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Sponsors

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moderna®

 **Pfizer**

 **Bristol Myers Squibb**



About the Conference

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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 and Organizing Committee

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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

Stan Broskey – Merck

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

Organizing Committee

Ruojia Li – BMS (Co-Chair)

Jia Liu – Pfizer (Co-Chair)

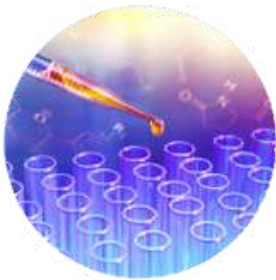
José Ramírez - Kite Pharma, a Gilead Company (Co-Chair)

Madinina Cox - Events Manager, IABS/MC'Com



Upcoming IABS Conferences and Workshops

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AFSA – IABS Conference about Animal testing replacement for vaccines: A One Health View: global outlook and future strategy

Bangkok, Thailand
December 2-4, 2025



2nd IABS Real World Evidence Workshop : The Role of Alternative Approaches to Phase 3 Clinical Trials for Vaccine Efficacy and Licensure

Montreal, Canada
December 10-11, 2025



Advances in Analytical Technologies for Biopharmaceutical Products

Virtual Meeting
June 3-5, 2026



Workshop Program

Monday, October 20, 2025

Times are indicated Eastern Daylight Time

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09:15-09:25

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

09:25-10:10

Keynote: Conveying the Value of Statistical Contributions
Dr. Robert Rodriguez

SESSION 1 - Contribution & Differentiation

Moderators : Oyeniran Oluyemi & Fang Chen

10:10-10:15

Session introduction

Oluyemi Oyeniran – Johnson & Johnson

Fang Chen - SAS

10:15-10:45

Expanding Our Reach by Reviewing Our Roots

Jim Garrett - Replicate! Statistical Planning and Analysis

10:45-11:15

Collaborating with Impact: Differentiating CMC Statistics in a Data-Driven Industry

Stan Altan - JJIM



Workshop Program

Monday, October 20, 2025

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11:15-11:45

CMC Statistics in a Data Science World
Mark DiMartino - Amgen

11:45-12:00

Break

12:00-1:00 PM

Panel Discussion
All speakers

13:00-1:40 PM

Parallel Breakout Sessions

#1 – The Statisticians' Seat at the Table – Strategies for building effective, cross-functional collaborations : **Fang Chen** - SAS
#2 - How can AI be leveraged to advance CMC statistics?
Moderator : **Ruojia Li** - BMS

1:40 PM

Conclusion & End of Day 1



Workshop Program

Tuesday, October 21, 2025

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SESSION 2 - Experimentation & Investigation

Moderators : Kristi Griffiths & Travis Wolter

10:00-10:05

Session introduction

Kristi Griffiths - Eli Lilly & Co.

Travis Wolter - Amgen

10:05-10:35

Bayesian Hierarchical Models for Enhanced Experimental Design

Adam Rauk - Eli Lilly & Co.

10:35-11:05

DoE as a process discovery tool in compositional systems

Rick Kramer - Ferring Microbiome Inc.

11:05-11:35

Statistical Empowerment through Collaboration with Method SMEs

David Ciciora - Regeneron

11:35-11:50

Break

11:50-12:50 PM

Panel Discussion

All Speakers



Workshop Program

Tuesday, October 21, 2025

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12:50-13:30 PM

Parallel Breakout Sessions

#1 – TBC

Travis Wolter - Amgen

#2 – **Statisticians as Agents of Change – Real-world examples of how statistical collaboration has led to meaningful change in drug development**

Ashley Giambrone - Regeneron

1:30 PM

Conclusion & End of Day 2



Workshop Program

Wednesday, October 22, 2025

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SESSION 3 - Collaboration & Recognition

Moderators : Timo Bailer & Laura Pack

10:00-10:05

Session introduction

Timo Bailer – Boehringer Ingelheim

Laura Pack – Moderna

10:05-10:35

CMC Statisticians – the backbone from Development to Lifecycle Management

Bianca Teodorescu - UCB

10:35-11:05

Recognition & Collaboration: A Customer's Perspective

John Farris - Kyverna Therapeutics

11:05 -11:35

The Stability Scientist and the Statistician – An Essential Partnership that Delivers

Lori McCaig - Stability Strategist & Expert (former Seagen/Pfizer)

11:35 -11:50

Break

11:50-12:50 PM

Panel Discussion

All Speakers with Catherine Njue, BRDD / DMBR and Andreas Brandt, BfArM



Workshop Program

Wednesday, October 22, 2025

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12:50-13:30 PM

Parallel Breakout Sessions

#1 – Beyond the Numbers – How to tell compelling stories about statistical contributions to non-statistical audiences

Jia Liu - Pfizer

#2 - Accelerated Stability Modeling: Applying ICH Q1 to Predict Long-Term Degradation

Cristian Oliva-Aviles - Genentech

1:30 PM

Conclusion & End of Day 3



Workshop Program

Thursday, October 23, 2025

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SESSION 4 - Innovation & Acceleration

Moderators : Jayda Siggers, Chris Thompson & Cristian Oliva Aviles

10:00-10:05

Session introduction

Jayda Siggers – Health Canada

Christopher Thompson – AstraZeneca

Cristian M. Oliva-Aviles – Genentech

10:05-10:35

Applying Bayesian Methods to Flow Cytometry in Cell Therapy

Christopher Kot - AstraZeneca

10:35-11:05

Shelf-Life Estimation and Internal Release Limits accounting for a Series of Storage Excursions through Bayesian Kinetic Hierarchical Model

Ji Young Kim - Takeda

11:05-11:35

Enhancing Yield Investigations through Interpretable Machine Learning

Shu Yang - Pfizer

11:35-11:50

Break

11:50-12:50 PM

Panel Discussion

All Speakers; Paula Russell - Health Canada & **Bernard Francq** - GSK



Workshop Program

Thursday, October 23, 2025

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12:50-1:30 PM

#1 – Accelerating Innovation through Statistical Leadership – How innovative statistical methods are shaping science, business, and policy

Jose Ramirez - Kite Pharma, a Gilead Company & **Timo Bailer** - Boehringer Ingelheim

#2 - Lessons from Regulatory Reviews of Statistical Analyses

Laura Pack - Moderna & **Jayda Siggers** - Health Canada

1:30-1:40 PM

Workshop Summary

1:40 PM

Closing of the Workshop and Invitation to 2026 Workshop

Biosketch



Timo Bailer

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Timo studied econo-mathmatics at Ulm University and the University of West Florida. He finished his M.Sc thesis within the pharmaceutical area on Bayesian Modelling of Adverse Events in 2014. Afterwards he joined Boehringer Ingelheim and held different positions within the field of CMC Statistics.

Currently he is heading the global CMC Statistics BioPharma department of Boehringer Ingelheim responsible for the life-cycle products at all global production sites in Germany, Austria, USA and China.

Timo is part of the IABS Statistics Workshop since 2018 and supports the Scientific Organization Committee since 2021. From 2023 - 2024, Timo was also co-chairing the Scientific Organization Committee of the IABS Statistics Workshop.



Abstract

Stan Altan

Collaborating with Impact: Differentiating CMC Statistics in a Data-Driven Industry

CMC statisticians have often been viewed as service providers, engaged on an as-needed basis for specific tasks. Today, the rise of data-intensive roles and advanced technologies creates an opportunity to redefine this perception. By integrating statistical rigor with process understanding, regulatory insight, and lifecycle thinking, CMC statisticians can become strategic partners who drive drug development and enhance product quality.

This talk will explore how statisticians can differentiate themselves and deliver measurable business value through collaboration. Key contributions include:

1. Designed experimentation to build robust, efficient methods and processes,
2. Bayesian, risk-based decision-making aligned with regulatory expectations, and
3. Multivariate approaches that enable real-time release testing (RTRT) in continuous manufacturing and improved quality outcomes.

Real-world examples—such as PPQ acceleration, surrogate modeling, and strategies to enhance patient centricity—will illustrate how these capabilities set CMC statisticians apart from other quantitative stakeholders. By leveraging these differentiators, statisticians can move beyond a support role to become equal partners in shaping the future of drug development.

Biosketch



Robert N. Rodriguez, PhD

2012 President

American Statistical Association

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Robert N. Rodriguez served as the 2012 president of the American Statistical Association. Prior to retirement, Bob was senior director of statistical software development at SAS. He received his PhD in statistics from the University of North Carolina at Chapel Hill and began his career as a research statistician at General Motors Research Laboratories.



Abstract

Robert N. Rodriguez, PhD

Conveying the Value of Statistical Contributions

Few people outside our field understand the intrinsic value of statistical contributions. It's up to us to convey that value. When we don't, our contributions are diminished and we lose influence. This presentation will address three questions:

1. What is the popular perception of statistics?
2. What is the essence of statistics?
3. How do we demonstrate the value of statistics?

Biosketch



Stan Broskey

Director, Data Science

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Stan Broskey is a seasoned leader in Statistical Analyses and Quality Engineering with over 25 years of experience in pharmaceutical and consumer healthcare industries. Currently, he serves as Director, Data Science at Merck's Center for Mathematical Sciences, where he leads a team providing CMC statistical and mathematical expertise to support small molecule, vaccine and biologics products. Stan is recognized for his expertise in statistical process control (SPC), statistical sampling, and problem-solving.

Prior to Merck, Stan held senior roles at Johnson & Johnson and McNeil Consumer Healthcare, including Senior Principal Engineer and Master Black Belt, where he led Six Sigma initiatives, process improvements, and compliance programs under regulatory frameworks. He has a strong track record of delivering cost savings, coaching Six Sigma certifications, and implementing data-driven quality solutions.

Stan holds an MBA with concentrations in Quality Science (Applied Statistics) and Operations Management from Drexel University and a BS in Operations Management from La Salle University. He was certified as a Six Sigma Master Black Belt and Quality Manager by the American Society for Quality. His technical skills include expertise in R, Minitab, JMP and advanced statistical methods applied to pharmaceutical manufacturing and quality assurance.

Biosketch



Fang Chen

Director

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Fang Chen is a Director of Advanced Statistical Methods at SAS Institute Inc. and a Fellow of the American Statistical Association. He manages the development of statistical software for SAS/STAT®, SAS/QC®, and analytical components that drive SAS® Visual Statistics software. Also among his responsibilities are the development of Bayesian analysis software and the MCMC procedure. Before joining SAS, he received his Ph.D. in statistics from Carnegie Mellon University.

Biosketch



Catherine Cheng

Director, Biostatistics

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Catherine Cheng is a CMC statistical lead at Novartis Gene Therapies. Her team provides technical expertise and statistical support from analytical development to commercialization. Prior to joining Novartis Gene Therapies, Catherine worked at Merck, BMS and Eli Lilly from 2001 to 2020. Catherine holds a BS in Chemical Engineering and MS in Statistics and Engineering.

Biosketch



David Ciciora

Statistician

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David received his M.S. in Biostatistics from the State University of New York at Albany. Prior to his statistical career, David worked in manufacturing, supporting the downstream purification process at Regeneron. Currently, he is a statistician at Regeneron where he primarily supports Quality Control subject matter experts in the design and analysis of experiments.



Abstract

David Ciciora

Statistical Empowerment through Collaboration with Method SMEs

Updates to regulatory guidance on assay validations present a vital opportunity for statisticians to collaborate effectively with method subject matter experts (SMEs) in establishing robust acceptance criteria. These new guidelines stress the need for statistical intervals to align with predefined criteria, a challenge that goes beyond the straightforward assessments of averages and standard deviations typically performed by method SMEs.

This presentation will explore the collaborative synergy between statisticians and method SMEs in developing meaningful statistical interval criteria to evaluate accuracy and precision in assay validations. We will discuss leveraging historical data to inform these criteria, the impact of sample sizes on interval widths, and a methodology for transitioning from standard point estimates to interval-based criteria. Through case studies, we will illustrate how statisticians can engage proactively with method SMEs, shaping discussions and decision-making processes from the outset.

Our ultimate goal is to equip method SMEs with the necessary knowledge and tools to independently generate and refine their criteria for future assay validations. By fostering early collaboration and mutual understanding, we can ensure the adoption of scientifically sound and regulatory-compliant practices, thereby enhancing the reliability and credibility of assay validation outcomes. This approach not only elevates the role of statisticians but also positions them as strategic partners in the validation process.



Abstract

Mark DiMartino

CMC Statistics in a Data Science World

Digital transformation is the rage in the pharmaceutical industry. Companies are looking to develop and grow data science teams with a desire to utilize Gen-AI and machine learning to cut costs and improve decision making. Statisticians, CMC statisticians in particular, are the original data scientists marrying domain knowledge with advanced data analysis capabilities who are finding themselves in competition and often left behind in the data science movement. While these roles often employ similar methods—statistical modeling, machine learning, and large-scale data analysis—the unique contributions of CMC statisticians remain essential for ensuring drug quality, regulatory compliance, and manufacturing excellence. Drawing on my experience leading both CMC statistics and data science teams, I will explore the differences and synergies between these disciplines. I will highlight how CMC statisticians' deep understanding of the product lifecycle, regulatory expectations, and process robustness distinguishes their contributions, while also demonstrating how data science can enhance and complement traditional statistical approaches. Finally, I will discuss strategies for statisticians to effectively advocate for their impact, articulate their value to leadership, and position themselves as indispensable partners in an increasingly data-driven landscape.



Abstract

John Farris

Recognition & Collaboration: A Customer's Perspective

Statisticians can be transformative partners when engaged at the moment problems are defined—not after designs are locked. From the customer's perspective, this session shows how early statistical involvement elevates decision quality, compresses timelines, and strengthens regulatory credibility. Using real-world vignettes (comparability, investigations, and inspection-ready quality analytics), we outline a practical engagement model: a decision-making governance co-authored with statistics, governance gates requiring statistical sign-off, and reviews before pivotal milestones. We also highlight small-n toolkits (tolerance intervals, t-tests, and other process monitoring tools) that translate uncertainty into clear decision making criteria. A leadership lens details structural, incentive, and cultural levers that normalize early engagement—RACI ownership for decision quality, and a “one slide of math” ritual for GMP and other major decisions. Attendees should take away a plan to reposition statisticians as strategic co-architects of outcomes—early, often, and credibly.

Biosketch



Bernard G Francq, PhD

Director, CMC Statistical Innovation

CMC Statistical Modeling, GSK
Belgium

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Bernard G Francq is Director at GSK, driving statistical innovation for CMC projects worldwide. He has held roles in non-clinical statistics at GSK, biostatistical research in academia, and clinical trials at the University of Glasgow, fostering collaborations with industry and health authorities. He earned MSc degrees in Molecular Biology Engineering, and Industrial Statistics, as well as a PhD in Statistics.

He has earned several international prizes for his research and excellence in technical communication. He is the principal author of the award-winning GSK Statistical Paper on tolerance intervals in bridging studies (*Stat in Med*, 2020), and he (co)-authored two of Wiley's most downloaded papers (*Stat in Med*, 2019; *Analytical Science Advances*, 2022). He is also the creator of the R packages *BivRegBLS* and *AccelStab*.

His current research focuses on design of experiments, (non)-linear mixed models, tolerance intervals, and (accelerated) stability analysis. He is passionate about sharing his expertise, mentoring (PhD) students, and delivering innovative statistical training courses.

Biosketch



Andreas Brandt, PhD

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Andreas Brandt is a statistical assessor at BfArM (Federal Institute for Drugs and Medical Devices). He received a MSc in Mathematics from the University of Bonn in 2006 and obtained a PhD in Genetic Epidemiology from the University of Heidelberg in 2010. In 2010, Dr. Brandt joined the Biostatistics and Special Pharmacokinetics unit at BfArM. He is an expert in working groups of the European Medicines Agency (EMA).

Biosketch



Jim Garrett

Proprietor

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Replicate! Statistical planning and analysis

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Jim Garrett has been working in the diagnostic, pharmaceutical, and gene therapy areas for almost 3 decades. He earned his PhD from the University of Minnesota in 1996 and subsequently worked for Becton Dickinson and, later, Novartis. His areas of interest have been exploratory modeling, experimental design, and quality control;

technically, he has found occasional application for Bayesian methods, machine learning, semiparametrics, and computer-intensive inference methods. Coincidentally, by virtue of being in the right place at the right time with the right skills, he developed the first incoming material specifications for gene therapy submitted for FDA approval for marketing, for Kymriah (tisagenlecleucel). Recently he started his own consulting business, "Replicate! Statistical planning and analysis".



Abstract

Jim Garrett

Expanding Our Reach by Reviewing Our Roots

Historically, statistics has contributed significantly to bioinformatics and machine learning. I identify some uniquely statistical ideas that contributed. Today, however, many statisticians find themselves pigeon-holed into roles with narrow expectations. How did we get here? I suggest that the statistics community itself has contributed substantially to the present state. In order to have our full value recognized, I recommend some specific strategies we can each apply individually, and also some directions for which we should advocate to our leadership--both statistical leadership general business leadership.

Biosketch



Ji Young Kim, PhD

Director, Head of CMC Statistics
Quantitative Sciences

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Ji Young received her Ph.D. in Statistics from the University of Illinois at Urbana-Champaign (UIUC) in 2010. She currently leads the CMC Statistics team at Takeda and serves as a co-lead of the ASA Biopharmaceutical Section's Nonclinical Biostatistics Bayesian CMC Scientific Working Group.

Prior to joining Takeda, Ji Young worked at Merck for six years at the Center for Mathematical Sciences as a CMC statistician for vaccine programs. She also spent five years at the Children's Hospital of Philadelphia (CHOP), where she completed postdoctoral training in Biostatistics and then led biostatistics efforts for multiple sleep and nephrology studies at CHOP/UPenn. Earlier in her career, she was a statistics faculty member at Mount Holyoke College.



Abstract

Ji Young Kim

Shelf-Life Estimation and Internal Release Limits accounting for a Series of Storage Excursions through Bayesian Modeling

In this presentation, a Bayesian kinetic hierarchical model is proposed to be fitted to real time and accelerated studies together to estimate both the shelf-life and internal release limits for a target shelf-life considering a series of excursions.

Creation of an experimental design for the accelerated stability study will be illustrated. Accelerated stability data can either be used to provide prior information to the real time stability model or the two data sets can be fitted together. In either case, a posterior probability of the reaction rates and other associated regression parameters can be jointly estimated for all conditions, which can be directly used to derive the shelf-life and internal release limits accounting for storage excursions. In the examples shown in this talk, data were generated based on an Arrhenius equation with pre-identified excursions in the real-time stability data.

Biosketch



Jennifer L. Kirk, Ph.D.

Jennifer L. Kirk, Ph.D.
Lead Mathematical Statistician

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Jennifer L. Kirk received her doctorate in biostatistics from the University of Washington. Previously, she completed a two-year postbaccalaureate fellowship at the National Institute of Allergy and Infectious Diseases. In 2017, she joined the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research as a statistical reviewer of clinical and product quality/CMC statistics for vaccines, allergenics, and live biotherapeutics. She is currently a Lead Mathematical Statistician in the Device and Non-Clinical Evaluation branch, where she leads the product quality/CMC team for all of CBER's products.

Biosketch



Christopher Kot, MPH

Senior Statistician, CMC Statistics

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Chris Kot is a Senior CMC Statistician within AstraZeneca's Biopharmaceutical Development business unit. He holds an MPH with a concentration in Biostatistics from the University of Maryland, College Park, and has a decade of experience in biologics development and commercialization. At AstraZeneca, Chris supports CMC activities for biologics in stages of development ranging from pre-clinical to commercialization. Prior to joining AstraZeneca, he spent nine years at Emergent BioSolutions developing statistically complex assays for both developmental and commercial vaccines and other late-stage biologics.



Abstract

Christopher Kot

Case Study: Bayesian Methods for Qualification of Flow Cytometry Method for Cell Therapies

Flow cytometry methods are critical in characterizing and assessing the quality of cell therapies. Manufacturing cell therapies is a complex process by which the cells are engineered to perform certain functions, while still being tolerated by the patient. This can be achieved by modifying a patient's own cells (autologous therapies) or universal donor cells (allogenic therapies). These processes intend to alter the phenotype of individual cells to fit a target protein expression profile for the intended function and treatment. Verification that the cells express proteins in alignment with the intended phenotype and protein expression profile is crucial and flow cytometry methods offer a solution to directly measuring individual cells. The nature of these single-cell measurements and the relationship between proteins complicates the analytical profile of these methods, even for seemingly simple immunophenotyping measurements. These complex analytical profiles often pose unique statistical challenges to estimating the analytical performance characteristics described in ICH Q2R2.

Bayesian methods offer a practical solution to these unique challenges, easily estimating the accuracy and precision of methods with complex analytical profiles. Three case studies utilizing Bayesian methods for analyzing flow cytometry method qualifications for both simple and complex flow cytometry responses are discussed here. These case studies include methods with independent responses, multivariate responses, and responses with non-normal likelihood distributions, such as the Poisson distribution. Analyses are performed with accessibility to assay scientists in mind, using only functions available in SAS version 9.4 and highlighting the use of prior knowledge to analogous parts of the analytical method lifecycle. The advantages of Bayesian estimates for repeatability, reproducibility, intermediate precision, and accuracy are discussed, with a focus on preparing methods for method validation under the Quality by Design paradigm.

Biosketch



Richard R. Kramer, MS

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Richard R. Kramer received a Masters in Cell and Molecular Biology from St. Cloud State University and a Bachelor of Biology from Bemidji State University. He has held positions in biotech and biopharma developing and improving innovative upstream bioprocesses from benchtop to production scale bioreactors. Currently, he is a member of the research and development team at Ferring Microbiome, a part of the broader Science and Medical organization at Ferring Pharmaceuticals.



Abstract

Rick Kramer

DoE as a process discovery tool in compositional systems

The human microbiome and its impact on human health is a dynamic discovery space. The development of live biotherapeutic products (LBPs) to influence patient microbiomes is an emerging field containing multiple treatment paths. Described by composition, microbiome communities are defined by the relative abundances of organisms to each other rather than absolute values. Through early and frequent collaboration, scientists and statisticians clarified goals, selected designs, and implement a DoE based discovery platform to maximize limited development cycles. The multiple design types were leveraged to understand factors that influence and shape the composition of a broad consortium LBP. The result of this collaboration was an early-stage clinical asset delivered ahead of schedule.

Biosketch



Irina Gershgorin

Director, Analytics and Statistics, Global MSAT

Legend Biotech

Irina Gershgorin is currently leading Analytics and Statistics within Global MSAT at Legend Biotech, where she supports commercial manufacturing. She holds an Hon. B.Sc. from the University of Toronto and a PhD in computational biology from the Courant Institute at NYU. Prior to joining Legend, Irina spent nearly eight years at Novartis Cell and Gene Therapies, supporting KYMRIA, the first ever cell therapy to be approved, as well as other pipeline programs. In addition to regular CMC support, Irina's work has focused on correlational analyses. She has applied statistical and machine learning methods to investigate relationships between product attributes, manufacturability and clinical outcomes, with findings presented at ASH, ASCGT, AACR, and IABS.

Biosketch



Ashley Giambrone, PhD

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Ashley studied Biostatistics at State University of New York at Albany. She finished her PhD in the statistical area of non-likelihood-based model evaluation in 2013. Afterwards she completed a post-doctoral program at Weill Cornell Medical College in the School of Epidemiology and Biostatistics. Currently, she is leading a team of statisticians at Regeneron Pharmaceuticals, Inc. supporting all aspects of drug manufacturing. Ashley joined the IABS Scientific Organizing Committee in 2022.

Biosketch



Kristi L. Griffiths, Ph.D.

Associate Vice President, CMC Statistics

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Kristi L. Griffiths received a doctorate in statistics from Virginia Tech in 1995 and joined Eli Lilly and Company to support pharmaceutical product development. She has provided technical contributions for numerous product development programs and has been instrumental in the design and implementation of the Lilly Quality by Design strategy.

Kristi is an Associate Vice President and leads the CMC statistics team. She actively served on the International Pharmaceutical Aerosol Consortium on Regulation and Science (2000-2006) and the USP Statistics Expert Committee (2005-2010). She was an associate editor of the American Statistical Association's Biopharmaceutical Report (2021-2022) and continues to serve on the IABS Statistics Workshop Scientific Organizing Committee.

Biosketch



Ruoja Li, PhD

Scientific Director

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Ruoja Li leads the Quantitative Sciences & Digital Transformation group within the Biologics Development organization at Bristol-Myers Squibb. Her team is responsible for CMC statistics, data science, clinical method performance monitoring, and manages digital transformation efforts across the organization. Ruoja holds a bachelor's in Mathematics from Peking University, and a Ph.D. in Statistics from University of Wisconsin-Madison.

Biosketch



Jia Liu, PhD.

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Jia got her PhD degree in statistics from Iowa State University. She has worked as a CMC statistician in Pfizer since 2013. Jia has substantial knowledge and experience in analytical method development, bioassay evaluation, reference material bridging, assay validation and transfer. She has successfully supported multiple CMC regulatory submissions. Jia is also interested in Bayesian methodology, machine learning, design of experiments, and linear-mixed models.

Biosketch



Lori McCaig, Ph.D.

Stability Strategist & Expert

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Lori McCaig has led global functions in Stability Program Management at companies such as Pfizer, Seagen, Genentech/Roche, and Stiefel/GSK. With oversight and management at the policy and program level she has ensured that stability for both pipeline and commercial products meets the highest industry standards through governance and innovation in stability program design, data evaluation, and knowledge management. Lori has greatly enjoyed collaboration with stability scientists and statisticians through service on the USP Biologics Stability Expert Panel and Physical Stability Subcommittee, as former chair of the AAPS Stability Community and IQ Consortium Science & Risk Based Stability Workgroup, and as faculty and scientific advisor to support the ICH Training Associate at Northeastern University.



Abstract

Lori McCaig

The Stability Scientist and Statistician – An Essential Partnership that Delivers

Examples abound demonstrating the criticality of statisticians throughout pharmaceutical development, registration, and product lifecycle. In this session we will look specifically at how the partnership between stability experts and statisticians has continued to grow and change as science and risk-based stability strategy and program design have evolved. Stability, always essential, has moved beyond a simple compliance mindset with a checklist of studies and data to providing product knowledge and evidence to accommodate global needs and accelerated timelines. We will discuss the importance of communication and collaboration between the stability team and statisticians needed to develop a mutual understanding of the challenges and constraints in the generation and evaluation of stability data. We'll show how this understanding can be used to establish standardized approaches that can be routinely applied within the quality system, provide statistical expertise and solutions for non-routine work, and identify and incorporate innovative approaches as new standards. We'll discuss how updates to international stability guidelines provide even more opportunities (and expectations) within the stability landscape requiring access to statistical partners that are a strategic part of the team, and what this means to smaller/growing companies.

Biosketch



Cristian Oliva-Aviles, PhD

Principal Statistical Scientist

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Cristian joined Genentech in 2018 as a nonclinical biostatistician, specializing in providing statistical support to enable CMC activities. In recent years, he has focused on exploring innovative statistical approaches for analyzing stability data. Prior to Genentech, he earned his PhD in Statistics from Colorado State University, where he refined his expertise in developing statistical methodologies for linear models. In his early years, Cristian was awarded a Bronze Medal at the International Mathematical Olympiad.

Biosketch



Catherine Njue

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Dr. Catherine Njue is the manager for the Office of Biostatistics in the Biologic and Radiopharmaceutical Drugs Directorate (BRDD), Health Canada. In this position, she leads the biostatistics team that is primarily involved in evaluating the statistical methodology of clinical trials and other sources of evidence for biologics (e.g., vaccines, blood products) and related biotechnology products and radiopharmaceuticals. She also provides statistical expertise in the drafting, review and implementation of standards and guidelines developed by Health Canada, ICH, and WHO working groups.

Dr. Njue received her Ph.D. in Statistics from the University of Manitoba in Winnipeg, Manitoba, Canada. After two years as a Biostatistician at CancerCare Manitoba, she joined Health Canada where she remains. Dr. Njue has extensive experience as a statistical consultant, which began at the Statistical Advisory Service, University of Manitoba, where she worked throughout her doctoral program. At CancerCare Manitoba, she collaborated with researchers in the Department of Preventive Oncology and Epidemiology on the design and analysis of epidemiological studies. She also provided statistical consultation to researchers from various other departments within CancerCare Manitoba.

Biosketch



Oluyemi Oyeniran

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Olu is a Senior Principal Scientist in the Statistics and Decision Sciences Department at Johnson and Johnson Innovative Medicine. He specializes in providing advanced statistical support across the biologics development and manufacturing lifecycle, including CMC regulatory filings (specification setting, shelf-life determination), analytical methods (development, method validation and transfers), manufacturing and formulation (cell banking, risk assessment, process validation), and continuous manufacturing. His areas of focus include experimental design, the use of linear and non-linear mixed effects models, Bayesian methods, machine learning, and statistical applications in continuous manufacturing. He holds a PhD in Statistics from the Bowling Green State University.

Biosketch



Laura Pack

Sr. Director, CMC Quantitative Sciences

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Laura has leveraged her scientific and statistical expertise to drive innovation in biotechnology operations functions for the past 20+ years. Throughout her career, Laura has focused on supporting clinical, latestage, and commercial biologics and small molecule programs, CMC statistics and overall product quality strategy. She is passionate about teaching statistics to the many dedicated scientists that she encounters in the CMC community.

Laura currently leads the CMC Quantitative Sciences function at Moderna, Inc. Her team includes CMC statisticians, data scientists, & mechanistic/predictive modelers who partner with scientists across CMC functions to support objective decision making so that the company can bring important medicines to patients.

Laura holds bachelor's degrees in chemistry and biochemistry from the University of Colorado and a master's in applied statistics from Colorado State University. She has served on the IABS Statistics Workshop Scientific Organizing Committee since 2018 and on the AAPS CMC Statistics Community Leadership Team since 2016.

Biosketch



Adam Rauk

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Adam Rauk holds a Masters of Science in statistics from the University of Chicago. He has 20 years of experience in the pharmaceutical industry within chemistry manufacturing and controls, and currently supports bioproduct research and development.



Abstract

Adam Rauk

Bayesian Hierarchical Models for Enhanced Experimental Design

Text Statistical experimental design is a central component of many development activities, such as process characterization, formulation robustness, and analytical method robustness. Experimental design, though, has become so common that it can be viewed as a check-the-box activity, where scientists follow the procedure out of obligation rather than appreciating it as a tool to improve knowledge. This talk shows how Bayesian hierarchical modelling offers a new opportunity for collaboration by quantifying platform knowledge, as demonstrated through a recently published example on Protein A purification process characterization. Also, infusing Bayesian statistics into the experimental design process, can improve engagement with scientists to participate more directly in the design process, offering designs that are commensurate with available, justifiable prior knowledge.

Biosketch



José G. Ramírez, Ph.D.

Chief Statistician

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José is currently the Chief Statistician within the Global MSAT group at Kite, a GILEAD company. In this role, he provides statistical leadership in the use, promotion, and adoption of best statistical approaches, including Bayesian methods.

Prior to Kite, José was the Chief Statistician in the Quality Data Sciences group at Amgen, Inc, where he provided statistical leadership for both biosimilars and mAbs. He has worked in the semiconductor and electronics industries as a member of the Quality and Reliability group of the Semiconductor division of Digital Semiconductor, and the electronics division of W.L. Gore & Associates. In his many years of experience in the semiconductor, electronics, and biotech industries, he has worked closely with engineers and scientists to help them make sense of data, and through collaborative education, help promote statistical thinking.

José received a licentiate degree in mathematics from Universidad Simón Bolívar in Caracas, Venezuela, and both an MS in applied statistics and a PhD in statistics from the University Wisconsin-Madison, where he was one of the founding members of the Center for Quality and Productivity Improvement. He has won both the SAS Users Group International (SUGI) best-contributed statistics paper, and the SAS User Feedback Award, and has written two books for SAS Press.

Biosketch



Paula Russell, PhD

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Dr. Paula Russell is a Sr. Biologist/Evaluator with the Centre for Blood, Blood Products, and Biotherapeutics (CBBB) in the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) at Health Canada. She holds a PhD in Protein Biochemistry from the University of Guelph. Paula joined BRDD in 2017 and has been involved in the review of CMC information for many different types of biotherapeutic products. Paula is currently serving as Health Canada's Topic Lead on the ICH Q1/Q5C Stability Guideline Expert Working Group

Biosketch



Jayda Siggers, PhD

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Dr. Jayda Siggers is a Senior Biologist/Evaluator in the Biotherapeutics Quality Divisions (BQD) of the Centre for Blood, Blood Products, and Biotherapeutics (CBBB) within the Biologics and Radiopharmaceutical Drugs Directorate (BRDD) at Health Canada. Since joining Health Canada in 2015, she has led the quality review of pre- and post-market drug submissions for biologic drugs.

Dr. Siggers holds a Master of Science in Toxicology from the University of Saskatchewan, a PhD in Immunology from the University of Copenhagen, and completed a postdoctoral fellowship in the Department of Biochemistry, Microbiology, and Immunology at the University of Ottawa.

She actively contributes to the advancement of biologics and regulatory standards. She represented Health Canada on the WHO drafting group for guidelines on monoclonal antibodies and related products and developed a training module for PAHO on the evaluation of therapeutic antibodies. She also co-chairs a PDA standard on analytical method transfer and comparability for biologics and leads an internal working group for the implementation of ICH Q2(R2)/Q14. Additionally, she contributed to the drafting of the new agile food and drug regulations and is currently revising Health Canada's biosimilars guidance. Outside of work, Dr. Siggers enjoys cycling and can often be found chasing her family up hills and down mountains on one of her bikes.

Biosketch



Christopher Thompson

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Chris leads the CMC statistics group for biologics development at AstraZeneca. He has spent the last 20 years working in CMC both in the lab and as a statistician. His recent focus has been how statistics can leverage platform knowledge to improve decision making. In addition to IABS, Chris is also involved with the IQ consortium and co-chairs the workgroup for Bayesian statistics in CMC for the ASA.

Biosketch



Bianca Teodorescu, PhD

Head CMC Statistical Sciences

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Bianca Teodorescu is Head of CMC Statistical Sciences and Corporate Process Owner for Quality by Design at UCB. She holds a PhD in Statistics from Université catholique de Louvain.

Since she joined UCB in 2012 she has been giving support to both development and commercial CMC activities for chemical, biological and gene therapy products. In parallel, she has been driving the vision and strategy for Quality by Design at UCB, while ensuring common practice in QbD implementation across the company.

Previously, she worked as a consultant for GSK biologicals in the Global Industrial Operations department and she worked on the development of Stab-e-lity software with Cencora Pharmalex.



Abstract

Bianca Teodorescu

CMC Statisticians – the backbone from Development to Lifecycle Management

In a Quality by Design context, the CMC Statisticians have a key role in the product Development and through the Lifecycle Management. They can be seen as the backbone that connects all the other CMC departments: Analytical Development, Process Development, Devices, Manufacturing/MSAT, QA, QC and Regulatory Affairs. They define the statistical strategy of the product and help navigate the interactions with the Health Authorities.

Their work in Development is one of the cornerstones of the Control Strategy of the product: Scale Down Model Verification, Process Characterization studies and PAR, CPP determination, Justification of Specifications including Room temperature allowance, Process and Analytical Method validation/comparability, as well as the introduction of a Drug Delivery device.

Once the product becomes commercial, the work continues with the support of the Manufacturing/MSAT for investigations and process improvement using Advanced Analytics tools, as well as tech transfer and continuous support to Development for the new generations of analytical methods and processes.

The presentation will focus on the structure and the ways the CMC statistics team functions and interacts with other departments through Development and Lifecycle Management, while giving some examples of key collaborations/successes.

Biosketch



Travis R. Wolter, MSPA

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Travis R. Wolter received a masters in predictive analytics from Northwestern University and bachelors of science in statistics from the University of Wisconsin Madison. He has held multiple positions in biotech product and process development with a focus on statistical applications to address novel unmet need. Currently he is a member of the global CMC statistics team at Amgen, part of the wider Quality and Operations team.

Biosketch



Shu Yang, PhD

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Shu Yang is Manager of Manufacturing Intelligence & Global Automation (MIGA) at Pfizer, where they lead the development of novel AI and digital solutions to support manufacturing operations. Shu holds a Ph.D. in Chemical Engineering from Rensselaer Polytechnic Institute (RPI) and has a strong background in Six-Sigma process optimization, advanced control, and data science. Currently, Shu is applying Interpretable Machine Learning (IML) to improve bioprocess performance and uncover actionable insights that enhance yield and reliability.



Abstract

Shu Yang

Enhancing Yield Investigations through Interpretable Machine Learning

Investigating yield issues in commercial manufacturing often begins with a tedious parameter screening phase before hypotheses can be formulated and tested. In this work, we present a collaboration between the Statistics & Data Science team and the Commercial Manufacturing/Process Science team to streamline this process using Interpretable Machine Learning (IML).

IML techniques—specifically Shapley value-based model interrogation—were applied to high-dimensional, nonlinear batch record data to identify and rank process variables most associated with yield outcomes. This approach helped narrow the field of potential factors early in the investigation, providing biostatisticians with a data-driven foundation for hypothesis formulation and experimental validation.

To support continuous improvement, we also developed a structured workflow and digital dashboard that integrates domain knowledge and enables automatic analysis of new batches. This infrastructure facilitates ongoing feedback and engagement with process scientists, making the analytical process more efficient and transparent.

Overall, IML served as a front-end screening tool that accelerated hypothesis generation, improved collaboration, and enhanced the impact of statistical modeling in manufacturing investigations.

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