Newsletter

February 2025 Issue

The Bayesian Scientific Working Group (BSWG) was formed in 2011 with the vision to ensure that Bayesian methods are well understood and broadly utilized for design and analysis throughout the medical product development process and to improve industrial, regulatory, and economic decision-making. The group is comprised of individuals from academia, industry, and regulatory authorities.

BSWG new website: https://bayesscientific.github.io/

Chair	Pritibha Singh
Vice– Chair	Melissa Spann
Advisors	Karen Price, Amy Xia, Fanni Natanegara, Freda Cooner
Secretary	Spener Woody, Hao Sun
Next-Generation Officer	Jane Lin
Publication Officer	*Position Open*
KOL Organizer	Haijun Ma
Webmasters	Melvin Munsaka, Haijun Ma, Spencer Woody

BSWG Newsletter 2025 Issue 1 guest column: Benefit-Risk Sub-team

Guest Column BIO

Madhurima Majumder, PhD is an Associate Director working within the Clinical Statistics and Analytics department at Bayer US LLC and is based in Whippany, New Jersey, US. She is responsible for the statistical aspects of clinical trials, from endpoint selection and design to regulatory approval, which she has done successfully in cardiovascular, oncology and hematology therapeutic areas. This makes her passionate about developing a deep understanding of the scientific rigor of cutting-edge innovative statistical methodologies that helps make data-driven decision to bring life-saving treatments to patients faster. Throughout her career, Madhurima has been active in the pharmaceutical statistics world and regularly participates in a variety of working groups and activities across a broad spectrum. Currently, she is a co-chair of the ASA BIOP Bayesian Scientific Working Group Benefit Risk sub-team and in the past, has been a member and published with the DIA Clinically Meaningful Change group, the Forum for Collaborative Research, etc. With colleagues within Bayer, she has developed and published on Bayer's in-house data-driven initiatives on state-of-the-art topics, e.g, data visualization apps (elaborator and megaplots) and novel digital measures. She is also a Steering Committee member of Bayer's Biostatistical Innovation Center and is always eager to be involved at every possible data-driven collaborative opportunity. After graduating with a PhD in Statistics from the University of Rochester in western New York, Madhurima lives in northern New Jersey with her husband and two young daughters and loves kid-friendly outdoor activities, especially in the spring and fall.

BSWG Newsletter 2025 Issue 1 guest column: Benefit-Risk Sub-team

Guest Column BIO

Dr. Carl Di Casoli is currently head of biometrics (senior director) at Cabaletta Bio, a company focusing on CAR-T therapies to potentially cure patients with autoimmune and rare diseases. Prior to Cabaletta Bio, he had worked at Sumitomo Pharma America, Apellis, Celgene, Bayer, and Vertex. He had led FDA approvals for hematology at Apellis (pegcetacoplan) and radiology at Bayer (Gadavist) and has worked in diverse therapeutic areas including medical devices, diagnostics, cardiovascular, oncology (both solid and liquid tumours), rare disease, neuroscience, nephrology, immunology, and infectious disease across all phases of clinical trials. In addition, he leads the Bayesian Benefit risk group and published a statistical paper in 2017 in the journal Therapeutic Innovation and Regulatory Science and a chapter entitled "Bayesian Benefit-Risk Evaluation in Pharmaceutical Research" in the book Bayesian Methods in Pharmaceutical Research, edited by Emmanuel Lesaffre, Gianluca Baio, Bruno Boulanger, Chapman and Hall / CRC Publishing. Furthermore, he has published several articles in medical journals such as in the American Journal of Hematology and in Blood and presented at numerous conferences and workshops throughout the world including in Germany, Belgium, US and Canada. Carl received his PhD at NC State University where his thesis concentrated on Bayesian Survival Analysis. Finaly, Carl is an amateur classical pianist performing in New York City venues such as Merkin Hall, Zankel Hall and Weill Hall at Carnegie Hall, and with the New Horizons Symphony at New Mexico State University in Las Cruces, New Mexico.

BSWG Newsletter 2025 Issue 1 guest column: Benefit-Risk Sub-team

Join us at our session at the DIA Global Meet, June 15-19, 2025, Washington D.C.

As the landscape of drug development continues to evolve, pharmaceutical statisticians are more important than ever to play a pivotal role in the benefit-risk assessment of a new medicinal product or intervention. Establishing the benefit-risk profile of a new medicinal product or intervention is a fundamental requirement for sponsors and regulators. It is also one of the most complex tasks. It involves communicating the trade-off of benefits and risks to stakeholders like payers, physicians, and patients, who may have different notions of benefits and risks. Therefore, communicating the trade-off of benefits and risks clearly and transparently and using all available evidence is critical to ensure that the best decisions are made for patients. Bayesian inference allows for integrating different sources of information and uncertainty, along with its links to optimal decision theory. It provides a natural framework to perform quantitative assessments of the benefit-risk trade-off.

The ASA BIOP Bayesian Scientific Working Group's Benefit-Risk Subteam comprises professionals from pharmaceutical companies and regulatory agencies with a special interest and expertise in benefit-risk evaluation. Our group broadly focuses on understanding and recommending how to apply Benefit-Risk Methodologies across the drug development and approval landscape. As a group, we have organized and participated in numerous conference sessions and disseminated our research findings in scientific publications. Some of our achievements in the past years for furthering the science of quantitative benefit-risk assessments are a case study on incorporating prior information for quantitative benefit-risk assessment from sNDA filing of rivaroxaban published in the TIRS journal, a book chapter in Bayesian Methods in Pharmaceutical Research, conference presentations at Joint Statistical Meetings (JSM), Regulatory Industry Statistics Workshop (RISW), International Symposium on Biopharmaceutical Statistics (ISBS), Bayes Pharma, Midwest Biopharmaceutical Statistics Workshop, R Pharma, etc., workshops on hot topics by experts in the field, e.g., Dan Rubin, Andrew Trigg. Some of the software we have developed include an R Shiny App for Bayesian Multi-Criteria Decision Analysis / Stochastic Multi-Criteria Acceptability Analysis, an R Shiny App and package for Hierarchical Bayesian Benefit-Risk, and an R packages for holistic benefit-risk analysis.

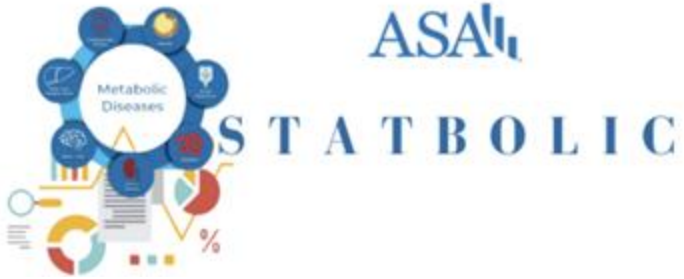
The impact of our work is evident in the increased ability of stakeholders to make more informed decisions regarding benefit-risk assessments, ultimately contributing to improved patient safety and healthcare outcomes. Additionally, we have recruited new members and kept the group thriving, with plans to collaborate with other working groups, e.g., ASA Benefit Risk Assessment Planning (BRAP) Working Group. We look forward to actively continuing to understand how best to apply Benefit-Risk Methodologies in the drug development landscape, specifically publishing a white paper on guidance and recommendations for applying Bayesian Methods in Benefit-Risk Analysis, thereby empowering statisticians with data-driven benefit-risk assessments and decision-making.

By Dr. Madhurima Majumder, Associate Director, Clinical Statistics, Bayer, and Dr. Carl Di Casoli, Senior Director (Head of Biometrics) at Cabaletta Bio; on behalf of the BSWG Benefit-Risk Sub-team

Upcoming Conferences / Webinars

[Penn Causal Inference Winter Institute]

Philadelphia, PA | Jan 13th - Jan 17th



[STATBOLIC 2025]

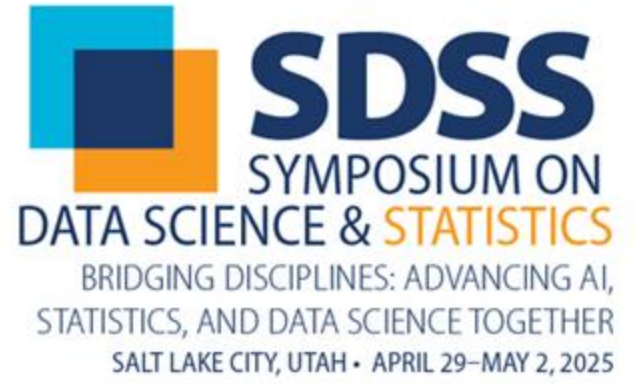
Silver Spring, MD | Feb 6th

[Biostatistics Symposium of Southern California]

Newport Beach, CA | Feb 21st - Feb 22nd

[ENAR 2025 Spring Meeting]

New Orleans, LA | Mar 23rd - Mar 26th



[Symposium on Data Science and Statistics]

Salt Lake City, UT | Apr 29th - May 2nd

[The 10th Workshop on Biostatistics and Bioinformatics]

Atlanta, GA | May 9th – May 11th

STAT4ONC where Oncology and Statistics meet, communicate, and synergize!

BIOSTAT 2025

ICSA 泛華統計協會

[STAT4ONC Annual Symposium]

Stanford University, CA | May 16th - May 17th, 2025

[27th International Scientific Symposium on Biometrics BIOSTAT 2025]

Varazdin, Croatia| Jun 11th - Jun 14th

[2025 Applied Statistics Symposium]

Storrs, CT| Jun 15th - Jun 18th

IBS WNAR
The Western North American Region of The International Biometric Society

JSM NASHVILLE TENNESSEE AUGUST 2–7, 2025
Statistics, Data Science, and AI Enriching Society

[Bayes Comp 2025]

Singapore | Jun 16th - Jun 20th

[WNAR/IMS Annual Meeting]

Whistler, Canada | Jun 15th - Jun 19th

[Joint Statistical Meeting]

Nashville, TN | Aug 2nd – Aug 7th

2025 UCSF-Stanford CERSI Bayesian Thinking in Clinical Research Course

Date: Jan 23rd, 2025 – Apr 10th, 2025 (from 10 am to 11:30 am Pacific Time)
Location: Held Virtually on Thursdays
Information and Registration: https://pharm.ucsf.edu/cersi/2025Bayesian

Overview

The UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (CERSI) is pleased to announce the new 2025 Bayesian Thinking in Clinical Research Course.

Target audience

- Early- to mid-career professionals involved in clinical trials (industry, academia, and government) who would like a broad overview of the latest developments in the application of Bayesian methods in clinical research.
- Faculty members who are interested in using clinical trials to advance medical practice.
- Trainees (students/residents/postdocs) who would like to complement their training and research in basic and applied statistics through the review of case studies and examples.

Why this course?

There are a variety of 4-hour or one-day short courses that cover some Bayesian concepts or examples. There are also many in-depth statistical courses that are steeped in mathematics, computation, and inference.

This course is designed to be in the sweet spot: A more in-depth course on Bayesian thinking with real-life examples and applications that do not involve mathematics. The UCSF-Stanford CERSI Bayesian Thinking in Clinical Research Course is meant to focus on concepts that will allow students to have engaging conversations with statisticians and review the clinical trial literature with a more educated perspective on inferring what is likely to be true.

The material should be accessible to a broad scientific and clinical audience and may also help statisticians who have not been exposed to Bayesian methods.

2025 Pharmaceutical Data Science (PharmaDS) Conference: Re-imagining the Future of Pharma: AI-Powered Value Creation

Date: Apr 7th, 2025 – Apr 9th, 2025
Location: Crowne Plaza, Edison, NJ
Information and Registration: https://phds.nestat.org/

Overview

The pharmaceutical industry is undergoing an unprecedented transformation driven by the rapid evolution of AI, machine learning, and cutting-edge technologies. These advancements are reimagining every stage of drug development and patient care, positioning us at the forefront of a new era of innovation and value creation.

Why this conference? (Apr 8th – Apr 9th)

Join us at this year's conference, **Re-imagining the Future of Pharma: AI-Powered Value Creation**, where data scientists, pharmaceutical sponsors, researchers, and technology enthusiasts will converge to explore AI's transformative potential. This event is full of applications and use cases, critical insights, and collaborative opportunities that redefine how we innovate and lead in healthcare.

This conference is a unique opportunity to immerse yourself in the multidisciplinary fusion of AI and pharmaceutical science. Engage with industry leaders, cutting-edge innovators, and thought-provoking sessions to unlock new possibilities, address challenges, and explore the balance of risks and benefits inherent in these advancements.

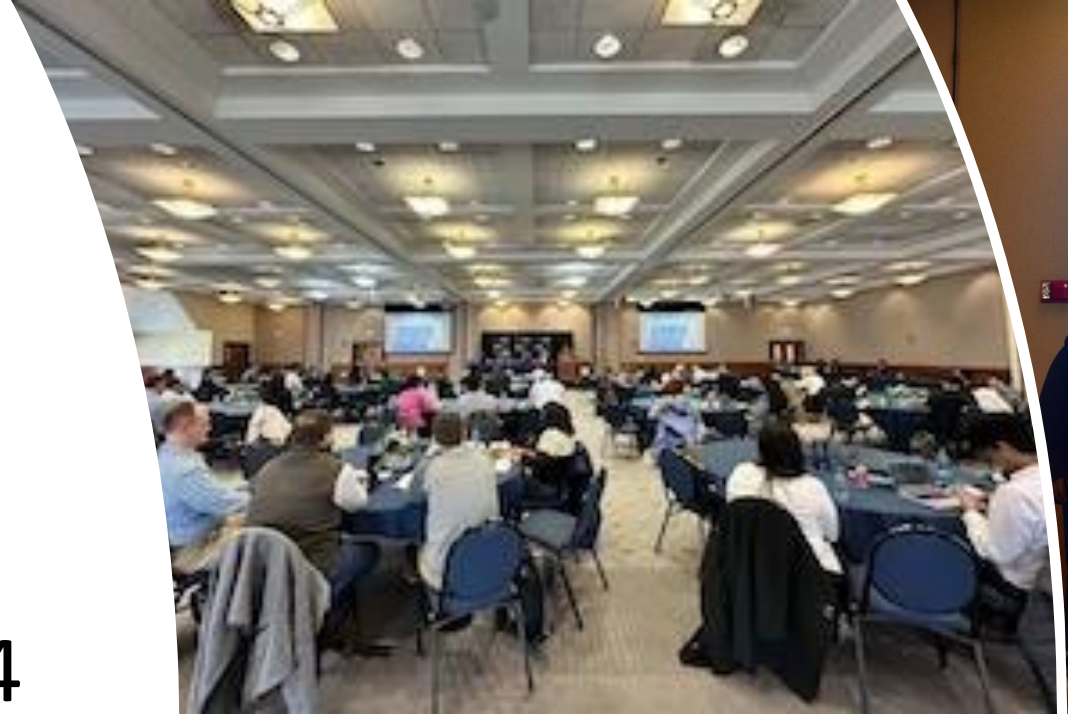
Conference short-courses (April 7th)

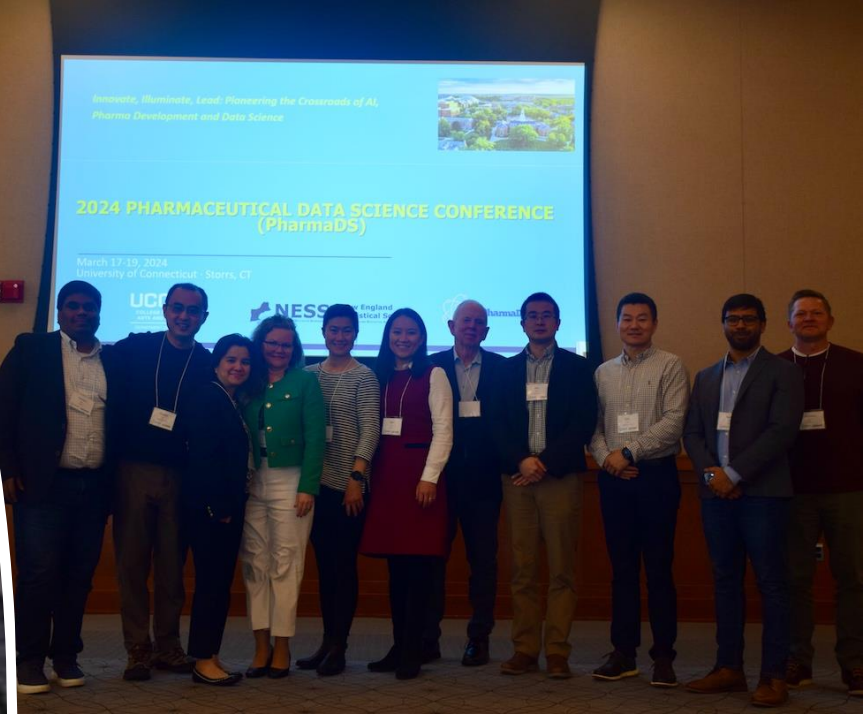
Our conference offers four short course opportunities.

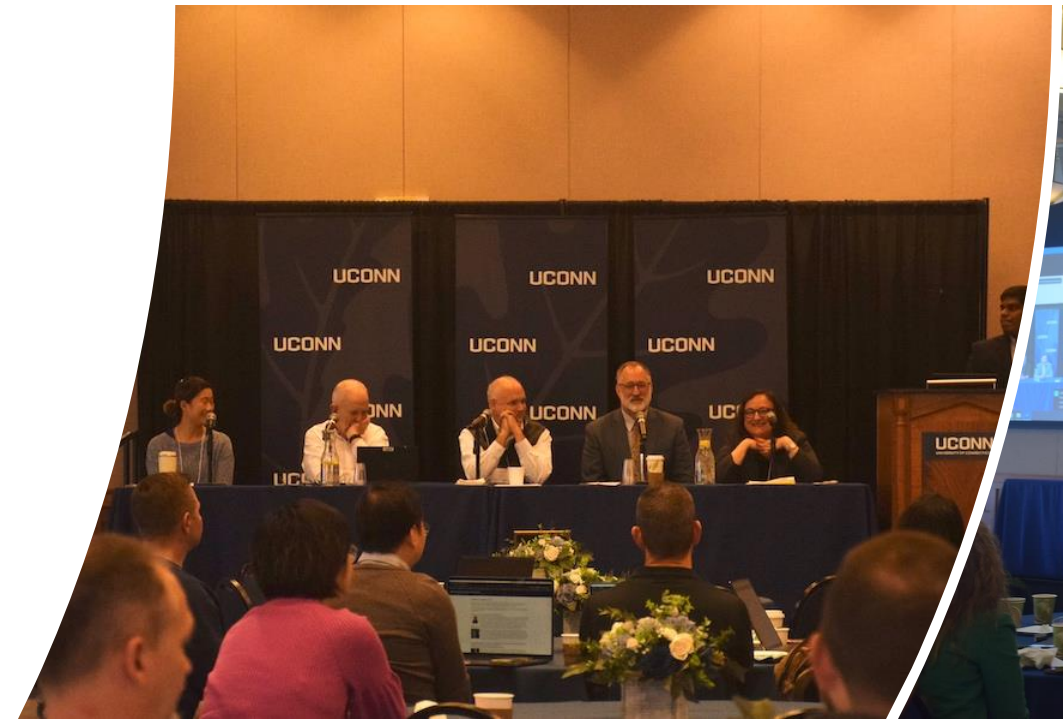
- Tutorial Deep on Learning and Generative AI Intelligence
- GenAI Content in Pharmaceutical Development: Exploring methods and Techniques for Output Evaluation
- Unleasing the Power of Mahcine Learning and Deep Learning to Accelerate Clinical Development
- Biomedical Large Language Models – Development and Application

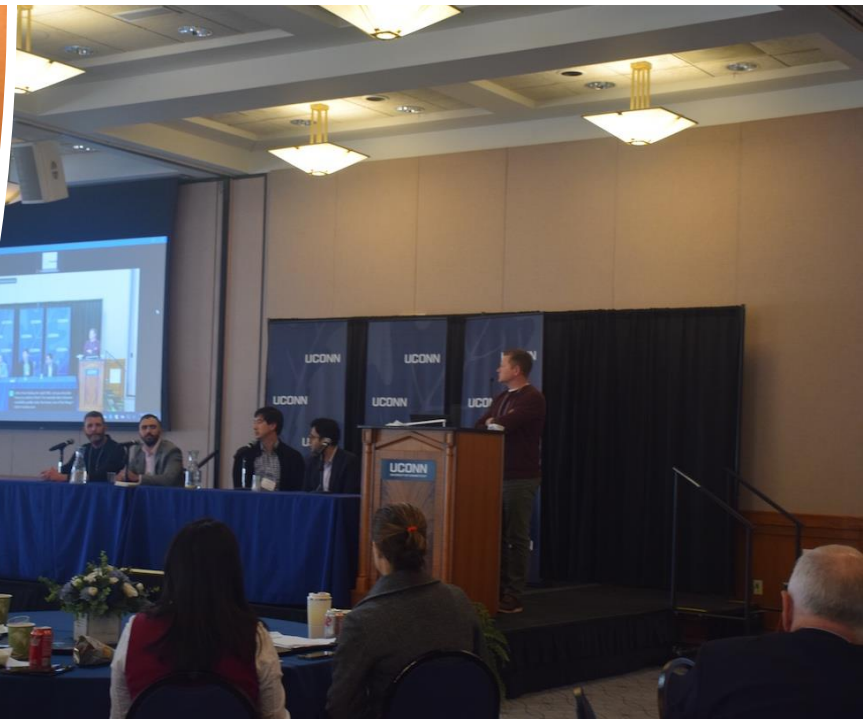
Mark your calendars and secure your place today. Join us for this transformative moment in reimagining the future of our industry

PharmaDS 2024 Highlights









BSWG Sub-Teams

Adaptive Design and Decision Making

Pritibha Singh
Yuan Ji

The BSWG Adaptive Design and Decision-Making Sub-team is focused on advancing clinical trial innovation and strategic decision-making across drug programs and portfolios. Our sub-team advocates practical feasibility and theoretical rigor in adaptive Bayesian methodology development and use. We build on posterior inference and quantify statistical errors that differ from classical metrics like type I error rate. Our work aims to facilitate more flexible, data-driven, and efficient decision-making.

AI, ML, and Bayesian

Pritibha Singh

The AI, ML, and Bayesian Sub-Team is launching with a focus on advancing the integration of artificial intelligence (AI) and machine learning (ML) within Bayesian methodologies with decision-making in pharmaceutical research. Pritibha Singh (sub-team leader) actively seeks team members with AI, ML, and Bayesian methods expertise. The specific focus is on recruiting team members who can actively contribute. At a later stage, the subteam will open up to interested parties. However, the initial core group needs to focus on the progress of the subteam's agenda to benefit the wider BSWG community and beyond.

Bayesian Preclinical/ Discovery

Tony Pourmohamad
Erina Paul

In partnership with ASA Biopharm WG, our goals are to influence regulatory guidelines, elevate industry practices, and raise awareness of Bayesian methods in nonclinical areas. We aim to develop specific use-cases in CMC and non-CMC areas, fostering an inclusive, diverse, and transformative impact. Join us.

Benefit Risk

Madhurima Majumder
Carl DiCasoli

The benefit-risk (B-R) assessment of a new medicinal product is one of the most complex tasks that sponsors, regulators, payers, physicians, and patients face. Several quantitative methods have been proposed in recent years that try to provide insight into this challenging problem. Bayesian inference, with its coherent approach for integrating different sources of information and uncertainty, along with its links to optimal decision theory, provides a natural framework to perform quantitative assessments of the B-R trade-off.

Best Practices

Fanni Natanegara
Cory Heilmann

The increase in use and acceptance of Bayesian methodology in clinical trials has led to a need for guidance on how to report and document such methodology. ICH and various regulatory agencies recommend including language regarding the planned analyses for primary and other key analyses in the protocol and in a pre-specified analysis plan. This subteam's goal is to provide recommendations on the level of detail to include in protocols and analysis plan as well as simulation plan involving Bayesian designs and analyses.

COVID-19

Joan Buenconsejo
Fanni Natanegara

This subteam has partnered with the Statistical Community to find statistical opportunities to accelerate the development of COVD-19 therapeutics by way of innovative trial designs, standardized clinical outcomes, core data elements, and data sharing to enable efficient decision making and bring safe and effective therapeutics to the market.

DCTs

Pritibha Singh

Opening for co-lead

This subteam has a core focus to explore and shape the way Bayesian methods (e.g., missing data handling) are utilized in drug development from concept to read-out of the Decentralized Clinical Trial.

Contact Pritibha Singh if you are interested in joining the sub-team

Education

Fanni Natanegara
Yuan Ji

The goal is to coordinate and provide Bayesian educational support which will help implement Bayesian approaches in drug development on a more regular basis as appropriate. We intend to provide education at a variety of levels, i.e., to meet the needs of statisticians and non-statisticians working in different organizations (e.g., industry and regulatory).

Joint Modeling

Open for lead and co-lead

The goal is to explore Bayesian approaches to the joint modeling of longitudinal and survival-type outcomes. The aims include providing recommendations for how such models could or should be constructed, illustrating how they might be used, and elucidating the potential advantages they present and their limitations.

Medical Outreach

Natasha Muhlemann
Purvi Prajapati

The Medical Outreach Group was formed with the vision to ensure that Bayesian methods are well-understood and broadly utilized for design and analysis throughout the medical product development process and to improve industrial, regulatory and economic decision making. Our goal is to coordinate and provide adaptive and educational support, which will help our medical colleagues collaborate with statisticians in implementing adaptive and Bayesian approaches in drug development as appropriate. This includes frank and balanced discussions of both advantages and disadvantages of these methods. We intend to provide education at a variety of levels, to meet the needs of medical colleagues working in different organizations (e.g. industry, regulatory).

Medicine Adaptive Pathway to Patients

Open for lead and co-lead

This is a subteam of the Bayesian Scientific (BSWG) and Innovative Design (IDSWG) Scientific Working Groups, focused on expedited approvals. Our first work was with stakeholders exploring ways to link platform trials across development phases (published 2016). We then developed a framework to model how divergent stakeholders can make conflicting decisions from the same evidence (published 2022). We are building on this framework to analyze case examples of divergent decisions and their impacts.

Missing Data

Jiajun Liu

Goals: 1) Review and understand the new framework for constructing estimand from the ICH E9 (R1) addendum. 2) Use case studies to illustrate the applications of Bayesian methods under the new framework. 3) Summarize and investigate the Bayesian methods for handling missing data under the new framework in the ICH E9 (R1) addendum, and to provide recommendations and guidance to the statistical community.

Nonclinical (CMC)

Christopher Thompson
Ji Young Kim

As part of the ASA Biopharm Non-Clinical WG, ASA Biopharmaceutical Nonclinical Biostatistics Bayesian CMC Scientific working Group aims to advance the use and acceptance of Bayesian methods in the nonclinical biopharmaceutical CMC statistics. More specifically:
1) Influence regulatory guidelines and standard industry practice in the context of applying Bayesian methods and philosophy in nonclinical areas
2) Foster broader awareness of the relevance, validity and potential advantages of Bayesian methods applied in the nonclinical space among statisticians and non-statisticians
3) Develop specific use-cases within CMC space

Noninferiority

Open for lead and co-lead

Substantial historical data may be available on the active-control and placebo before an active controlled trial is planned in a clinical development. Bayesian approaches provide a natural framework for synthesizing the historical data that can effectively be used in designing a non-inferiority clinical trial. Despite flurry of recent research activities in this area, there are still substantial gaps in recognition and acceptance of such application in clinical trial development.

Pediatrics/Small Population

Open for lead and co-lead

Goals: 1) Explore statistical methodology that can be applicable in the design of analysis of clinical trials with particular interest in applying Bayesian methodology. 2) Illustrate and provide advice on best practices that could be used by statisticians in designing trials for pediatric and orphan therapeutics. 3) Collaborate with pharma, academia and regulatory bodies to exchange problems/issues as well as possibilities where consensus in solutions can be made 4) Disseminate information on research and best practices to broader scientific community as through conferences, workshops and seminars.

Prior/Historical Data

Satrajit Roychoudhury

Methods for borrowing historical information, and the ramifications of these methods, are less well understood in terms of benefits, effects, and regulatory ramifications. The goal of this subteam is to illustrate and compare methods, understand considerations for integrating historical information into confirmatory trials, and participate in external Taskforce to influence regulatory policy change on the use of historical data.

Reporting/Tools

Open for lead and co-lead

Although there is a wide variety of books and numerous journal articles written on Bayesian approaches in the analysis of data, not much has been written about reporting of these analyses, particularly as this pertains to clinical research. The goal of this subteam is to provide recommendations on good practices for Bayesian reporting and overview to selected software tools for Bayesian analysis.

RWE

Xiang Zhang

The inclusion of RWD/E to enhance regulatory decision making, especially for efficacy/effectiveness decision, has been advocated by FDA (and also other regulatory agencies such as EMA/MHRA/Health Canada/China NMPA) in recent years starting with the 21st Century Cures Act, PDUFA VI, and recently 2018 FDA's RWE strategic framework. This subteam aims to leverage Bayesian methods to analyze RWD and generate RWE for regulatory decision making, which includes improving reproducibility for more credible and reliable RWE and the use of RWE in both clinical trials (e.g., hybrid control, synthetic control) and clinical planning (e.g., endpoint validation, targeting appropriate trial population).

Safety

Karen Price, Amy Xia
Melvin Munsaka

Safety assessment is essential throughout medical product development. The goal of this subteam is to evaluate challenges associated with current methods for designing and analyzing safety trials including making the case for Bayesian meta-analyses in safety data and extending Bayesian hierarchical models for safety signal detection in clinical trials. Another objective is to promote routine use of Bayesian methods in drug safety throughout the drug lifecycle.

Thank You!

Thank you for your continued dedication and transformative contributions. Together, we drive innovation and embrace the urgency of our mission. Your commitment empowers our our inclusive community, shaping a transformative future. Let’s continue to inspire and elevate each other on this shared journey toward excellence and impactful change.

Pritibha Singh, Chair
On behalf of the BSWG Leadership Team