Newsletter

November 2024 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.

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, Mathangi Gopalakrishnan
Webmasters	Melvin Munsaka, Haijun Ma, Spencer Woody

Cultivating the Next Generation of Bayesian Statisticians: A Vision for 2025-2027

Guest Column BIO

Dr. Jane Lin, a dedicated Bayesian Scientific Working Group member since 2014, is an Associate Director in Oncology Statistics at Takeda Pharmaceuticals. She is a program statistics lead for oncology drugs in early and late development phases, utilizing Bayesian methodologies to guide decision-making and regulatory strategies. In addition to her primary role, she has led several internal working groups to promote innovative statistical methods.

Dr. Lin is passionate about enhancing drug development through innovative statistical approaches, including Bayesian designs and analyses, real-world evidence (RWE), and artificial intelligence/ machine learning. She has authored over 20 methodological publications and serves as an Associate Editor for the Journal of Biopharmaceutical Statistics, where she has also guest-edited special issues on RWE.

In addition, Dr. Lin served on the steering committee for the ASA Biopharmaceutical Section Regulatory-Industry Workshop in 2023 and 2024. With a PhD in Statistics and Applied Probability from the University of California at Santa Barbara, she has previously worked at AbbVie. She is currently based in Cambridge, MA, where she enjoys the local culture and outdoor activities.

Cultivating the Next Generation of Bayesian Statisticians: A Vision for 2025-2027

- By Dr. Junjing 'Jane' Lin, Associate Director, Oncology Statistics, Takeda Pharmaceuticals & Next Gen Officer, BSWG

As we look toward the future of Bayesian statistics, our mission remains clear: to foster an inter-connected community that champions innovation, collaboration, and the development of the next generation of statisticians. I've seen firsthand how nurturing talent and embracing cutting-edge methodologies can drive transformative change. As the Next Gen Officer, I'm excited to share our strategic roadmap for the next three years.

In 2025, we plan to expand our digital presence to better connect with students and early-career professionals. By creating a digital ecosystem, we aim to foster collaboration and growth across our community. Our LinkedIn Page will serve as the primary hub for public-facing content, including conference updates, regulatory initiatives, and webinars.

As we move into 2026, we will focus on mentorship and professional development, creating pathways for students and early-career professionals to expand their skills and knowledge. We plan to collaborate with ASA's Lipcom mentorship program to emphasize developing soft skills, such as resilience, adaptability, and growth mindset, essential for success in our evolving field.

Additionally, we will bring together influential statisticians and leaders from adjacent sectors to help propagate Bayesian methods and demonstrate their practical applications across different industries. By organizing practical talks and workshops, we will provide valuable career guidance, with experienced statisticians offering insights and expertise at school and regional conferences.

Looking further ahead to 2027 and beyond, our vision is to solidify partnerships that bridge the gap between academic learning and industry application. We plan to collaborate with universities to develop educational programs modeled after UCSF's Bayesian course, ensuring that Bayesian education remains accessible and engaging for students worldwide. To make these methodologies more approachable, we will organize targeted workshops for statisticians and non-statisticians, translating complex theories into practical applications. Our engagement will extend to senior academic advisors as we explore innovative ways to inspire and prepare the next generation of statisticians, equipping them to tackle the challenges of tomorrow. Through these initiatives, we envision a future where Bayesian statisticians are at the forefront of data-driven decision-making, and our community serves as a beacon of knowledge, collaboration, and innovation. We invite all members to join us on this exciting journey to learn, contribute, and grow together.

Dr. Jane Lin, on behalf of the BSWG Leadership Team

Upcoming Conferences / Webinars

[ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop (RISW)]

Rockville, MD | Sep 25th - Sep 27th

[New England Rare Disease Statistics (NERDS) Workshop]

Boston, MA | Oct 10th - Oct 11th

[Bay Area Biotech-Pharma Statistics Workshop (BBSW)]

Foster City, CA | Oct 24th - Oct 25th

[Bayesian Biostatistics Conference]

Rockville, MD | Oct 23rd - Oct 25th

[Boston Pharmaceutical Statistics Symposium]

Cambridge, MA | Oct 31st - Nov 1st

[Friends of Cancer Research Annual Meeting]

Washington, DC | Nov 12th

International Biometric Conference (IBC)

Atlanta, GA | Dec 8th - Dec 13th

ASA STATBOLIC

STATBOLIC 2025

Silver Spring, MD | Feb 6th, 2025

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

STAT4ONC Annual Symposium

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

Berry Consultants Statistical Innovation

Upcoming FACTS Software Public Webinars Series: Case Studies in using FACTS to design Clinical Trials

1. A Seamless Phase 2/3 multiple endpoint diabetes trial
   Virtual | Oct 17th
2. A two-arm study with adherence model driven effect size and irregular interim analyses
   Virtual | Oct 24th
3. An open enrollment CRM dose escalation study
   Virtual | Oct 31st
4. A trial in hemorrhagic stroke with adaptive enrichment Virtual | Nov 7th
5. An Alzheimer's Phase 2 dose finding study
   Virtual | Nov 14th
6. A 2-arm MACE safety study
   Virtual | Nov 21st

2025 UCSF-Stanford CERSI Bayesian Thinking in Clinical Research Course

Date: Jan 23, 2025 – Apr 10, 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.

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.

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.

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.

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.

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.

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).

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