Newsletter

July 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	Pritibha Singh, Hao Sun
KOL Organizer	Haijun Ma
Webmasters	Melvin Munsaka, Haijun Ma, Spencer Woody

BSWG Newsletter 2025 Issue 2 guest column: Bayesian adaptive designs and decision making

Guest Column BIO

Dr. Yuan Ji is Professor of Biostatistics at The University of Chicago. His research focuses on innovative Bayesian statistical methods for translational cancer research. Dr. Ji is author of over 170 publications in peer-reviewed journals including across medical and statistical journals. He is the inventor of many innovative Bayesian adaptive designs such as the mTPI and i3+3 designs, which have been widely applied in dose-finding clinical trials worldwide. His work on cancer genomics has been reported by a large number of media outlets in 2015. He received Mitchell Prize in 2015 by the International Society for Bayesian Analysis. He is an elected fellow of the American Statistical Association.

BSWG Newsletter 2025 Issue 2 guest column: Bayesian adaptive designs and decision making

Guest Column BIO

Pritibha Singh is a strategic leader in drug development, with over 18 years of experience shaping data-driven, patient-centric solutions across the industry. Formerly, at Novartis, her most recent role was in the Corporate Affairs Analytics team. Currently completing her doctorate at ETH Zurich on sustainability in clinical research, she blends expertise in statistics, psychology, and business to drive scalable change. As Chair of the Bayesian Scientific Working Group (BSWG), she champions the application of Bayesian thinking, interdisciplinary collaboration, and the next generation of scientific leadership.

BSWG Newsletter 2025 Issue 2 guest column: Bayesian adaptive designs and decision making

Under the leadership of the American Statistical Association (ASA) Biopharmaceutical Section Working Group (BSWG), the Adaptive Design and Decision-Making sub-team is advancing a critical agenda: a renewed and urgent focus on reshaping the landscape of clinical trials through Bayesian philosophies and approaches. As the complexity and richness of therapeutic development increase, so too does the need for designs that offer flexibility, efficiency, and the ability to learn and adapt in real-time.

Bayesian trial designs provide a robust framework for modern clinical trials, enabling continuous learning and informed decision-making in the face of uncertainty. By incorporating prior information and dynamically updating beliefs as data accumulates, these designs enable critical decision-making, such as early stopping, dose adjustments, or population enrichment. The fundamental distinction of Bayesian designs and decision-making lies in their probabilistic inference of unknowns, such as treatment effects and benefit-risk tradeoffs, among others. These designs are not merely technical innovations but are increasingly essential tools in areas such as rare disease, pediatrics, oncology, and precision medicine—domains where traditional fixed designs often fall short.

Looking ahead, several trends are set up to shape the evolution of Bayesian adaptive designs and decision making:

Integration with Real-World Evidence (RWE): Regulatory and industry interest in leveraging real-world evidence (RWE) is expanding. Bayesian methods offer a natural framework for incorporating external control data and observational datasets, thereby improving efficiency while maintaining rigor.

Regulatory Alignment and Guidance: Recent dialogues among sponsors, regulators, and academic stakeholders have led to a more nuanced understanding of Bayesian methods. The FDA's use of Bayesian devices, along with the complex innovative trial designs, signal essential shifts in its growing openness to Bayesian proposals in drug development. The new C3TI program offers a new opportunity for Bayesian methods for simple trials and potentially in a pivotal setting.

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Seamless Platform Trials:
As multi-arm, multi-stage platform trials become more prevalent, Bayesian approaches enable the addition and removal of arms, dynamic randomization, and more nuanced decision rules that reflect the evolving evidence landscape.

Decision-Theoretic Utility Models:
Beyond type I error control and power, there is growing interest in explicit decision-analytic frameworks that quantify benefit-risk tradeoffs and stakeholder utilities. These models facilitate more transparent and patient-centered decision-making.

Education and Dissemination:
The BSWG recognizes the importance of training and advocacy. As Bayesian designs become more mainstream, emphasis must be placed on accessible tools, reproducible workflows, and cross-functional education for clinical teams, regulators, and statisticians alike.

The Adaptive Design and Decision Making subteam of BSWG is committed to advancing the practical application of Bayesian methods through collaboration, methodological innovation, and strategic outreach. We invite ASA members who share this vision to join us in shaping the next generation of clinical trial design.

In 2025, our program will feature webinars with leading global experts and practitioners, highlighting real-world applications of Bayesian tools. In September, we're proud to contribute a dedicated session on Bayesian designs at the FDA-Industry Workshop in Washington, D.C., a key forum for shaping regulatory and scientific dialogue.

We're also actively collaborating with other BSWG sub-teams, such as Benefit-Risk, to develop joint frameworks that unify design and decision-making under Bayesian principles. We believe these synergies are essential to building a cohesive, forward-looking Bayesian ecosystem.

To close, we've highlighted a few recent manuscripts below that may be of interest to our readers. *Go Bayes.*

By Dr. Yuan Ji, Professor of Biostatistics at the University of Chicago, and Pritibha Singh, BSWG Chair; on behalf of the BSWG Adaptive Design and Decision Making Sub-team

Upcoming Conferences / Webinars

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

[Bayes Comp 2025]

Singapore | Jun 16th - Jun 20th

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

[WNAR/IMS Annual Meeting]

Whistler, Canada | Jun 15th - Jun 19th

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

[Joint Statistical Meeting]

Nashville, TN | Aug 2nd – Aug 7th

ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop (RISW)

Rockville, MD | Sep 24th - Sep 26th

65th ISI World Statistics Congress

The Hague, the Netherlands | Oct 5th - Oct 9th

Bayesian Biostatistics Conference

Rockville, MD | Oct 22rd - Oct 24th

BBSW Bay Area Biotech-Pharma Statistics workshop

Bay Area Biotech-Pharma Statistics Workshop (BBSW)

Foster City, CA | Nov 6th - Nov 7th

Boston Pharmaceutical Statistics Symposium

Boston, MA | TBD

FRIENDS of CANCER RESEARCH

Friends of Cancer Research Annual Meeting

Washington, DC | Nov 4th

BSWG JSM F2F Meeting

Date: August-5th

Time: 4:00 pm – 6:00 pm,

Location: Room H - Broadway H, Omni Nashville Hotel, Nashville, TN

Presentation Topics:

- BSWG Overview (Pritibha Singh and Melissa Spann)
- Benefit-Risk Subteam update (Saurabh Mukhopadhyay)
- Updated versions of ASA BSWG website and official website (Melvin Munsaka)
- Academic topic “Controlling the type I error rate of repeated trials that do not exist: Why?” (Yuan Ji)

Fun Activity:

- A Jeopardy-style trivia game for attendee engagement.
- Prizes and BSWG-branded giveaways will be provided.

BSWG Sub-Teams

Adaptive Design and Decision Making

Yuan Ji
Pritibha Singh

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.

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.

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).

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).

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.

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.

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

Melvin Munsaka

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.

Recruitment

- Seeking a **Co-Lead for the BSWG Key Opinion Leader (KOL) Series** – a platform to bring experts to our community. This role offers the opportunity to shape the agenda for high-impact educational and technical sessions, spotlight innovations in Bayesian methods, and amplify the voice of thought leaders across industry, academia, and regulatory science. The co-lead will play a role in curating topics that inspire, challenge, and advance Bayesian thinking globally

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 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