ISBA Biostatistics and Pharmaceutical Section
Bayesian BioPharm Meeting 2025 (BBP 2025)
Friday, June 27 from 1:30pm – 6:30pm PT, UCLA
https://bnp14.org/bbp2025/

Meeting Schedule Detailed

1:30pm – 1:35pm: Welcome

1:35pm – 3:05pm: Plenary Speakers

- **1:35pm – 2:20pm Ben Saville,** Adaptix Trials LLC

Bayesian Clinical Trials: Applications, Challenges, and Opportunities

Abstract: As medical research continues to push into new frontiers of discovery and personalized patient care, it is imperative that clinical trial designs and statistical methodologies evolve to address the forthcoming challenges. In this talk, I explain why Bayesian methods are ideally suited to provide such innovation. I highlight two recent examples of Bayesian methods in clinical trials: 1) the ENRICH trial, an academia/industry collaboration and first randomized trial to successfully demonstrate benefit of minimally invasive surgery with combination technologies versus guideline-based management of intracerebral hemorrhage, in which Bayesian methods were essential to adaptively enrich the study population based on hemorrhage location; and 2) the ProtEmbo

pivotal trial, designed to evaluate the efficacy and safety of a cardiac device for cerebral embolic protection during Transcatheter Aortic Valve Replacement (TAVR), in which an FDA-approved device with marginal benefit motivates a hybrid control arm with Bayesian modeling. FDA regulatory considerations are highlighted, as well as challenges with the interpretation and communication of Bayesian trial results to the scientific community. Moving forward, there are great opportunities for both academia and industry to leverage Bayesian clinical trials to more efficiently evaluate new therapies in a rapidly evolving age of science and discovery.

- **2:20pm – 3:05pm Sam Behseta,** Kaiser Permanente Bernard J. Tyson School of Medicine

The Time Has Arrived: A Bayesian Time-to-Event Modeling Approach with Applications in Health Sciences

Abstract: A statistician's journey: spanning more than two decades of service within a traditional academic mathematics and statistics department into a newly established medical school dedicated to training future doctors committed to serving diverse patient populations. In this talk, I will share the story of my experience as a Professor and Applied Statistician. In particular, I will provide examples of the types of problems my students and collaborators previously worked on, as well as the statistical challenges I now encounter in my new role. Finally, I will highlight a collaborative effort to explore and expand time-to-event BNP models that aims to provide practical interpretations and an accessible model structure for applications in biomedical and health sciences.

(10 min break)

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3:15pm – 4:45pm: Invited Talks and Discussion

- **3:15pm –3:45pm Tony Pourmohamad,** Genentech and University of California Santa Cruz

Overcoming Barriers: Making Bayesian Analysis Accessible in Pharmaceutical Development

Abstract: Despite the increasing recognition of Bayesian methods in pharmaceutical development, their adoption remains limited, partly due to the perception that Bayesian analysis is difficult to implement in practice. A key contributor to this challenge is the lack of available, easy-to-understand resources for implementing Bayesian techniques practically. This talk will examine how the scarcity of practical resources hinders broader adoption and will highlight efforts to bridge this gap. Using examples from nonclinical statistics, we will demonstrate how the availability of well-documented code and user-friendly implementations can facilitate the use of Bayesian methods in pharmaceutical settings. Attendees will gain insights into the importance of reproducible workflows and how increased access to computational tools can lower the barrier to entry for Bayesian analysis in regulatory and industry applications.

- **3:45pm – 4:15pm Joseph Ibrahim,** University of North Carolina Gillings School of Global Public Health

Bayesian dynamic borrowing with robust covariate adjustment via the latent exchangeability prior and Gaussian processes

Abstract: In randomized controlled trials (RCTs), two popular approaches for increasing efficiency are via (i) robust covariate adjustment and (ii) informative prior elicitation. While the recent FDA guidance recommends the use of prognostic baseline covariates to improve statistical efficiency for estimating and testing treatment effects, it fails to mention how to do so while also leveraging historical data. On the other hand, traditional historical data borrowing approaches

typically assume that the current and historical data models are correctly specified, which is unlikely to occur in practice. We propose a hierarchical Bayesian model that uses a finite mixture of Gaussian processes (MGP) to both account for heterogeneity and adjust for covariates. Using a latent exchangeability prior (LEAP), our approach averages over all possible partitions of the historical data into exchangeable and nonexchangeable groups. Meanwhile, the Gaussian process flexibly provides covariate adjustments for the outcome of interest and can be particularly useful in cases where the relationship between predictors and outcomes is non-linear. By addressing heterogeneity and accounting for complex covariate-outcome relationships, our method is particularly suited for trials in rare diseases and other challenging settings with limited sample sizes.

- **4:15pm – 4:45pm Discussion**

(15min break)

5pm – 6pm: 2024 Paper Awards

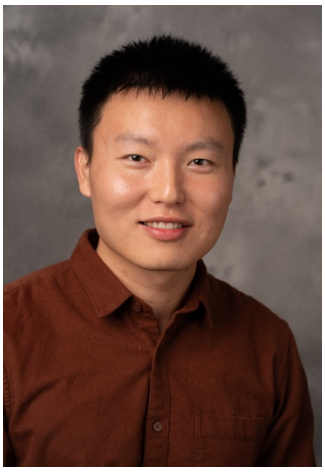
- **5pm – 5:30pm Junior Researcher Award, Anupreet Porwal (left),** Google Inc., **presented by Himel Mallick (right)** Weill Cornell Medical College

An integrated Bayesian framework for multi-omics prediction and classification

Abstract: With the growing commonality of multi-omics datasets, there is now increasing evidence that integrated omics profiles lead to more efficient discovery of clinically actionable biomarkers that enable better disease outcome prediction and patient stratification. Several methods exist to perform host phenotype prediction from cross-

sectional, single-omics data modalities but decentralized frameworks that jointly analyze multiple time-dependent omics data to highlight the integrative and dynamic impact of repeatedly measured biomarkers are currently limited. In this article, we propose a novel Bayesian ensemble method to consolidate prediction by combining information across several longitudinal and cross-sectional omics data layers. Unlike existing frequentist paradigms, our approach enables uncertainty quantification in prediction as well as interval estimation for a variety of quantities of interest based on posterior summaries.
We apply our method to four published multi-omics datasets and demonstrate that it recapitulates known biology in addition to providing novel insights while also outperforming existing methods in estimation, prediction, and uncertainty quantification. Our open-source software is publicly available at https://github.com/himelmallick/IntegratedLearner.

- **5:30pm – 6pm Best Paper, Jason Xu** (left), University of California Los Angeles, presented by **Fan Bu** (right), University of Michigan, Ann Arbor.



Inferring HIV transmission patterns from viral deep-sequence data via latent typed point processes

Abstract: Viral deep-sequencing data play a crucial role toward understanding disease transmission network flows, because the higher resolution of these data compared to standard Sanger sequencing provide evidence into the direction of infectious disease transmission. To more fully utilize these rich data and account for the uncertainties in phylogenetic analysis outcomes, we propose a spatial Poisson process model to uncover HIV transmission flow patterns at the population level. We represent pairings of two individuals with viral sequence data as typed points, with coordinates representing covariates such as gender and age, and the point type representing the unobserved transmission statuses (linkage and direction). Points are associated with observed scores on the strength of evidence for each transmission status that are obtained through standard deep-sequence phylogenetic analysis. Our method is able to jointly infer the latent transmission statuses for all pairings and the transmission flow surface on the source-recipient covariate space. In contrast to existing methods, our framework does not require pre-classification of the transmission statuses of data points, instead learning them probabilistically through a fully Bayesian inference scheme.

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By directly modeling continuous spatial processes with smooth densities, our method enjoys significant computational advantages compared to previous methods that rely on discretization of the covariate space. We demonstrate that our framework can capture age structures in HIV transmission at high resolution and bring valuable insights in a case study on viral deep-sequencing data from Southern Uganda.

6pm – 6:30pm: Award Recognition and Closing