

BBSW
2019

Program Book

BBSW Day 1 (Nov 7th)

Keynotes

Invited Sessions

BBSW Day 2 (Nov 8th)

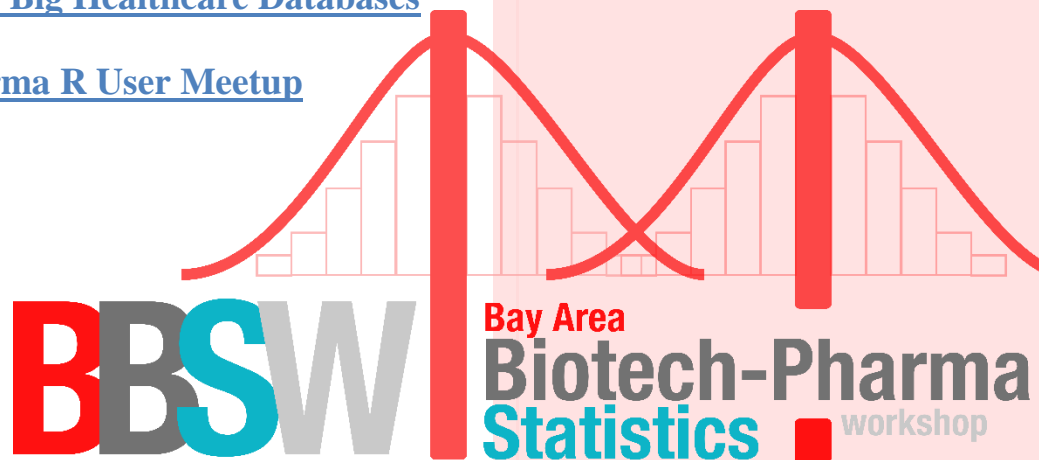
Invited Sessions

Panel

BBSW Day 0 Events (Nov 6th)

Short course: Analysis of Big Healthcare Databases

Free event: Biotech-Pharma R User Meetup



Bay area Biotech-pharma Statistics Workshop (BBSW)

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CONFERENCE HOST

BBSW

BBSW 2019

Innovation and Leadership

Foster City, CA on November 7-8, 2019

Website: bbsw.org Contact: bbsw2019@gmail.com

Our mission is to promote the practice and impact of statistics in the San Francisco Bay Area. We started as a community of statisticians and are open to participation from broader communities. Our ultimate goal is to improve human health. We bring statistics expertise to inform decision-making in a data-rich world: from articulating questions to furthering scientific understanding of diseases and prevention, from developing innovative methods tailored to particular data types to ultimately bringing transformative solutions to patients and society. We foster collaboration across multi-disciplinary groups, companies, and academic institutions.

Our inaugural [2018 BBSW conference](#) was held in Foster City, CA, November 5-6, 2018, under the leadership of Dr. Liang Fang and 25+ colleagues from different companies and academic institutions. It was truly a team effort that demonstrated the need and the will in the community. The 2018 BBSW conference was a resounding success. With more than 200 participants, it brought the community together and promoted innovation, collaboration, and excellence of our profession. The BBSW nonprofit organization was established to support the long-term mission of the conference as a platform for the convergence of the biotech, pharma, and tech industries.

In 2019, we are building on the momentum from 2018 and working toward our second conference. Our aim continues to be a long-lasting annual conference for the local community in the San Francisco Bay area. We hope that these meetings will encourage the formation of smaller interest groups that can meet throughout the year outside of the BBSW conference.



BBSW Day 1 (Thursday, November 7th)



07:30-08:30	Registration and Breakfast
08:30-09:00	Opening Remarks: Imola Fodor (Genentech)
09:00-10:00	<p>Keynote: The Future of Data Science in Biotech-Pharma Chair: Imola Fodor (Genentech) Speaker: Jeff Helterbrand (SVP, Global Head of Biometrics, Genentech)</p>
10:00-10:30	Break
10:30-12:00	<p>Invited Session on Complex Innovative Designs, Examples and Aspirations (Part I) Chair: Chang-Heok Soh (AbbVie)</p> <p>Adaptive Clinical Trial Designs for Optimizing the Intended Use Population (Richard Simon, Independent consultant at R Simon Consulting and former Chief, Biometric Research Branch, NCI)</p> <p>Master Protocols, Basket Trials, and Umbrella Trials: Overviews, Features, Challenges, and Examples (Lindsay Renfro, Associate Professor of Research, University of Southern California and Associate Group Statistician, Children's Oncology Group)</p> <p>Randomized Clinical Trials with Hybrid Controls - Designs and Considerations (Jiawen Zhu, Principal Statistical Scientist, Genentech)</p>
12:00-13:30	Lunch & Networking
13:30-15:00	<p>Invited Session on Informing Personalized Health Care - Bringing Together Data from Clinical Trials and Real World Chair: Jane Fridlyand (Genentech)</p> <p>Using Natural History Data as a Comparator in an Ultra-Orphan Disease Indication (Peter Slasor, Senior Director, Biomarin)</p> <p>Unlocking Personalized Healthcare Through Real World Evidence (Meghna Samant, Senior Director, Flatiron)</p> <p>Characterizing NHL by Analyzing Patient Data from Clinical Trials and Real World (Joe Paulson, Principal Statistical Scientist, Genentech)</p> <p>Speakers' Panel (Moderator: Jane Fridlyand)</p>
15:00-15:15	Break
15:15-16:15	<p>Keynote: TBD Chair: Ruixiao Lu (Genomic Health) Speaker: Steve Goodman (Faculty, Stanford)</p>
16:15-16:55	<p>Lightning Talks on Emerging Technologies Part 1 Chair: Ray Lin (Genentech)</p> <p>Computational Drug Discovery (Marina Sirota, Faculty, UC San Francisco)</p> <p>The Power of Billions: Data-driven Innovation (Shirley Wu, Director, 23andMe)</p>
16:55-18:00	Reception/Mixer
18:00-20:00	<p>Banquet with Leadership and Career Panel Chair: Whedy Wang (Theravance)</p> <p>Panelists: Merrill Birkner (Vice President, Therapeutics Portfolio Management and Business Operations, 23andMe), Mike Crager (Sr. Fellow, Genomic Health), Imola Fodor (Sr Director, Genentech), Jing Huang (SVP, Veracyte), Corsee Sanders (Executive Vice President and Head of Development Operations, Juno Therapeutics), Richard Simon (former Chief, Biometric Research Branch, NCI)</p>

BBSW Day 2 (Friday, November 8th)



08:00-08:30	Registration and Breakfast
08:30-10:00	<p>Invited Session on Complex Innovative Designs, Examples and Aspirations (Part II) Chair: Ying Lu (Stanford)</p> <p>Bayesian Design in Master Protocols (Kun He, Chief Statistician, R&G US Inc.)</p> <p>Optimal Sample Size Re-estimation in Adaptive Design based on Return on Investment (Yi Liu, Sr. Director, Nektar)</p> <p>Use of Complex Innovative Trial Designs in VA Cooperative Studies (Mei-Chiung Shih, Faculty, VA and Stanford)</p>
10:00-10:30	Break
10:30-12:00	<p>Invited Session on Biomarker and Machine Learning Chair: Ruixiao Lu (Genomic Health)</p> <p>Clinical diagnostics in Non-Invasive Prenatal Testing (Theresa Boomer, Illumina)</p> <p>Joint Propensity Scores for the Analysis of Real-World Data with Biomarker Driven Treatment Selection (Mike Crager, Sr. Fellow, Genomic Health)</p> <p>Machine Learning for Protein Engineering (Jennifer Listgarten, Faculty, UC Berkeley)</p>
12:00-13:30	Lunch & Networking
13:30-14:30	<p>Panel on Collaboration at the Intersection of Statistics, Bioinformatics, and Data Science Chair: Tara Maddala (TMBiostats, NDA Partners)</p> <p>Panelists: Gregory Alexander (Biostatistics Director, Grail), Sandrine Dudoit (Faculty, UC Berkeley), Jing Huang (SVP Bioinformatics and Data Science, Veracyte), Jacqueline Law (Head of Personalized Healthcare Data Science, Genentech), Anil Patwardhan (Biostatistician/Quantitative Scientist, Verily)</p>
14:30-15:10	<p>Lightning Talks on Emerging Technologies Part 2 Chair: Ray Lin (Genentech)</p> <p>Automated Tumor Burden Assessment from CT-scans (Thomas Bengtsson, Director, Genentech)</p> <p>Interactive and Reproducible Analysis Reports in R (Daniel Civello, Director, GRAIL)</p>
15:10-15:30	Raffle and Sponsor Appreciation
15:30-15:40	Closing



BBSW Day 0 Events

6th Nov 2019

Building 323 Melbourne Room at Gilead Sciences

323 Vintage Park Drive, Foster City, CA

Event 1: 9am-1:50pm

Short course - Analysis of Big Healthcare Databases

Instructor: Rebecca Hubbard, University of Pennsylvania

[Registration link](#)

Event 2: 4pm-6pm

Biotech-Pharma R User Meetup

Free event! Separate registration required. [Registration link](#)

Keynote speakers:

- Software Engineering with Shiny
 - Alan Dipert, Rstudio
- Artificial Intelligence & Analytical Innovation – Enhance the power of R tools in clinical development
 - Qinghua Song, Director Biostatistics, Gilead/Kite Pharma
- Establishing a collaborative software culture through inner sourcing
 - Michael Lawrence, Scientist, Genentech Research and Early Development



Short course sponsored by ASA Council of Chapters and co-sponsored by SFASA and BBSW

Topic: Analysis of Big Healthcare Databases

Instructor: Rebecca Hubbard, University of Pennsylvania

Time: 9:00am – 1:50pm

Location: Gilead Sciences, Foster City

Abstract: The widespread adoption of electronic health records (EHR) as a means of documenting medical care has created a vast resource for the study of health conditions, interventions, and outcomes in routine clinical practice. Using healthcare databases, including EHR and administrative claims data, for research facilitates the efficient creation of large research databases, execution of pragmatic clinical trials, and study of rare diseases. Despite these advantages, there are many challenges for research conducted using these data. To make valid inference, statisticians must be aware of data generation, capture, and availability issues and utilize appropriate study designs and statistical analysis methods to account for these issues. In this course, we will discuss topics related to the design and analysis of research studies using big healthcare databases. We will cover issues related to the structure and quality of the data, including data types and methods for extracting variables of interest; sources of missing data; error in covariates and outcomes extracted from EHR and claims data; and data capture considerations such as informative visit processes and medical records coding procedures. In the second half of the course, we will discuss statistical approaches to address some of the challenges and unique features of healthcare databases, including missing data and error in automated algorithm-derived covariates and outcomes. We will also discuss some cutting-edge methods developed to address the unique challenges of this context such as privacy-preserving computation for use in distributed research networks. The overarching objective of this course is to provide participants with an introduction to the structure and content of healthcare databases and equip them with a set of appropriate tools to investigate and analyze this rich data resource.

About the instructor: Rebecca Hubbard is an Associate Professor of Biostatistics in the Department of Biostatistics, Epidemiology and Informatics at the University of Pennsylvania. Her methodological research emphasizes development of statistical tools to support valid inference for EHR-based analyses, accounting for complex data availability and data quality issues, and has been applied across a variety of domains including studies of cancer epidemiology, aging and dementia, and pharmacoepidemiology. She has experience conducting analyses using data from a number of large healthcare databases including Medicare, PCORnet, Kaiser Permanente, Flatiron Health, and Optum. Results of this work have been published in over 100 peer-reviewed papers in the statistical and medical literature. She has taught short courses at ENAR, the FDA, and the Summer Institutes in Statistical Genetics and Statistics for Clinical Research at the University of Washington over the past 10 years.

