BBSW

2019

NOVEMBER 7 - 8

CROWNE PLAZA, FOSTER CITY

BBSW Bay Area Biotech-Pharma Statistics workshop

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WELCOME TO BBSW 2019!

Bay area Biotech-pharma Statistics Workshop (BBSW) is a collaborative initiative supported by companies, academic institutes, and nonprofit organizations in the San Francisco Bay Area. The theme for this year's conference is ***Innovation and Leadership***.

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 built on the momentum from 2018 to organize 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.

We welcome you to join this exciting initiative. For volunteer opportunities in BBSW 2020, please contact us at bbsw2019@gmail.com

PROGRAM

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	**Keynote: The Future of Data Science in Biotech-Pharma** Chair: Imola Fodor (Genentech) Speaker: Jeff Helterbrand (SVP, Global Head of Biometrics, Genentech)
10:00-10:30	**Break**
10:30-12:00	**Invited Session on Complex Innovative Designs, Examples and Aspirations (Part I)** Chair: Chang-Heok Soh (AbbVie) • 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) • 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) • Randomized Clinical Trials with Hybrid Controls - Designs and Considerations (Jiawen Zhu, Principal Statistical Scientist, Genentech)
12:00-13:30	**Lunch & Networking**
13:30-15:00	**Invited Session on Informing Personalized Health Care - Bringing Together Data from Clinical Trials and Real World** Chair: Jane Fridlyand (Genentech) • Using Natural History Data as a Comparator in an Ultra-Orphan Disease Indication (Peter Slasor, Senior Director, BioMarin) • Unlocking Personalized Healthcare Through Real World Evidence (Meghna Samant, Senior Director, Flatiron) • Characterizing NHL by Analyzing Patient Data from Clinical Trials and Real World (Joe Paulson, Principal Statistical Scientist, Genentech) • Speakers' Panel (Moderator: Jane Fridlyand)
15:00-15:15	**Break**
15:15-16:15	**Keynote: TBD** Chair: Ruixiao Lu (Genomic Health) Speaker: Steve Goodman (Faculty, Stanford)
16:15-16:55	**Lightning Talks on Emerging Technologies Part 1** Chair: Ray Lin (Genentech) • Computational Drug Discovery (Marina Sirota, Faculty, UC San Francisco) • The Power of Billions: Data-driven Innovation (Shirley Wu, Director, 23andMe)
16:55-18:00	**Reception/Mixer**

Day 1 Banquet (Thursday, November 7th)

18:00-20:00	**Banquet with Leadership and Career Panel** Chair: Whedy Wang (Theravance) 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)

Day 2 (Friday, November 8th)

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

Day 0 Events (Wednesday, November 6th)

Building 323 Melbourne Room at Gilead Sciences

323 Vintage Park Drive, Foster City, CA

1. Short course - Analysis of Big Healthcare Databases (9am-1:50pm)

Sponsored by ASA Council of Chapters and co-sponsored by SFASA and BBSW

Instructor: Rebecca Hubbard, University of Pennsylvania

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.

2. Biotech-Pharma R User Meetup (4pm-6pm)

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

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EDETEK has been proudly supporting biostatistics and standard development communities and working closely together to bring paradigm-shifting solutions to support clinical trials of the future.

Nektar Therapeutics is a research-based development stage biopharmaceutical company that discovers and develops innovative medicines in areas of high unmet medical need. Our R&D pipeline of new investigational medicines includes treatments for cancer, auto-immune disease and chronic pain. We leverage Nektar's proprietary and proven chemistry platform in the discovery and design of our new drug candidates.

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Seattle Genetics is an emerging multi-product, global biotechnology company that develops and commercializes transformative therapies targeting cancer to make a meaningful difference in people's lives. ADCETRIS® (brentuximab vedotin) uses the company's industry-leading antibody-drug conjugate (ADC) technology and is approved for the treatment of multiple CD30-expressing lymphomas.

Beyond ADCETRIS, the company has established a pipeline of novel targeted therapies at various stages of clinical testing, including three in ongoing or planned pivotal trials for solid tumors. Enfortumab vedotin for metastatic urothelial cancer and tisotumab vedotin for metastatic cervical cancer use our proprietary ADC technology. Tucatinib, a small molecule tyrosine kinase inhibitor, is in a pivotal trial for HER2-positive metastatic breast cancer. In addition, we are leveraging our expertise in empowered antibodies to build a portfolio of proprietary immuno-oncology agents in clinical trials targeting hematologic malignancies and solid tumors.

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KEYNOTE SPEAKERS

Jeff Helterbrand

SVP, Global Head of Biometrics, Genentech

Jeff Helterbrand, Ph.D, is the Global Head of Biometrics at Roche. Biometrics at Roche includes statisticians, patient-centered outcomes researchers, statistical programmers, clinical data managers, and technology specialists. Jeff is a member of the Roche Product Development Leadership Team (PDLT) and the Company's Late Stage Portfolio Committee (LSPC). Previously, Jeff was Head of Biostatistics and Epidemiology at Genentech and a member of the Company's Drug Safety Committee (DSC).

Prior to joining Genentech in 2002, Jeff worked at Eli Lilly & Company focusing on programs in Cardiovascular and Critical Care Medicine. Jeff received his undergraduate degrees in Mathematics and Economics from St. Olaf College, his Ph.D. in statistics from Iowa State, and was a Visiting Scholar at Stanford.

Steve Goodman

Professor of Medicine and of Health Research & Policy

Steven Goodman, MD, MHS, PhD is Associate Dean of Clinical and Translational Research and Professor of Medicine and of Health Research & Policy, directing Stanford's CTSA/Spectrum training programs in medical research methods and serving as chief of the Division of Epidemiology in HRP. He is co-founder and co-director of the Meta-research innovation Center at Stanford (METRICS), a group dedicated to examining and improving the reproducibility and efficiency of biomedical research.

Dr. Goodman's own research concerns the proper measurement, conceptualization and synthesis of research evidence, with particular emphasis on Bayesian approaches to quantitation, and qualitative approaches arising from the philosophy of science. He is also interested in developing methods to use shared data to confirm and extend published science, as well as to explore new hypotheses. He also has worked on the connections between ethics and scientific methods, particularly in the domain of interventional research, and policy making. Finally, he has a strong interest in developing curricula and new models for teaching the foundations of good scientific practice, from question development to proper study design, conduct, analysis and inference.

PANELISTS

Gregory Alexander

Dr. Gregory Alexander is Director of Assay Biostatistics at GRAIL. Throughout his career, Gregory has applied statistical methodology to the development of multi-analytic assay systems and algorithms. He works in collaboration with laboratory scientists, bioinformaticians, and data scientists to design and analyze experiments that support the development, optimization, automation, and analytical validation for GRAIL's multi-cancer detection assay. Prior to GRAIL, he supported R&D at Genomic Health, Inc. for over 7 years, where his contributions led to the validation and launch of multiple tests on various platforms including IHC, qPCR/RNA expression signatures to predict cancer recurrence, and NGS tests to detect DNA alterations in the blood of cancer patients and aid therapy selection. Gregory also served on an interdisciplinary team at Cytokinetics, Inc. where he developed algorithms for fluorescent microscopy and live cell imaging which were used in high content cell based screening drug discovery applications . He earned his BS degree in mathematics from the University of California at Santa Barbara and a Ph.D in Statistics from The American University in Washington, D.C.

Merrill Birkner

Dr. Merrill Birkner is a Vice President at 23andMe, where she heads the Portfolio Management and Business Operations group within the Therapeutics organization. In this role, she is responsible for portfolio management, program management, alliance management, early stage commercial assessments and the operations of the 90+ employee Therapeutics organization. She also leads the alliance and program management for the GSK-23andMe collaboration. Merrill came to 23andMe in 2016 after spending over a decade at Genentech where she had roles in research and development as well as the commercial organization of the company.

Merrill began her career as a biostatistician in Genentech's Product Development organization. She expanded her business expertise with leadership roles in both the company's Commercial organization and Pipeline and Portfolio Planning. Merrill was also the Director of Business Operations within Genentech's Research and Early Development (gRED) group.

Merrill received her Ph.D. in Biostatistics from UC Berkeley, and an M.P.H. in Epidemiology & Biostatistics, also from UC Berkeley. Her undergraduate studies were at the University of Maryland, College Park where she received a B.S. in Biology.

Mike Crager

Dr. Michael Crager received his Ph.D. in Statistics from Stanford University in 1982. He worked as a statistician in the pharmaceutical industry for 26 years with increasing management responsibilities at companies including G.D. Searle, Syntex, Roche, and CV Therapeutics. Mike supported successful regulatory filings in the cardiovascular, antiviral, and endocrinology therapeutic areas. In 2008, he joined Genomic Health as a Biostatistics Fellow to perform research and development in statistical methodology relative to the company's work on prognostic and predictive tests for breast, colon and prostate cancer and other areas. He has published statistical methodology papers in the areas of analysis of covariance, false discovery rates, correction for regression to the mean and power calculation for discovery analyses, and survival analysis.

Sandrine Dudoit

Dr. Sandrine Dudoit is professor of biostatistics and statistics and chair of the graduate group in biostatistics at the University of California, Berkeley. Professor Dudoit's methodological research interests regard high-dimensional inference and include exploratory data analysis, visualization, loss-based estimation with cross-validation (e.g., density estimation, regression, model selection), and multiple hypothesis testing. Much of her methodological work is motivated by statistical inference questions arising in biological research and, in particular, the design and analysis of high-throughput microarray and sequencing gene expression experiments, for example, mRNA-Seq for transcriptome analysis and genome annotation and ChIP-Seq for DNA-protein interaction profiling (e.g., transcription factor binding). Her contributions include exploratory data analysis, normalization and expression quantitation, differential expression analysis, class discovery, prediction, integration of biological annotation metadata (e.g., gene ontology annotation). She is also interested in statistical computing and, in particular, reproducible research. She is a founding core developer of the Bioconductor Project, an open source and open development software project for the analysis of biomedical and genomic data.

Professor Dudoit is a coauthor of the book Multiple Testing Procedures with Applications to Genomics and a co-editor of the book Bioinformatics and Computational Biology Solutions Using R and Bioconductor. She is associate editor of three journals, including The Annals of Applied Statistics and IEEE/ACM Transactions on Computational Biology and Bioinformatics. Professor Dudoit was named fellow of the American Statistical Association in 2010 and elected member of the International Statistical Institute in 2014.

Imola Fodor

Dr. Imola Fodor is the Global Head of Oncology Biostatistics for Early Development and for the Hematology Franchise at Genentech/Roche. She joined Genentech as a Senior Statistical Scientist in the Nonclinical Biostatistics group in 2007. Since then, she held positions of increasing responsibility, including Director of the Nonclinical and Statistical Methods and Research groups, and Senior Director of the Breast Cancer Franchise. Her experience spans from research and early development through late stage clinical development and manufacturing.

Prior to joining Genentech, Imola spent seven years at the Center for Applied Scientific Computing at Lawrence Livermore National Laboratory, where she collaborated with computer scientists, astronomers, and climate scientists to obtain insights from large and complex datasets. Imola holds a Ph.D. in statistics from the University of California at Berkeley.

Jing Huang

Dr. Jing Huang received her B.A. in Statistics and Probability from Peking University and her Ph.D.in Statistics and M.S. in Epidemiology from Stanford University. She has been working in the biomedical field for over 15 years and her research interest focuses on statistical methodologies in clinical trial design, genomic analysis, and machine learning. She is currently the SVP of Bioinformatics & Data Science at Veracyte Inc., a molecular diagnostic company, responsible for creating, implementing and executing bioinformatics pipelines, algorithm development, and statistical analyses across all phases of product development.

Jing has co-authored more than 30 articles in peer-reviewed scientific journals with more than ten thousand citations and is co-inventor of over 20 patent filings. Besides her daily work, she actively promotes data science through many of her volunteer activities: She is the founding president of DahShu (www.dahshu.org), a 501(c)(3) nonprofit organization with the mission of promoting research and education in data science. She is currently the chapter representative of American Statistical Association San Francisco Bay Area Chapter (SFASA); and has served the organization for many years in various roles including Past president (term 2016-2017), President (term 2015-2016), President Elect (term 2014-2015) and VP of Biostatistics (term 2013-2014). She is also a board member of BBSW (the Bay area Biotech-pharma Statistical Workshop).

Jacqueline Law

Dr. Jacqueline Law is the Vice President, Global Head of Personalized Healthcare Data Science at Roche. In this role, Jacqueline is leading a team of data scientists with expertise in Real-World Data (RWD), responsible for RWD strategy and implementation for late stage development,

medical affairs and market access across all therapeutic areas including oncology, neuroscience, infectious disease, inflammation and ophthalmology. Jacqueline's team also comprises of data scientists with the focus of building Roche capabilities in imaging, advanced analytics, personalized healthcare tools and applications. Jacqueline has been with Roche/ Genentech for 16 years, having led quantitative science teams in both Pharma and DIA divisions. Jacqueline received her Ph.D. in Biostatistics from the University of California, Los Angeles.

Anil Patwardhan

Dr. Anil Patwardhan is a Biostatistician/Data Scientist at Verily Life Sciences, where he works as part of a cross-functional team supporting clinical research and medical device development. He enjoys mixing problem-solving, coding, public speaking, writing, and applying statistics to address clinical problems. Anil's past work experience has spanned both start-up molecular diagnostic companies and companies more traditionally considered technology focused (e.g. Intel, Google, Verily). He has held both senior bioinformatics and biostatistics roles focusing on a range of disease areas and across various stages of product development. He has worked on products related to molecular diagnostics, electronic health records, wearable sensors, and most recently image-based diagnostics. Anil holds a PhD in Bioinformatics from the University of California- San Francisco. He lives in the east bay with his wife and two children.

Corsee Sanders

Dr. Corsee Sanders is currently a Strategic Advisor to the Office of the CMO at Celgene Corporations. Prior to this role she served as a member of the Juno Therapeutics Executive Committee as Executive Vice President, leading Quantitative Sciences and the Strategic and Development Operations organizations from Jan 2017. Quantitative Sciences included Clinical Biostatistics, Data Operations, Research Data Sciences, CMC Statistics. Strategic Operations included Project Leadership & Management, Patient Operations. Development Operations included Biosample and Clinical Operations.

Prior to joining Juno, Corsee spent 20+ years at Genentech/Roche with increasing responsibilities including Global Head of Clinical Operations, Global Head of Biometrics, as well as member of the Genentech/Roche Late Stage Portfolio Committee. In addition to her organizational achievements, Corsee had contributed to bringing a wide-array of much needed therapies to patients in several therapeutic areas: Claritin, Rituxan, Herceptin, TNKase, Cathflo, Xolair, Avastin, Tarceva, Lucentis, Zelboraf, Perjeta, Erivedge, Gazyva, Kadcyla, Alecensa, Cotellic, Venclexta, Tecentriq, Ocrevus, Hemlibra, JCAR017, a CAR T cell therapy for NHL.

Corsee obtained her Ph.D. in Statistics from University of Pennsylvania, Wharton Doctoral

Programs. She is also a very proud mom of a young opera singer!

Richard Simon

Dr. Richard Simon retired from the National Cancer Institute as Director of the Biometric Research Program and Chief of the Computational and Systems Biology Branch and has a private consultancy business (R Simon Consulting). He holds a doctorate in Applied Mathematics & Computer Science from Washington University in St. Louis. He has authored and co-authored over 550 research papers and three books on genomic data analysis and biomarker driven clinical trial design. He is the architect of the widely used BRB-ArrayTools and BRB SeqTools software packages. He is an elected Fellow of the American Statistical Association and past member of the Oncologic Drug Advisory Committee of the U.S. Food & Drug Administration. He is the recipient of the 2013 Karl Peace award "for contributions that have played a pivotal role in bridging the gap among statistics, clinical research, and translational medicine to improve human health". He is also the recipient of the 2017 Marvin Zelen award for leadership in Statistical Science from the Department of Biostatistics at Harvard University.

INVITED SPEAKERS

Thomas Bengtsson

Dr. Thomas Bengtsson joined Biostatistics at Genentech in 2009 to support Clinical Imaging Group (CIG), and from 2014-18 split his time between supporting CIG and the Methods, Collaborations, and Outreach (MCO) group in Biostat. In March of 2018 he joined the PHC CoE/RWD to start a small group focusing on how Roche can leverage machine learning techniques in clinical imaging in drug development. Prior to joining Roche/Genentech he was a Visiting Scientist in the Geophysical Statistics Project at the National Center for Atmospheric Research, Boulder, CO from 2000-03; the Neyman Visiting Professor in the Statistics Department at University of California-Berkeley from 2003-05; a Member of Technical Staff in the Mathematical Sciences Department, Bell Labs, Murray Hill, NJ from 2005-09. He is currently an Adjunct Professor of Statistics at UC-Berkeley.

Theresa Boomer

Dr. Theresa started her genetics career as a laboratory technologist 26 years ago and transitioned to clinical genetics and graduate school for genetic counseling shortly thereafter. Her career path has been varied and non-traditional, spanning from bench top cancer research to pediatric genetics clinic to her current role as a laboratory genetic counselor. She recently graduated from a post-graduate Bioinformatics program at Johns Hopkins and looks forward to integrating her newly minted skills in the clinical genetics laboratory at Illumina.

Daniel Civello

Dr. Daniel Civello has twenty years of industry experience in the pharma and diagnostic space in a variety of roles -- software engineer, bioinformatician, statistical analyst, and most recently data scientist. He has gained valuable experience in numerous groups spanning discovery research, clinical development, and translational medicine and has supported many functions, such as validation and commercialization. His passion comes from building new tools and applying emerging technology to help solve challenging problems.

Mike Crager

Dr. Michael Crager received his Ph.D. in Statistics from Stanford University in 1982. He worked as a statistician in the pharmaceutical industry for 26 years with increasing management

responsibilities at companies including G.D. Searle, Syntex, Roche, and CV Therapeutics. Mike supported successful regulatory filings in the cardiovascular, antiviral, and endocrinology therapeutic areas. In 2008, he joined Genomic Health as a Biostatistics Fellow to perform research and development in statistical methodology relative to the company's work on prognostic and predictive tests for breast, colon and prostate cancer and other areas. He has published statistical methodology papers in the areas of analysis of covariance, false discovery rates, correction for regression to the mean and power calculation for discovery analyses, and survival analysis.

Kun He

Dr. Kun He is Chief Statistician of R&G US Inc (CRO), a subsidiary of R&G Pharma Studies which has 1,500 employees. He received a Ph.D. in Statistics from Cornell University in 1991. After serving on the faculties of the University of Minnesota and the University of Kansas, he joined FDA in 1999 and worked there until this past January, most recently serving as Associate Division Director of the Division of Biometrics V, supporting the Office of Hematology and Oncology Products. During the past decade, he provided authoritative statistical decisions for all NDA/BLAs and INDs submitted to the Division of Oncology Products 2, and accumulated extensive experience in regulatory, clinical, and statistical science.

Jennifer Listgarten

Since Jan. 2018, Dr. Jennifer Listgarten is a Professor in the Department of Electrical Engineering and Computer Science, and Center for Computational Biology, at the University of California, Berkeley. She is also a member of the steering committee for the Berkeley AI Research (BAIR) Lab, and a Chan Zuckerberg investigator. From 2007 to 2017 she was at Microsoft Research, through Cambridge, MA (2014-2017), Los Angeles (2008-2014), and Redmond, WA (2007-2008). She completed her Ph.D. in the machine learning group in the Department of Computer Science at the University of Toronto, located in her hometown. She has two undergraduate degrees, one in Physics and one in Computer Science, from Queen's University in Kingston, Ontario. Jennifer's research interests are broadly at the intersection of machine learning, applied statistics, molecular biology and science.

Yi Liu

Dr. Yi Liu is currently a Sr. Director in Data Science and Systems at Nektar Therapeutics responsible for several pivotal oncology clinical trials and CMC, nonclinical and biomarker related statistical support. Prior to that, she spent 8 years in Takeda Pharmaceuticals leading a team with methodological research responsibilities. She got her Ph.D. degree in Statistics from the

Department of Statistics at The Ohio State University. Her research interest includes multiple comparisons, adaptive designs, and issues with efficacy measures and estimands in time-to-event endpoint setting.

Joseph Paulson

Dr. Joseph Paulson is a Principal Statistical Scientist at Genentech working in early clinical trial development and personalized health care (PHC). His work ranges from the design of trials for bi-specifics and Personalized Cancer Vaccines to holistically integrating and analyzing data from variety of sources to inform understanding of hematological malignancies. Prior to joining Genentech he was at the Dana-Farber Cancer Institute and Harvard School of Public Health and received his PhD at the University of Maryland, College Park where he was an NSF Fellow.

Lindsay Renfro

Dr. Lindsay Renfro is an Associate Professor of Research in the Division of Biostatistics at University of Southern California. There, she serves as the Associate Group Statistician for Children's Oncology Group, the pediatric cooperative group member of the National Cancer Institute's National Clinical Trials Network and world's largest research organization dedicated exclusively to pediatric cancer. Her methodology research areas include biomarker-driven trials and other designs for personalized medicine, Bayesian adaptive design, evaluation of surrogate endpoints, and trial designs for rare diseases.

Maghna Samant

Dr. Meghna Samant is Senior Director, Quantitative Sciences at Flatiron Health, and oversees a group of data scientists in NY and SF working on real world observational studies and clinico-genomics data applications. Prior to joining Flatiron, Meghna spent 12 years in the oncology biostatistics group at Roche/Genentech spanning early, late and post-marketing phases of drug development. She has also held cross-functional leadership positions – including development team leader for one of the leading molecules in oncology. Meghna is a biostatistician by training and received her PhD in Biostatistics from UCLA.

Mei-Chiung Shih

Dr. Mei-Chiung Shih is Acting Director of the Department of Veterans Affairs (VA) Palo Alto Cooperative Studies Program Coordinating Center (CSPCC), and Adjunct Professor at the Department of Biomedical Data Science at Stanford University. Dr. Shih's methodological

research has focused in the areas of group sequential and adaptive designs for clinical trials, comparative effectiveness research, and longitudinal data analysis. She has developed efficient group sequential designs for randomized clinical trials and novel group sequential designs for phase II-III cancer trials, testing of biomarker-based personalized therapies, vaccine safety monitoring, and comparative effectiveness trials in health care systems. She has co-authored a book on sequential experimentation in clinical trials. Dr. Shih's collaborative research has focused in the area of clinical trials. As Acting Director at VA Palo Alto CSPCC, she is responsible for directing, facilitating, and coordinating scientific and operational activities and programs in the design, conduct, and analysis of CSP studies, the majority of which are large-scale multi-center randomized controlled clinical trials.

Richard Simon

Dr. Richard Simon retired from the National Cancer Institute as Director of the Biometric Research Program and Chief of the Computational and Systems Biology Branch and has a private consultancy business (R Simon Consulting). He holds a doctorate in Applied Mathematics & Computer Science from Washington University in St. Louis. He has authored and co-authored over 550 research papers and three books on genomic data analysis and biomarker driven clinical trial design. He is the architect of the widely used BRB-ArrayTools and BRB SeqTools software packages. He is an elected Fellow of the American Statistical Association and a past member of the Oncologic Drug Advisory Committee of the U.S. Food & Drug Administration. He is the recipient of the 2013 Karl Peace award "for contributions that have played a pivotal role in bridging the gap among statistics, clinical research, and translational medicine to improve human health". He is also the recipient of the 2017 Marvin Zelen award for leadership in Statistical Science from the Department of Biostatistics at Harvard University.

Marina Sirota

Dr. Marina Sirota is currently an Assistant Professor at the Bakar Computational Health Sciences Institute at UCSF. Prior to that she has worked as a Senior Research Scientist at Pfizer where she focused on developing Precision Medicine strategies in drug discovery. She completed her PhD in Biomedical Informatics at Stanford University. Dr. Sirota's research experience in translational bioinformatics spans over 10 years during which she has co-authored over 60 scientific publications. Her research interests lie in developing computational integrative methods and applying these approaches in the context of disease diagnostics and therapeutics with a special focus on studying the role of the immune system in disease. The Sirota laboratory is funded by NIA, NLM, NIAMS, Pfizer, March of Dimes and the Burroughs Wellcome Fund. As a young leader

in the field, she has been awarded the AMIA Young Investigator Award in 2017.

Peter Slasor

Dr. Peter Slasor is Senior Director of Biostatistics at BioMarin Pharmaceutical and has 20+ years of experience in clinical trials. Therapeutic disease areas span large populations to ultra-rare populations and includes experience in registries for health resource utilization and natural history databases for comparison to single arm registration trials. Peter received his ScD in Biostatistics at the Harvard School of Public Health.

Shirley Wu

Dr. Shirley Wu leads Health Product at 23andMe and is dedicated to empowering consumers to access, understand, and benefit from the human genome. Her team focuses on developing and delivering genetic insights so people can live healthier lives, by pioneering the only FDA-authorized direct-to-consumer genetic health service and leveraging big data and 23andMe's incredible research platform. She holds an Sc.B. in Computational Biology from Brown University and a PhD in Biomedical Informatics from Stanford University.

Jiawen Zhu

Dr. Jiawen Zhu joined Genentech/Roche in 2015 and is currently a Principal Statistical Scientist in Biostatistics, Product Development. Jiawen has rich experience in research and early development oncology programs and serves as the project lead statistician. She has been a key contributor to numerous strategic, scientific and operational topics ranging from clinical development plan, fast-to-market strategies, incorporation of synthetic controls, novel clinical trial designs and so on. Besides the clinical work, Jiawen has been focusing on statistical methodology of Bayesian adaptive designs including phase I dose escalation designs and designs incorporating external control in both single arm and RCT setting. She has been viewed as a technically excellent strategic partner who is able to identify fit-for-purpose statistical methods and apply them in practice. Jiawen holds a Ph.D. in Statistics from State University of New York at Stony Brook and B.S. in Mathematics from Xiamen University, China.

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BBSW 2020

Looking For Nomination

- Two open *President-Elect* positions in
  - Board of Directors
  - Officers
- Election will be conducted 2019 Nov/Dec
  - *President-Elect* will become official in the following January
  - All the conference attendees are eligible to nominate candidates for the election
  - Nominate up to 3 candidates
  - You are also welcome to nominate yourself
  - Send your nomination to BBSW2019@gmail.com **by Nov30 2019**
- Nominated candidates will be vetted through by the Board of Directors and then be contacted for further information and confirmation of interests
- Board Directors, Officers, and Advisory Board will vote and the candidate with highest votes will become *President-Elect*
- In case of ties, the President will have the 'tie-breaker' vote

Looking For Volunteers

If you are interested in volunteering for BBSW 2020, please contact BBSW2019@gmail.com

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