12th Annual Conference on Statistical Issues in Clinical Trials
April 17, 2019
Arthur H. Rubenstein Auditorium
Smilow Center for Translational Research (SCTR)

Speaker & Panelist Bios

Bill Capra, PhD is Senior Group Director of Real World Data, Oncology for Genentech/Roche. Bill leads a group of over 30 Data Scientists located in Basel, Switzerland, Welwyn, England, and South San Francisco, USA. Bill joined Genentech 13 years in the Biostatistics function after a decade at Chiron. His focus in both Biostatistics groups was in the design and analyses of clinical trials, with a focus primarily on the oncology and infectious diseases therapeutic areas. In 2014 he joined Roche's newly formed Data Science function when it was launched to build a group to find innovative uses for real world data in drug development. Bill has a B.S in Mathematics from Drexel University and a Ph.D. in Statistics from the University of California, Davis.

Jinbo Chen, PhD is a Professor of Biostatistics in the Department of Biostatistics, Epidemiology and Informatics at the University of Pennsylvania Perelman School of Medicine. She received her Ph.D. in Biostatistics from the Department of Biostatistics at the University of Washington in 2002, and was a research fellow in the Biostatistics Branch, Division of Cancer Epidemiology and Genetics at the NCI for three years before joining Penn Biostatistics faculty in 2006. Her methodological research interests include efficient design and analysis methods for biomedical studies that involve complex outcome dependent sampling, risk model development and evaluation towards precision medicine, and statistical methods for genetic epidemiology. Her recent efforts have focused on addressing study design issues and analytical challenges arising from electronic health record (EHR) data. Her research group developed bias-correction methods for addressing inaccuracy in subject identification and cost-effective methods for EHR phenotyping. Dr. Chen's method research has been largely application driven, motivated by her collaborative research on breast cancer risk prediction, breast imaging biomarker evaluation, maternal and child health, and cardiovascular health studies using Penn Medicine and Veteran Affairs EHRs.

Susan S. Ellenberg, PhD is a Professor of Biostatistics in the Department of Biostatistics, Epidemiology and Informatics at the University of Pennsylvania Perelman School of Medicine. Her interests have focused on issues in the design and analysis of clinical trials, and on assessment of medical product safety. Particular areas of interest include efficient trial designs, interim monitoring and the operation of data monitoring committees, evaluation of surrogate endpoints, ethical issues in clinical research, and special issues in trials of cancer and AIDS therapies, and of vaccines. She is an associate editor of Clinical Trials and of the Journal of the National Cancer Institute. Dr. Ellenberg is a fellow of the American Statistical Association, the American Association for the Advancement of Science and the Society for Clinical Trials, and an elected member of the International Statistical Institute. She has served as president of the

Society for Clinical Trials and the Eastern North American Region of the International Biometric Society, and has chaired the Statistics Section of the AAAS and the Board of Trustees for the National Institute of Statistical Sciences. Her book on clinical trials data monitoring committees, co-authored with Drs. Thomas Fleming (University of Washington) and David DeMets (University of Wisconsin), was named Wiley Europe Statistics Book of the Year for 2002.;the second edition has just been released. She is the recipient of the 2018 Janet Norwood award for outstanding achievement by a woman in the statistical sciences and the 2019 FN David award granted every other year to a female statistician who serves as a role model to other women by her contributions to the profession through excellence in research, leadership of multidisciplinary collaborative groups, statistics education, or service to the professional societies.

Denise Esserman, PhD is an Associate Professor of Biostatistics at the Yale School of Public Health. She is an applied statistician with a focus on the design and analysis of pragmatic clinical trials. She has two main methodological areas of interest. The first pertains to methods related to cluster randomized trials with time-to-event outcomes and semi-competing risks, including the estimation of the design effect and its impact on decisions concerning monitoring and extending trials. Her second area of interest focuses on methods for incorporating and measuring the impact of patient preference in clinical trials. She has previously extended the two-stage clinical trial design for estimating patient treatment, selection, and preference effects to binary and count outcomes and to include stratification. She is currently working on incorporating propensity scores into the partially randomized preference design Dr. Esserman enjoys working on problems that have a direct impact on the conduct of clinical trials and will have a meaningful impact on patients' lives.

Benjamin A. Goldstein, PhD is Associate Professor of Biostatistics and Bioinformatics at Duke University. He is a member of the Duke Clinical Research Institute and serves as the Data Science Lead for the Children's Health Discovery Initiative. Dr. Goldstein's research focuses on the meaningful use of Electronic Health Records Data. His work sits at the intersection of Biostatistics, Biomedical Informatics, Machine Learning and Epidemiology. He works closely with the Duke University Health System developing, implementing and evaluating risk prediction and clinical decision support tools. He also studies how patients' informative visit process can impact inference in EHR based studies – something he has termed Informed Presence. Dr. Goldstein received his PhD in Biostatistics and MPH in Biostatistics and Epidemiology from UC Berkeley.

Patrick J. Heagerty, PhD is Professor and Chair of the Department of Biostatistics at the University of Washington, and Gilbert S. Omenn Endowed Chair in Biostatistics. He received a PhD from the Johns Hopkins University, and a BS from Cornell University. He has extensive experience as an educator, independent and collaborative scientist, and administrator. Dr. Heagerty has developed fundamental methods for longitudinal studies with a focus on prognostic model evaluation and structural longitudinal models, and he has detailed methods for the design, analysis, and interpretation of cluster-randomized trials conducted within health care delivery systems. Dr. Heagerty has co-authored two leading texts (Analysis of Longitudinal Data, Oxford 2002; Biostatistics: A Methodology for the Health Sciences, Wiley 2004). Dr. Heagerty is an elected Fellow of the American Statistical Association, and has twice been honored by professional societies for specific research contributions (in 2000 as the Snedecor

Award winner; and in 2005 by the International Biometrics Society for the best paper published in the society's flagship journal, Biometrics). Dr. Heagerty directs the Center for Biomedical Statistics (CBS), a core partially funded by the NIH Clinical and Translational Science Award (CTSA) with responsibility for coordination of biostatistical collaboration in Seattle and the greater Northwest region (Wyoming, Alaska, Idaho, Montana). The CBS houses the data coordinating centers for several U01 and R01 funded projects including GARNET (Genomics and Randomized Trials), BOLD (Backpain Outcomes using Longitudinal Data), UH3 funded pragmatic trials including LIRE (Lumbar Imaging Reporting with Epidemiology), and PCORI funded trials. The CBS has previously conducted high-impact multi-site randomized trials including INVEST (Investigational Vertebroplasty Safety and Efficacy Trial, NEJM 2009), the Carpal Tunnel Surgical Trial (Lancet 2009), and LESS (Lumbar Epidural Steroid Injections for Spinal Stenosis, NEJM 2014). Dr. Heagerty is also a licensed teacher (NY State: Mathematics, Biology, and Chemistry) and has taught from middle school to graduate school (UW SPH Outstanding Teacher Award, 2009).

Rebecca A. Hubbard, PhD is an Associate Professor of Biostatistics in the Department of Biostatistics, Epidemiology and Informatics at the University of Pennsylvania. Her research focuses on development and application of statistical methodology for studies using data from electronic health records (EHR). This work encompasses evaluation of screening and diagnostic tests, methods for comparative-effectiveness studies, and health services research. Dr. Hubbard's methodological research emphasizes development of statistical tools to support valid inference for EHR-based analyses with a focus on methods to account for complex missing data and data quality issues. She has contributed statistical leadership to analyses of data from a variety of real world data sources including Medicare and private payer claims databases, multi-site EHR-based networks, and data from integrated healthcare systems.

Mark Levenson, PhD is currently the Director of the Division of Biometrics 7 in the Office of Biostatistics/Office of Translational Sciences/Center for Drug Evaluation and Research of FDA. At FDA, he has been the primary reviewer or secondary reviewer on many major pre-market and post-market drug safety problems. He contributes to statistical policy and guidance development in the areas of drug safety and real-world evidence. He is a member of the Drug Safety Oversight Board. He is active in CDER's efforts in the Sentinel Initiative including methods development and surveillance studies. He is a member of the CDER working group on developing a framework for the regulatory use of real-world evidence. He has contributed to the methodology of the application of meta-analysis and propensity score analysis to the regulatory setting. Dr. Levenson received a Ph.D. in Statistics from the University of Chicago and B.A. from Cornell University in Mathematics. Prior to coming to FDA, Dr. Levenson was a member of the Statistical Engineering Division of the National Institute of Standards and Technology and a member of the Division of Hazard Analysis of the Consumer Product Safety Commission.

Kristin A. Linn, PhD is an Assistant Professor of Biostatistics at the University of Pennsylvania. Prior to joining the faculty, Kristin was a post-doctoral researcher at Penn working on statistical imaging. She earned her Ph.D. in Statistics from North Carolina State University in 2014 and her Bachelor's degree from the University of Michigan in 2008. Dr. Linn's research program spans two broad areas: statistical methods for high-dimensional medical imaging data and sequentially randomized clinical trials. As a co-investigator, she provides biostatistical

leadership on projects in psychiatry, dermatology and behavioral health economics. She works to develop statistical methods that improve understanding of the neurobiological mechanisms of psychiatric illnesses. She is actively working on statistical frameworks for harmonizing imaging data from multi-site studies and estimating spatially varying patterns of multimodal image associations. She is also interested in adapting methods from causal inference to address confounding in imaging pattern analyses. Dr. Linn has experience designing sequential multiple assignment randomized trials (SMARTs) in a number of research areas. She is particularly interested in using data from SMART designs to estimate individualized dynamic interventions that improve long-term patient outcomes.

Richard Platt, MD, MSc is Professor and Chair of the Harvard Medical School Department of Population Medicine at the Harvard Pilgrim Health Care Institute. He is principal investigator of the FDA's Sentinel System that studies of the safety and effectiveness of marketed medical products. Dr. Platt is also co-principal investigator of the coordinating center of PCORI's Patient Centered Outcomes Research Network, leads the NIH Health Care Systems Research Collaboratory's Distributed Research Network, and is co-principal investigator of a CDC Prevention Epicenter. He is a member of the Association of American Medical Colleges' Advisory Panel on Research. He is a former chair of the FDA's Drug Safety and Risk Management Advisory Committee, and co-chair of the Board of Scientific Counselors of the CDC's Center for Infectious Diseases.

Matthew T. Roe, MD, MHS received his MD and MHS (Masters of Health Sciences in Clinical Research) degrees from Duke University School of Medicine in 1993 and 2001, respectively. Dr. Roe completed an Internal Medicine residency at Duke University Medical Center in 1996 and a Cardiovascular Fellowship at the Cleveland Clinic Foundation in 1999. Dr. Roe has been a faculty member at Duke University School of Medicine and the Duke Clinical Research Institute (DCRI) since 1999. Dr. Roe is a senior investigator at the DCRI focusing upon innovative research initiatives that leverage real world data, patient engagement, and novel research networks to transform the processes and approaches for clinical research. Dr. Roe has been the principal investigator for numerous phase II-IV cardiovascular clinical trials and is currently a co-principal investigator for the ADAPTABLE trial (theaspirinstudy.org) which is the first, large-scale pragmatic trial being conducted in the PCORnet network. Additionally, Dr. Roe has also served in leadership roles for several observational registries focusing upon the treatment and outcomes of patients with cardiovascular disease and has served as the Director of the DCRI Clinical Research Fellowship since 2010.

Pamela Ann Shaw, PhD joined the faculty at the University of Pennsylvania after seven years at the National Institute of Allergy and Infectious Diseases. Her statistical research interests include methodology to address covariate and outcome measurement error, the evaluation of diagnostic tests, and design of medical studies. Her current statistical research is focused on methods that adjust analyses for complex measurement error structures that can occur in electronic health records data, such as correlated errors in failure time outcomes and exposures. She also has a particular interest in the use biomarker studies to calibrate exposure measurements in the fields of nutritional and physical activity epidemiology and environmental health. More recently she has developed a novel rank test to evaluate a composite survival outcome in the presence of interval censoring. She has continued collaborations in a variety of epidemiologic and clinical studies, with a focus on infectious and chronic disease. Dr. Shaw

received her BA (French and Mathematics) Grinnell College in 1990, and her MS (Mathematics) in 1994 and her PhD (Biostatistics) from the University of Washington in 2006. She is co-author Essentials of Probability Theory for Statisticians. CRC Press Mar 2016.

Susan Shortreed, PhD conducts research that brings together statistics and machine learning methods to address health science problems, with a special emphasis on analyzing complex longitudinal data and overcoming missing-data challenges. Much of her methodological work is focused on developing and evaluating statistical inference approaches for observational data, such as data from electronic health care records or from randomized clinical trials with missing information. Dr. Shortreed is also interested in developing new machine learning methods and extending current best-practice methods, specifically for personalized dynamic treatment strategies, clustering, and model selection methods. Dr. Shortreed earned her PhD in statistics from the University of Washington in 2006. After completing her degree, she spent two years in the Department of Epidemiology and Preventive Medicine at Monash University in Melbourne, Australia, and two years in the School of Computer Science at McGill University. Dr. Shortreed has collaborated with scientists in a broad range of areas including cancer screening, cardiovascular disease, and medication and vaccine safety. Currently, she works most often with researchers in mental and behavioral health, evaluating and comparing treatments for chronic pain, depression, and bipolar disorder, and interventions to prevent alcohol misuse, smoking, and suicide. Dr. Shortreed is an investigator with the Mental Health Research Network, designing studies to address important public health concerns, such as determining which antidepressant medications work best for which patients. In addition to her work at Kaiser Permanente Washington Health Research Institute, Dr. Shortreed is an affiliate associate professor at the University of Washington Biostatistics Department. She serves on the executive board for the American Statistical Association's Section on Statistics in Epidemiology and the editorial board of the Journal of the Royal Statistical Society, Series C: Applied Statistics.

Steven B. Zeliadt PhD is a Research Associate Professor, Department of Health Services at the University of Washington. His interests are Decision-making and quality of life in prostate cancer treatment; cancer screening; costs of health care interventions; evaluation of informed decision making strategies; comparative effectiveness using large databases; quality of life assessment among cancer survivors; decision modeling; and assessment of health care costs. Dr. Zeliadt received his BA from Grinnel College in 1994, his MPH from the University of Washington in 2000 (Health Services) and his PhD from the University of Washington in 2004 (Health Services).