BBSW2021 PROGRAM BOOK

Nov 3-5, Crowne Plaza Hotel, Foster City, CA 94404

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Making a Broader Impact with the Power of Data and an Entrepreneurial Mindset

Day 1: November 3, 2021 (Wednesday)

Time	Speaker	Topic
7:30-8:45	**Breakfast**	
8:45-9:00	**David Zhang** **(Esker)**	**Welcome and Opening Remarks**
9:00-10:00	**Robert O'Neill** **(Former FDA)**	**Keynote Speech: Regulatory Science, Statistics and Innovation: A Paradigm shift in Training and Education**
10:00-11:30	**Technical Session #1: Real World Evidence** **Organizers: Ron Yu, Whedy Wang, Brian Wiens, Lu Tian, Godwin Yung** **Co-organizer: ASA Biopharmaceutical Section** **Session Chair: Lu Tian**	
10:00-10:30	Antara Majumdar (GSK)	Effective utilization of an external control arm (ECA) in Oncology drug development
10:30-11:00	James Zou (Stanford)	Making clinical trials more efficient and inclusive with real-world data and AI
11:00-11:30	Yueqin Zhao (FDA)	Regulatory Considerations for Designing and Evaluating Studies Using Real-World Evidence
11:30-1:30	**Lunch/Business Meetings/Vendor Exhibits**	

1:30-3:00	**Entrepreneurial Session #1: Venturing Beyond Statistics Organizers: Julia Varshavsky, Shariq Alavi, Maja Miloslavsky Session Chair: Maja Miloslavsky**	
1:30-2:00	Hoa Nguyen (Roche)	Making A Career-Road-Less-Travelled Exciting and Rewarding
2:00-2:30	Devin Noblin (Jazz Pharmaceuticals)	Deal or No Deal: The role of biostatistics in biopharmaceutical business development and licensing
2:30-3:00	David Purdie (Global Blood Therapeutics)	The value of statistical training experience beyond the role of biostatistician
3:00-5:00	**Refreshments/Social Event/Vendor Exhibits**	

Day 2: November 4, 2021 (Thursday)

Time	Speaker	Topic
7:30-8:45	**Breakfast**	
9:00-10:00	Janet Wittes (WCG Clinical)	**Fireside Chat hosted by Glen Wright Colopy, host of the Data&Science ASA podcast: *Statisticians as Entrepreneurs***
10:00-11:30	**Technical Session #2: Innovation Inspired by COVID-19 Pandemic Organizers: Ron Yu, Whedy Wang, Brian Wiens, Lu Tian, Godwin Yung Session Chair: Brian Wiens**	
10:00-10:30	Robert O'Neill (Former FDA)	Reacting to Crises: The COVID-19 Impact on Biostatistics and Epidemiology
10:30-11:00	Ruixiao Lu (QLHC)	Design, Data, System & Regulatory: Learnings from a Phase II, Pragmatic Platform Trial I-SPY COVID

11:00-11:30	Ilya Lipkovich (Eli Lilly)	Implementation of ICH E9 (R1): Estimands, Intercurrent Events and Missing Data
11:30-1:30	**Lunch/Business Meetings/Vendor Exhibits**	
1:30-3:00	**Entrepreneurial Session #2: Corporate Product Strategy Organizers: Julia Varshavsky, Shariq Alavi, Maja Miloslavsky Session Chair: Julia Varshavsky**	
1:30-2:00	Merril Birkner (Gilead)	Applying Quantitative Approaches to Support Portfolio Productivity and Strategy
2:00-2:30	Tara Maddala (Delfi)	Innovative Development of Genomic Diagnostics
2:30-3:00	Larry Shen (WuXi Clinical)	From Statistical Leadership to Entrepreneurship
3:00-5:00	**Refreshments/Social Event/Vendor Exhibits**	

Day 3: November 5, 2021 (Friday)

Time	Speaker	Topic
7:30-8:45	**Breakfast**	
9:00-10:00	**Bob Harrington, MD (Stanford)**	**Keynote Speech: Cardiovascular Medicine as a Data Science**
10:00-11:30	**Technical Session #3: Innovative Trial Design and Methodology Organizers: Ron Yu, Whedy Wang, Brian Wiens, Lu Tian, Godwin Yung Session Chair: Godwin Yung**	

10:00-10:30	Larry Leon (BMS)	Overview of Competing-Risk Analysis Methods in Hospitalization Settings with Death as a Competing Risk
10:30-11:00	Michael Sklar (Stanford)	A Rigorous Framework for Simulation-Based Trial Design
11:00-11:30	Priyanka Agarwal, MD (BMS)	Digital Health & Biotech: Opportunities, Challenges, and the MyoKardia/BMS Experience
11:30-1:30	**Lunch/Business Meetings/Vendor Exhibits**	
1:30-3:00	**Entrepreneurial Session #3: Thriving in Gig Economy Organizers: Julia Varshavsky, Shariq Alavi, Maja Miloslavsky Session Chair: Shariq Alavi**	
1:30-2:00	Jitendra "Jeetu" Ganju (Ganju Clinical Trials)	Extreme Consulting
2:00-2:30	Yuan Ji (Univ of Chicago)	A Statistician's Journey in Building a Software Company
2:30-3:00	Peng Yang (ClinData Insights)	How to Acquire Business Skills without an Getting an MBA: My Self-Learning During 8 Years of Running a Consulting Business
3:00-3:15	**David Zhang (Esker)**	**Recognition and Concluding Remarks**
3:15	**Meeting Adjourns**	

Keynote Talks

ROBERT O'NEILL, PhD (Former FDA)

Regulatory Science, Statistics and Innovation: A Paradigm shift in Training and Education

Abstract: The motivation for this talk derives from a combination of issues, including my experience as a statistician in a regulatory agency, the skills and training beyond academic fields that are needed by statisticians and scientists/clinicians to be effective in modern drug development and regulation, the expectations for innovation in drug development, and addressing the perceived gaps that exist in the academic educational framework to meet current and future drug development needs. In particular, the focus in the talk will be on promoting exposure to and training of regulatory science into those modern academic curricula that prepare scientists to enter the pharmaceutical space. There are well known inefficiencies in drug development which hinder innovation, as well as impede the success of drug development programs and it is the goal of part of this talk to describe regulatory science and how its content can supplement the academic training of scientists in the field to improve development of safe and effective therapies.

Bio: Dr. Robert O'Neill retired from the Food and Drug Administration (FDA) in 2018. At the time of his retirement, he served as the Senior Statistical Advisor in the Office of Translational Sciences in the Center for Drug Evaluation and Research (CDER) FDA. From October of 1998 until June 2011, Dr. O'Neill was the Director of the Office of Biostatistics which provided biostatistical and scientific computational leadership and support to all CDER programs. Prior to October 1998 he was Director of the Office of Epidemiology and Biostatistics, responsible also for the post-market safety surveillance of new drugs.

Dr. O'Neill was the International Conference for Harmonization (ICH) FDA topics leader for two guidances, E9 and E5. He is a fellow of the American Statistical Association (1985) and the Society for Clinical Trials (2013). He received the Marvin Zelen Leadership Award from the Harvard School of Public Health in 2002, and the Reagan-Udall Foundation award in 2018 for Innovation in Regulatory Science.

JANET WITTES, PhD (WCG)

Statisticians as Entrepreneurs

Abstract: This is a story of a single entrepreneur who started a single company. As we statisticians know, inferences from a sample of size one are treacherous, but as those of us who work with physicians also know, sometimes a single story elucidates more general principles. In this discussion, we will address some principles that this single entrepreneur learned in her 30 year experience founding, building, and leading Statistics Collaborative. The founding started with a phone call from Jerry Sadoff, MD, the head of immunology at Walter Reed. "You are unemployed," he reminded me (as if I needed a reminder!), "how would you like to learn about malaria?" Not the way the self-help books say you should start a company. I had no plan, no finances, no staff, no office, no supplies – just curiosity about diseases I was unfamiliar with and a willingness to take risks. Thirty years later, we were a thriving boutique organization of 52, a veritable deck of cards – each of us a unique personage but all of us working together in teams that shifted from project to project like hands in a poker game. This chat will discuss the values I feel are most important if a statistician who shares my point of view is interested in starting a for-profit statistical company that will successfully compete in a crowded marketplace.

Bio: Dr. Janet Wittes is interested in how statisticians and the non-statistical world interact with each other. She is President of WCG Statistics Collaborative, which she founded in 1990. Previously, she was Biostatistician, Veterans Affairs Cooperative Studies Program (1989–90); Chief, Biostatistics Research Branch, National Heart, Lung, & Blood Institute (1983–89); and faculty member, Department of Mathematical Science, Hunter College of the City University of New York (1974 -1983). The monograph, "Statistical Monitoring of Clinical Trials – A Unified Approach" by Proschan, Lan, and Wittes, deals with sequential trials. Her research has focused on design of randomized clinical trials, capture-recapture methods in epidemiology, and sample size recalculation. She has served on a variety of advisory committees and data monitoring committees for government (NIH and FDA) and industry (big pharma and biotech). She is a Fellow of the American Statistical Association (ASA), the Society for Clinical Trials, the AAAS, and an elected member of the International Statistical Institute. From 1994-1998, she was Editor in Chief of Controlled Clinical Trials (1994-98). In 2006, she received the Janet L. Norwood Award for Outstanding Achievement by a Woman in the Statistical Sciences and in 2015 she received the W.J. Dixon Award for Excellence in Statistical Consulting, ASA (2015). She received her PhD in statistics from Harvard University in 1972.

Glen Wright Colopy, DPhil (Host of the Data & Science Podcast)

Bio: Glen has been a researcher in medical data science for the last 10 years. He began by working in pharmaceutical safety signal detection. In 2013, he joined the Oxford University hospital "ecosystem" and has focused on patient monitoring and precision medicine ever since. He specializes in techniques such as time-series analysis, anomaly detection, and optimization. Recently, he applied these same techniques to clinical supply chain optimization.

Glen's doctorate from Oxford University focused on probabilistic machine learning for patient monitoring and resulted in 2 patents, and over a dozen publications. He is an Associate Editor on the Journal of Data Science and sits on the executive committee of the ASA's Statistical Learning and Data Science Section and the IET's Healthcare Technology Professional Network.

In 2020, Glen launched the "Data & Science" podcast to increase the public discussion of critical scientific reasoning in statistics and data science.

ROBERT HARRINGTON, MD (STANFORD)

Cardiovascular Medicine as a Date Science

Abstract: Clinical medicine is typically considered a biological science but the increasing dependency on using data to gain insights for clinical practice and research means that clinicians need to have more experience and expertise in the data sciences. Cardiovascular medicine is an example of this. While this notion is not a new concept, the emerging importance of how to utilize enormous amounts of (often disparate) data, coupled with cloud computing that enables advanced computation, often at the point of care, creates an opportunity to innovate in clinical care delivery and to think differently about how to use these

data science tools in research and policy development as well. Thinking of cardiovascular medicine as a data science also means that clinicians need a new set of skills and tools to understand how to make decisions using large and complex data. We will review some of the history of data science in cardiovascular medicine, provide examples of the importance of data in contemporary clinical cardiovascular care and research. We will also discuss and provide examples of creative educational and training opportunities for the data-driven clinician.

Bio: Dr. Robert A. Harrington is a cardiologist and the Arthur L. Bloomfield Professor and Chairman of the Department of Medicine (DOM) at Stanford University. The DOM is the largest department at Stanford with 15 divisions and more than 650 faculty. He was previously the Richard Stack Distinguished Professor and the Director of the Duke Clinical Research Institute (DCRI) at Duke University. His research interests include evaluating antithrombotic therapies to treat acute ischemic heart disease, building local, national and international collaborations for the efficient conduct of innovative clinical research and trying to better understand and improve upon the methodology of clinical research, including the use of technologies to facilitate the conduct of clinical trials.

He has authored more than 720 peer-reviewed manuscripts, reviews, book chapters, and editorials. He is a senior editor of the 13th and 14th editions of Hurst's The Heart, one of the leading textbooks of cardiovascular medicine. He recently served a second term as a member and the chair of the US Food and Drug Administration Cardiovascular and Renal Drugs Advisory Committee.
Harrington is a member of the American Heart Association's (AHA's) Board of Directors. He served as AHA President-elect, President and Immediate Past President during 2019-2021. He is an elected member of the Association of American Physicians, the Association of University Cardiologists and the National Academy of Medicine/Institute of Medicine. In 2016, he was named a Master of the American College of Cardiology. He was awarded the AHA's Clinical Research Prize in 2017.

Harrington received his BA in English at the College of the Holy Cross, Worcester, MA and his MD from Tufts University School of Medicine, Boston MA. He did his internship, residency and served as the chief resident in internal medicine at the University of Massachusetts Medical Center. He trained in cardiology, interventional cardiology and clinical research (Duke Databank for Cardiovascular Disease) at Duke University Medical Center. Interested in innovative learning tools, Harrington can be followed on Twitter @HeartBobH and on a monthly podcast on theheart.org

BBSW2021 President-Elect

David Zhang, PhD, MBA (Esker Therapeutics)

Bio: David is currently Chief Information Officer and Senior VP at Esker Therapeutics, a precision immunology company. He has 25 years of industry experience in pharma and biotech product development. Prior to his current role, David was Vice President of Biometrics, Data Science and Digital Health at Bristol Myers Squibb, following the BMS acquisition of MyoKardia where he built the Biometrics, Digital Health and Data Science group from ground up and designed the phase 3 pivotal EXPLORER study with novel endpoints that led to successful NDA submission. Prior to MyoKardia, David spent 15 years at Roche/Genentech with increasing responsibilities leading and building Biostatistics and Strategic Innovation functions. David started his industry career at Eli Lilly and Abbott Laboratories. He received his Ph.D. in biostatistics with a minor in genetics from UCLA School of Public Health and completed post-doctoral research at Columbia University.

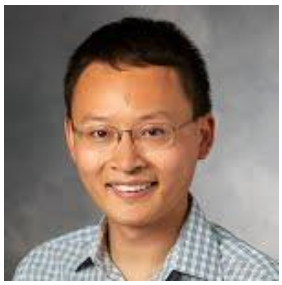
Invited Talks

Antara Majumdar, PhD (GSK)

Effective utilization of an external control arm (ECA) in Oncology drug development

Abstract: In clinical trials, a control arm built using patient-level data from previous clinical trials or real-world data (RWD) is known as an external control arm (ECA). ECAs can be valuable in accelerating Oncology drug development when the standard of care is reliably stable over time. ECA is a relatively novel concept in drug development, and like any other novel concept there are opportunities and challenges that need to be investigated and addressed. In this talk, we will present lessons learnt from building ECAs for quantitative decision making in Oncology drug development. We will share experience with selection of appropriate and adequate external data sources, methodological best practices for frequentist and Bayesian ECA approaches, and design considerations for augmented ECA trials.

Bio: Antara Majumdar is Director in Oncology Statistics at GSK. She leads external control arm implementation and data strategy for all phases of oncology drug development. She has wide ranging experience in the pharmaceutical industry, spanning clinical trials, translational medicine and drug discovery. Her interest is in innovative statistical approaches to drug development, including causal inference and Bayesian methods in clinical trials. She received her PhD in Biostatistics from the University at Buffalo.



James Zou, PhD (Stanford)

Making clinical trials more inclusive with real-world data and AI

Abstract: There is a growing focus on making clinical trials more inclusive but the design of trial eligibility criteria remains challenging. Here we systematically evaluate the effect of different eligibility criteria on cancer trial populations and outcomes with real-world data using the computational framework of Trial Pathfinder. We apply Trial Pathfinder to emulate completed trials of advanced non-small-cell lung cancer using data from a

nationwide database of electronic health records comprising 61,094 patients with advanced non-small-cell lung cancer. Our analyses reveal that many common criteria, including exclusions based on several laboratory values, had a minimal effect on the trial hazard ratios. When we used a data-driven approach to broaden restrictive criteria, the pool of eligible patients more than doubled on average and the hazard ratio of the overall survival decreased by an average of 0.05. This suggests that many patients who were not eligible under the original trial criteria could potentially benefit from the treatments. Our data-driven methodology for evaluating eligibility criteria can facilitate the design of more inclusive trials while maintaining safeguards for patient safety.

Bio: James Zou is an assistant professor of biomedical data science and, by courtesy, of CS and EE at Stanford University. James works on using machine learning to improve human health. He also studies how to make machine learning more reliable, fair, transparent and user friendly. He has received several best paper awards, the NSF CAREER Award, a Sloan Fellowship, Google and Amazon AI awards and is an inaugural Chan-Zuckerberg Investigator.

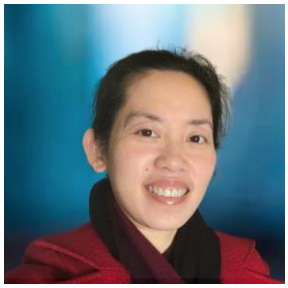
Yueqin Zhao, PhD (FDA)

Regulatory considerations for designing and evaluating studies using real-world evidence

Abstract: Real-world evidence (RWE) has long been used by regulatory agencies and pharmaceutical industries to monitor long-term safety and rare adverse events of marketed drug products. It is not until recently that stakeholders began embracing RWE as a key driver to support the approval of new drug indications. Within FDA, we have seen numerous applications trying to use RWE in various ways for drug development and research. The utilization of RWE continuously faces many design and implementation challenges.

In this talk, we will start with a brief review of the FDA's RWE framework. We will then present several promising study designs by which RWE could potentially support regulatory decision making. The designs include registry-based pragmatic trials, using external controls to supplement randomized clinical trials, and observational studies. After that, we will then illustrate key aspects that investigators could consider when designing or evaluating such studies. The considerations include but not limited to, data source selection, bias control and minimization, and data transparency and reproducibility.

Bio: Yueqin Zhao is the lead mathematical statistician in the Office of Biostatistics in CDER. In this position, she leads the biostatistics team that support the safety evaluation of medical products from various therapeutical areas. Her research work has a focus on safety signal detection, benefit risk assessment, causal inference and real-world evidence.



Hoa Nguyen (Roche)

Making a Career-Road-Less-Traveled Exciting and Rewarding

Abstract: My career coach once told me that CEOs as well as leadership can come and thrive from any background. I asked him, if he told our CEO at the time that one of the people in the product development statistics organization wanted to be a CEO, what a potential response/reaction would be. My coach instantly said 'He would want to talk to you'. In my 16+ years in the pharmaceutical industry, I have been given leadership opportunities in 3 large organizations spanning a very dynamic knowledge range and

skill sets from development to commercialization. I will share with you how these opportunities landed on me and how I seized each opportunity with equal excitement and commitment to learn and serve patients worldwide. Each new assignment poses its unique challenges as well as rewards. To stretch myself further, I recently founded a company that manufactures and commercializes keto desserts to support folks on the journey to healthier living by cutting out sugar and suboptimal carbs from their diet. What I have learned through this one year recent journey is that I still use statistical methodology to conduct market research to support my product development choices and commercialization decisions.

Bio: Dr. Hoa Nguyen has spent 16+ years in the pharmaceutical industry spanning 3 key organizations: Product Development, Pipeline and Portfolio Management, and Global Access & Commercialization. Her passion to bring effective drugs to patients worldwide is the key motivation for her strong commitment for her work every day. While she continues to be part of the Genentech's relentless search for innovative medicines to serve patients, Dr. Nguyen recently founded a company that manufactures and commercializes keto desserts to support folks on the journey to healthier living by cutting out sugar and suboptimal carbs from their diet.

Devin Noblin, PhD (Jazz Pharmaceuticals)

Deal or No Deal: The role of biostatistics in biopharmaceutical business development and licensing

Abstract: The biopharmaceutical industry is a major source of global business development activity, representing >$700B in deals across partnerships, licensing, investments, mergers, and acquisitions in 2020. Such large investments require rigorous diligence, and biostatisticians play an important role in evaluating potential deal opportunities. Biostatisticians can help a deal team understand the historical performance of a molecule, and anticipate regulatory agency feedback, through the evaluation of clinical trial data. Biostatisticians can also help a deal team anticipate future development costs through input on a development plan. These inputs help influence the deal thesis and Net Present Value (NPV) assumptions through an impact on anticipated costs, timelines, product profile, and probability of success.

Bio: Devin Noblin currently leads Search and Evaluation at Jazz Pharmaceuticals. The Search and Evaluation group is responsible for identifying and evaluating new business development and licensing opportunities for Jazz, particularly in the areas of oncology and neuroscience. During his tenure, Jazz has completed >10 deals, including the recent acquisition of GW Pharmaceuticals for >$7B. Prior to Jazz, Devin led market analysis and strategy work at Genentech, with a focus on oncology and neuroscience. Devin developed commercial strategies, evaluated research and development plans, and helped set key performance metrics for the marketing and sales team. Prior to Genentech, Devin worked at L.E.K. Consulting, with a focus on biopharmaceutical strategy projects. In this role, Devin led numerous consulting engagements related to therapeutic area strategies and opportunity assessments. Devin received his PhD in Molecular and Cell Biology from Yale University and his undergraduate degree from the University of California, Berkeley.

David Purdie, PhD (Global Blood Therapeutics)

The value of statistical training beyond the role of biostatistician

Abstract: Statistical training and quantitative skills are a valuable tool that can be used successfully in roles across the pharmaceutical, biotechnology and digital health industries. In this presentation, I will describe the different kinds of roles I have had in my many years in the industry, and how statistical training and thinking has helped me succeed in these roles. These roles range from product development, commercial strategy, medical affairs and digital health (eg software applications and wearable devices). Quantitative skills allow us to analyze a problem at a deeper level than many of our non-statistical colleagues, and to interpret data in a more rigorous way to quickly identify bias and prevent poor interpretation. I will provide examples of situations where a was able to utilize my statistical training in non-statistical settings to help leaders make better decisions.

Bio: David Purdie, Ph.D., M.Med.Sc, B.Sc. is the Executive Director of Medical Evidence at Global Blood Therapeutics (GBT), where he is responsible for the post-marketing research of approved treatments for Sickle Cell Disease.

Prior to joining GBT, David was the Vice President of Medical Affairs and Clinical Development at Proteus Digital Health, where he led the clinical development, evidence generation, and evidence communication/education for Proteus' work in digital medicines.

Previously, David held multiple roles at Genentech, including the Head of Patient Access and Quality of Care at Genentech, US Medical Affairs, the group responsible for communicating clinical and health economic information to payers and organizations that influence patients' access to therapies.

Other roles at Genentech included Director of Oncology Training and Director of Marketing Science. David was also a Senior Statistician in the Biostatistics Department at Genentech where he designed and performed statistical analyses for clinical oncology programs, and negotiated with the FDA on Biological Licensing Agreements.

Before his time at Genentech, David's positions include Principal Biostatistician at the Northern California Cancer Center, Lecturer in Statistics at Stanford University, Associate Professor of Medical Statistics in the School of Population Health at the University of Queensland and Director of Biostatistics at the Queensland Institute of Medical Research, Australia.

Dr. Purdie has a Bachelor's degree in Statistics, a Masters in Medical Science and a PhD in Epidemiology and Biostatistics from the University of Queensland in Brisbane, Australia.

Ruixiao Lu, PhD (QLHC)

Design, Data, System & Regulatory: Learnings from a Phase II, Pragmatic Platform Trial I-SPY COVID

Abstract: The COVID-19 has brought tremendous uncertainty on many fronts. Our understanding of the virus has evolved with the new variants and emerging hot spots. During this time, innovations in clinical trials have spurred and made huge impacts on improving patient care with COVID. In the meantime, there remained an unmet need for a phase 2 mechanism for rapid screening and triaging potential treatments for patients with severe COVID-19 in a systematic and expedient fashion.

In this talk, we will share some learnings from a phase II, open label, multi-center, adaptive platform trial, I-SPY COVID. Leveraging the pre-existing collaboration with the I-SPY consortium and infrastructure, the trial is designed to rapidly evaluate and prioritize promising agents for further confirmatory testing. We will discuss the use of master protocol, the setup of advanced study design, collaborations across a wide variety of stakeholders to drive innovations and executions, streamlining and automating data collection from EMR to ease burden of data entry and verification in the ICU, and timely engagement and feedback from Regulatory Agencies.

We hope that this novel framework and the lessons learned will have important implications for treatment of patients with severe COVID-19, and for future trials in critically ill patients beyond the COVID pandemic.

Bio: Ruixiao Lu is currently Vice President, Head of Statistics, Clinical Data Management & Data Science at Quantum Leap Healthcare, the sponsor of the large-scale clinical trials using master protocols such as I-SPY for Breast Cancer and COVID. Previously, she was Director, Clinical Biostatistics, at Exact Sciences/Genomic Health, an industry leader in personalized cancer diagnostics, leading the biostats and statistical programming function.

Ruixiao has been dedicated to building statistical & data science communities and promoting the profession through various non-profit organizations, including DahShu & BBSW. She is also currently the Treasurer and Board Member of the American Statistical Association (ASA).

Ilya Lipkovich, PhD (Eli Lilly)

Implementation of ICH E9 (R1): Estimands, intercurrent events and missing data

Abstract: In this presentation we revisit recent ICH E9 (R1) Addendum on Estimands and Sensitivity Analysis in Clinical Trials. We discuss various strategies for handling intercurrent events (ICEs) using the causal inference framework and suggest improvements in applying the ICH E9 (R1) addendum in practice. We emphasize the need for a mix of strategies in handling different types of ICEs, rather than taking a one-strategy-fit-all approach. Specifically, ICEs may be classified into categories related to adverse events, lack of efficacy, or other reasons not related to study efficacy or safety. We suggest that hypothetical strategies should be used more broadly and provide examples of different hypothetical strategies for different types of ICEs. A road map for handling intercurrent events in defining estimands, handling missing values in estimation and sensitivity analyses is provided. We conclude that the proposed framework helps automate translating clinical objectives into estimands and choose appropriate estimation procedure(s) even in non-standard ICE's such as caused by pandemic.

Bio: Ilya Lipkovich is a Sr. Research Advisor at Eli Lilly and Company. Ilya received his PhD in Statistics from Virginia Tech in 2002 and has more than 15 years of statistical consulting experience in pharmaceutical industry. He is an ASA Fellow and published on subgroup identification in clinical data, analysis with missing data, and causal inference. He is a frequent presenter at conferences, a co-developer of subgroup identification methods, and a co-author of the books "Analyzing Longitudinal Clinical Trial Data. A Practical Guide" and "Estimands, Estimators and Sensitivity Analysis in Clinical Trials."

Merrill Birkner, PhD MPH (Gilead)

Applying Quantitative Approaches to Support Portfolio Productivity and Strategy

Abstract: Portfolio strategy and analytical approaches to assess the assets and portfolio within a company are key to optimizing near, mid-, and long-term success. This presentation will focus on the application of qualitative and quantitative approaches to support portfolio productivity and strategy. These approaches can range from portfolio-level analyses, valuations, insights, information, and tools necessary for the achievement of corporate goals, pipeline planning, and decision-making. The overarching goal of these efforts is to increase R&D efficiency across a company. General case studies will be presented on how these methods are applied in both small and larger company settings.

Bio: Merrill Birkner is the Vice President of Portfolio Strategy and Analytics at Gilead Sciences. She is responsible for supporting portfolio productivity and strategy through portfolio-level analyses, insights, tools, and recommendations for the achievement of corporate goals, pipeline planning, and decision-making. Prior to Gilead, Merrill led the Portfolio Management, Operations, and Alliance Management functions at 23andMe, where she was responsible for portfolio & program management, alliance management, commercial assessments, and the operations of the 150+ employee Therapeutics organization. Prior to 23andMe, Merrill spent over a decade at Genentech where she had roles across the development and commercial organizations. Merrill began her career as a biostatistician in Genentech's Product Development organization. She expanded her business expertise with leadership roles in the company's commercial organization, portfolio planning, and business operations.

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

Tara Maddala, PhD (Delfi)

Innovative Development of Genomic Diagnostics

Abstract: Genomic diagnostics are a unique space in which statisticians/data scientists can take a lead role in product development. This talk will walk through the clinical development of two genomic products in the cancer prognosis and early cancer detection spaces. In these case studies, the product itself is the information given to patients and physicians based on the assay and algorithm developed with key input from statisticians. Accurate and actionable information can only be achieved with leadership from statisticians who think about bias and generalizability, can quantify uncertainty, navigate the complexities of genomic data discovery, and meaningfully interpret results.

Bio: Tara Maddala is Vice President of Clinical Development at Delfi Diagnostics. Tara has a proven track record of developing genomic diagnostic products from feasibility through commercialization. At Delfi, she leads a team of Statistical Scientists and Clinical Data Management and Operations individuals responsible for design, execution, and publication of Delfi's clinical trials. As a Vice President at GRAIL, she led a team of Clinical Data Scientists and Biosample Managers responsible for designing and analyzing foundational, large-scale genomic studies, sample collection, and biobanking. At Genomic Health, Tara was a co-inventor of the Oncotype DX® Genomic Prostate Score test, employing statistical machine learning for algorithm development. Tara co-invented several issued cancer genomic patents and co-authored approximately 20 peer-reviewed publications and over 40 congress presentations.

She enjoys volunteering with Women in Bio and coaching high-school tennis. Tara holds a PhD in Biostatistics from The University of Texas and Engineering BS and MS degrees from The University of Florida and Georgia Tech.

Larry Shen, PhD (WuXi Clinical)

From Statistical Leadership to Entrepreneurship

Abstract: Statisticians play many important roles in the development of human medicines. Strong statistical leadership will enable statisticians to maximize their influence and potential in drug development process. In my talk I will share my experience on how I have applied the principle of ownership and used it to transform myself from a passive and silent project statistician into a vocal statistical leader and eventually built a company. I want to demonstrate that statistical leadership is a learned skill, and it can help inject fun and fulfillment into our professional lives.

Bio: Dr. Shen was co-founder, President & CEO of Pharmapace, Inc., a biometrics consulting and CRO coßmpany to the biopharma industry, which was acquired by WuXi AppTec in 2019. He continues to serve as a senior statistical advisor to numerous biopharma companies to support their drug development programs.

Dr. Shen is a fellow of the American Statistical Association (ASA). He has authored many articles on statistical methodology and their applications to drug development.

Prior to founding Pharmapace, Dr. Shen was Vice President at Amylin Pharmaceuticals, in charge of their clinical development organizations including biometrics, Pharmacometrics, and Medical Writing.

Dr. Shen obtained his Ph.D. in Statistics from the University of California at Berkeley and both BS and MS degrees in mathematics/probability theory from Beijing University in China.

Larry Leon, PhD (BMS)

Overview of Competing-Risk Analysis Methods in Hospitalization Settings with Death as a Competing Risk

Abstract: In this talk we provide an overview of a recent adaptive platform trial, COMMUNITY, for evaluating Covid-19 treatments in the hospitalization setting. Platform trials have the potential to achieve efficiency gains by enabling therapies to be added or dropped throughout the study, with comparisons against a shared control. Group-sequential (GS) designs are commonly used to guide early decision-making (efficacy/futility boundaries). For the hospitalization setting the primary outcome is generally time-to-recovery (alive and discharged) within 29 days of hospitalization. We discuss analysis approaches and group-sequential design development. For the primary endpoint of time-to-recovery, an important aspect is how to incorporate early deaths. We discuss the seemingly controversial approach of competing risk analyses based on the Fine-Gray model with death as a competing risk, and present operating characteristics for a GS design (OBF) with futility analyses. Operating characteristics are evaluated in simulations with flexibility to generate outcomes under competing risk scenarios where treatment may be beneficial for the primary outcome (recovery) but negatively impact the competing risk outcome (death).

Bio: Larry Leon is a Biostatistician with 15 years of experience in the design and analysis of clinical trials across virology, oncology, and neuroscience. He specializes in survival analysis methodology and applications to non-randomized comparisons.

Michael Sklar, PhD (Stanford)

A Rigorous Framework for Simulation-Based Trial Design

Abstract: We show how to give rigorous Type I Error proofs for clinical trial designs using simulation. In principle, this can be done for designs with highly adaptive sampling, censored survival data, or complex null hypothesis spaces. The methods can also support mid-course re-design of complex trials, including unplanned addition or deletion of treatment arms. We require a well-specified exponential family model for observations (or, asymptotically, test statistics with a Brownian limit), a design with prespecified rules for sampling and hypothesis rejection, a compact region of interest in the null hypothesis space, and (lots of) simulations over a grid of parameter values within that region. Computational scale is a limiting factor, especially for hard-to-simulate trials or models with many parameters. We also propose a technique for tuning rejection thresholds to guarantee satisfaction of a fixed Type I Error upper bound. In this talk we will discuss the key ideas: large-scale Monte Carlo simulation, Taylor expansions, and some mathematical bounding arguments. We will also discuss possibilities for software implementation, aiming to shorten regulatory negotiations and reduce risk for new trial design techniques.

Bio: Michael Sklar is a Stein Fellow and recent doctoral graduate from Stanford's Department of Statistics. His research interests are in adaptive clinical trial design, multiple hypothesis testing, and optimization. His current project is a computational approach to complex clinical trial design, aiming to comprehensively and accurately bound Type I Error, with broader goals of speeding up regulatory negotiations and enabling the use of "black-box" design methods.

Priyanka Agarwal, MD MBA (BMS)

Digital Health & Biotech: Opportunities, Challenges, and the MyoKardia/BMS Experience

Abstract: During this session, I will share success and challenges in setting up therapeutically-focused digital health programs within biotech and big pharma. Topics covered will include:

- Digital Health framework using a therapeutic-area focused approach
- Digital Health to facilitate disease detection and monitoring
- Digital solutions to complement patient care or a clinical trial
- Digital therapeutics to directly impact clinical care and outcomes
- Key learnings for future DH infrastructure within biotech and pharma

Join Priyanka Agarwal, MD, MBA to discuss her experiences and insights in setting up and operating a digital health program within MyoKardia, and now within Bristol Myers Squibb, following its acquisition of MyoKardia.

Bio: Dr. Priyanka Agarwal, MD, MBA is the Director and Head of Digital Health at MyoKardia, now part of Bristol Myers Squibb, and Associate Clinical Professor of Medicine in the Division of Hospital Medicine at the University

of California, at San Francisco (UCSF). At BMS, Dr. Agarwal leads the digital health division focused on cardiomyopathies, with a focus on developing novel digital endpoints for clinical trials and applying AI methods to generate novel insights from clinical data. She has also worked extensively on designing decentralized approaches for clinical trials in the setting of the COVID-19 pandemic. Prior to joining MyoKardia, Dr. Agarwal was the Clinical Lead for Telehealth at UCSF, helping to design and implement novel telehealth approaches for patient care, and the Clinical Lead for the Digital Patient Experience Initiative at UCSF's Center for Digital Health. She completed medical school at Harvard University, her internship in internal medicine at Brigham and Women's Hospital, and her residency in internal medicine at UCSF.

Dr. Agarwal's interests are in the use of digital technology to improve health and healthcare. She believes strongly in empowering individuals to better manage their health, and she is excited about the power of technology to facilitate these efforts and to more broadly transform healthcare.

Jeetu Ganju, PhD (Ganju Clinical Trials)

Extreme Consulting

Abstract: In this personal talk, I will cover 3 topics: (1) Why I made the full-time employee (FTE) to working independently switch. (2) Why I am calling this style of work extreme. It has to do with the nudge provided by a highly unusual band of individuals, and the different work habits I developed as a result. I'll also note some of the tradeoffs involved in working independently compared to being an FTE. (3) I'll suggest consideration of a different arrangement for organizing the flow of work within clinical development.

Bio: Jeetu is an independent consultant with a focus on and interest in (a) clinical development plans, (b) speeding up development timelines, (c) improving endpoint selection for Phase 2 and 3 trials. Prior to his current role, he headed the Biometrics groups at Global Blood Therapeutics and Hyperion Therapeutics.

His educational background is in statistics and he has over 20 years of experience in clinical trials. In 2019 he gave a presentation to FDA Division Directors in a public meeting organized by FDA called Promoting Effective Drug Development Programs, on 'Strengthening the interpretation of clinical trial data.' He is currently working on the topic of hierarchically arranged endpoints with a couple of collaborators. The versatility of the subject matter allows unifying the assessment of benefit-risk, handling of the missing data problem, and providing a universal method for sizing trials. An interest of his is to listen to and share with others experiences in drug development.

Yuan Ji, PhD (University of Chicago)

A Statistician's Journey in Building a Software Company

Abstract: In this talk, I will share my experience in founding, growing and exiting a statistical software company. I will go over the original motivation of founding the company, the main ideas behind the business, the values the business provides to the customers and society, lessons learned from executing the business, and the exit strategy. While each company has its unique life cycle, certain elements are common across all successful cases. I will go over those elements and share my own views.

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 150 publications in peer-reviewed journals, conference papers, book chapters, and abstracts, including Nature, Nature Methods, JCO, JNCI, JASA, and Biometrics, 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, including trials published on Lancet Oncology, JAMA oncology and JCO. His work on cancer genomics has been reported by a large number of media outlets in 2015. In particular, he led a publication in Nature Methods and invention of a tool called TCGA-Assembler which has been downloaded over 10,000 times worldwide. His recent work on precision medicine was elected as one of the top 10 ideas of the Precision Trials Challenge hosted by The Harvard Business School 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.

Peng Yang, MS (ClinData Insights)

How to Acquire Business Skills without an Getting an MBA: My Self-Learning During 8 Years of Running a Consulting Business

Abstract: How can technical professionals become more business savvy? Peng did not attend any business school or executive training programs, and she acquired most business skills through self-learning. She will share her personal experience during her entrepreneurial journey on how various business skills can be acquired over time. She will discuss the time and cost associated with each method and give some real world examples. Many of the project management, people management and vendor management skills that you already have in a biopharma job can be further developed to fit different business needs, such as new business development, business operations and accounting. Whether you plan to run your business or not, acquiring new business skills is always great to have.

Bio: Peng has spent over 16 years supporting clinical trial projects, with extensive experience in all phases of clinical development and medical affairs within the pharmaceutical and biotechnology industry. In 2013, she founded Clindata Insight Inc, a niche consulting business in biometrics and grew the business into a premier service provider, winning numerous awards, including the *Top 100 Women Owned Businesses in the Bay Area* in 2019, 2020, and 2021. She attracted and developed a team of experts who provide the gold standard of consulting services in CDISC implementation, regulatory submissions, clinical data management, statistical programming, biostatistics, and CRO oversight.

Before founding Clindata Insight, she worked for pharmaceutical companies in various management roles. She was the Head of Statistical Programming and Data Management at Santen Inc, where she built the statistical programming functionality from the ground up. She was also the Manager of Statistical Programming and Global Product Lead Programmer at Amgen, where she led a global programming team to support the GCSF franchise.

Peng holds a Master's of Science in Computer Science from the University of Texas at Dallas and a Master's of Science in Genetics and Developmental Biology from the University of Texas Southwestern Medical Center in Dallas. She received her Bachelor's of Science in Biotechnology from Peking University.

Peng is a member of American Statistical Association (ASA SF Chapter), Women Presidents' Organization (WPO), and Pharmaceutical Software User Group (PHUSE). She is also a co-founder of the non-profit data science focused organization DahShu in the Silicon Valley. She has given numerous talks on career development and entrepreneurship.

Session Chairs and Organizers

Tian Lu, PhD (Stanford)

Bio: Tian is Professor at the Department of Biomedical Data Science of Stanford University. Lu Tian received his Sc.D. in Biostatistics from Harvard University. He has considerable experience in statistical methodological research, planning large epidemiological studies, performing data management for randomized clinical trials and conducting applied data analysis. His current research interest includes developing statistical methods in survival analysis, semiparametric regression modelling, high-dimensional data analysis, precision medicine and meta-analysis. He has published more than 200 peer reviewed journal articles and currently served as the Associate Editor of Chance, Biometrics and Statistics in Medicine.

Maja Miloslavsky, PhD (Eli Lilly)

Bio: Maja is currently Vice President, Biostatistics at Loxo Oncology at Lilly. Maja has worked in drug development throughout her 20 year career, across therapeutic areas and different organization types and sizes. She started her career as a study statistician at Alza, a Janssen Company, further developing her leadership, team and infrastructure building experience by starting a biometrics group at a small Japanese company Teikoku Pharma in the neurology space. Maja returned to Janssen for an opportunity to lead a statistics team in AD drug development and later joined Jazz Pharmaceuticals where over 7 years Maja served as the statistical lead for the oncology portfolio and later the department leader for biostatistics, statistical programming and medical writing and a member of the R&D leadership team. After an opportunity to once again contribute to the neurology space at Prothena Biosciences, Maja joined Loxo Oncology at Lilly with a focus on executive leadership, team development, and agile drug development in the oncology space. Maja is a pharma/biotech leader with a passion for problem solving, cross functional collaboration, and reading fiction. Maja received her PhD in Biostatistics from University of California Berkeley.

Brian Wiens, PhD (Acelyrin)

Bio: Brian is Vice President, Biostatistics and Data Sciences, at ACELYRIN, Inc., supporting clinical development activities for all phases of clinical research. Prior to joining ACELYRIN in 2021, Brian held positions of increasing responsibility with various companies including Merck, Amgen, Gilead, Alcon and Horizon.

Brian has been active in the American Statistical Association Biopharmaceutical Section, serving as section chair in 2007. Since 2011, he has chaired an annual pre-conference workshop at the Joint Statistics Meetings on Improving Statistical Presentations.

Brian holds a Ph.D. in statistics from Temple University and a M.S. in statistics from Colorado State University. He is a fellow of the American Statistical Association.

Julia Varshavsky, PhD (OccamPoint)

Bio: Julia is the founder and managing director of OccamPoint. She has over 15 years of drug development experience spanning areas from drug discovery through commercialization and life-cycle management. During her tenure in the industry, Dr. Varshavsky served in a variety of leadership roles in both large R&D (Eli Lilly, Genentech) and small-to-midsize pharma (Jazz Pharmaceuticals, Corcept Therapeutics) organizations, building and leading Biostatistical, Biometrics and Development teams.

In 2019 Dr. Varshavsky founded OccamPoint, a consortium of drug and combination product development professionals, to aid assessment of investment risk in healthcare and digital health products during due diligence and business development. As a Life Sciences Council member for Springboard Enterprises, Dr. Varshavsky works with peers in finance, legal and investment communities to foster success of female-led healthcare and digital health startups, coaching on a broad range of topics including indication-specific product development, use of AI in patient selection and diagnostics, as well as scalable and efficient data aggregation and sharing strategies.

Dr. Varshavsky holds a Ph.D. in Statistics from Purdue University.

Godwin Yung, PhD (Genentech)

Bio: Godwin is a Principal Statistical Methodologist and member of Methods, Collaboration, and Outreach at Genentech/Roche. As such, he conducts research in the areas of survival analysis, adaptive design, and causal inference; provides support in the use of appropriate quantitative methodology; and contributes to external networks such as BBSW to further the practice of statistics. Godwin previously worked as a hybrid methods/study statistician at Takeda Pharmaceuticals. He earned his doctoral degree in biostatistics from Harvard University in 2016 and bachelor degree in mathematics from Reed College in 2010.

Shariq Alavi, PhD (Consultant - Telperian CRO)

Bio: Shariq Alavi is a Sales, Business Development, and Marketing leader working with Clinical Development, Data Science and Statistical Technology platform companies. With a guiding principle to advance technologies that can bring therapeutics to market and reduce disease in an efficient and equitable manner, he enjoys working with Biostatisticians, Translational scientists, and Biologists.

Whedy Wang, PhD (Alector)

Bio: Whedy has over 20 years of experience in the biopharmaceutical industry, including directing biometrics efforts in more than ten NDA and sNDA submissions, three advisory committee meetings and multiple EX-US submissions, all leading to successful approvals. Whedy is currently VP of Biometrics at Theravance Biopharma, a company focusing on creating medicines that help improve the lives of patients suffering from serious illness. Prior to joining Theravance Biopharma, she held several senior positions including Vice President of Biometrics at Gilead Sciences Palo Alto (formerly CV Therapeutics), Senior Vice President of Bioinformatics at Orexigen, and Executive Director of Biometrics at Affymax.

At her current as well as previous job postings, Whedy provided strategic input and biometrics oversight to U.S. and EU development and commercial efforts. As a member of executive team at CV Therapeutics and Orexigen, Whedy contributed to the development of corporate strategy and led life cycle management planning. Additionally, Whedy was the global project leader for Lexiscan® and Ranexa® where her contributions included presenting development rationale and product life cycle management plan to the Board of Directors, and potential EU and Asia partners. Whedy also played a key role in business development discussions that led to successful collaborations such as royalty financing of $185 million for Lexiscan® Injection with TPG-Axon Capital, and license agreement for Ranexa® in 68 countries including EU with the Menarini Group. Whedy holds a M.P.H. in Epidemiology, and a Ph.D. in Biostatistics, both from the University of Michigan.

Whedy thrives to be a leader who inspires and empowers others to be their best!! She lives in Palo Alto with her husband and 3 toddler girls. Her favorite daily routine includes reading bedtime stories and singing off-key with her daughters.

Ron Yu, PhD (Gilead Sciences)

Bio: Ron is Senior Director of Biostatistics and Head of Center for Statistical Excellence at Gilead Sciences. He received his Ph.D. from Stanford University in 2005 and spent one year as a postdoctoral fellow at University of California San Diego before joining the Biostatistics Group at Genentech. After nearly ten years at Genentech, he joined Gilead Sciences in 2016 and has been working there since then.

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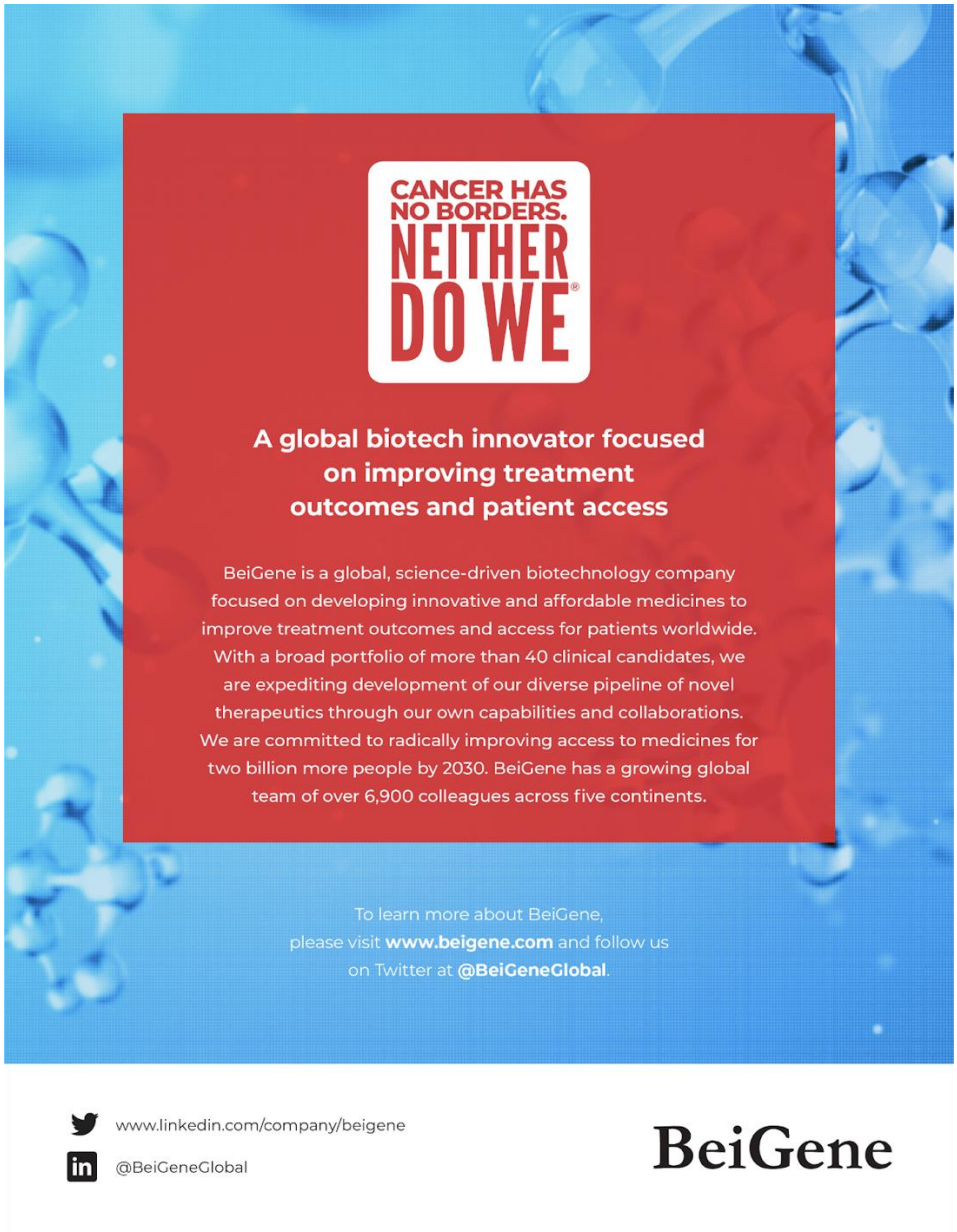

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Denali Therapeutics is dedicated to defeating neurodegenerative diseases through rigorous discovery and development of meaningful treatments for patients. Supported by our deep expertise in the biology of neurodegeneration and brain-delivery technology, we are advancing a broad portfolio of programs, including some that are progressing toward late-stage clinical development. We plan to strategically expand our capabilities with the long-term vision of becoming a fully integrated, global organization to serve patients.

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Loxo Oncology at Lilly was created in December 2019, combining the Lilly Research Laboratories oncology organization and Loxo Oncology, which was acquired by Lilly in early 2019. Loxo Oncology at Lilly brings together the focus and spirit of a biotech with the scale and resources of large pharma, with the goal of rapidly delivering impactful new medicines for people with cancer. Our approach centers on creating new medicines that unequivocally work early in clinical development and will matter to patients. We intend to curate a balanced pipeline of medicines,

either internally or externally discovered, with the potential to treat cancer with dramatic effect. Loxo Oncology at Lilly is a global organization with team members in Boulder, Colorado; Indianapolis, Indiana; New York City, New York; San Diego, California; South San Francisco, California; Stamford, Connecticut; and Madrid, Spain.

To discover more about life at Loxo Oncology at Lilly, please visit:

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