BBSW2023 PROGRAM BOOK

Oct 24-25, 2023
Crowne Plaza Hotel,
Foster City, CA 94404

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Agenda

Day 1: October 24, 2023 (Tuesday) [All in Magellan Main Room]

Time	Speaker	Topic
7:30-8:30 AM	**Registration, Breakfast and Networking**	
8:30-8:45 AM	**Welcome and Opening Remarks** Jing Huang (Senior Vice President, Veracyte)	
8:45-9:45 AM	**Keynote Speech:** **Does This Treatment Cause That Outcome? The Future of Inferring What is Likely to Be True** Stephen Ruberg (CEO, Analytix Thinking Consulting)	
9:45-10:15 AM	**Break**	
10:15 AM-12:15 PM	**Statistical Session #1: Innovative Trial Design/Analysis and New Endpoints** Chair: Haijun Ma (Exelixis) and Jeetu Ganju (Ganju Clinical Trials, LLC)	
10:15-10:45 AM	Haoda Fu (Eli Lilly)	Generative AI for Pharma R&D
10:45-11:15 AM	Ron Yu (Gilead)	Generalized Pairwise Comparison as a Highly Versatile Approach to the Design and Analysis of Clinical Trials
11:15-11:45 AM	Mengjia Yu (AbbVie)	Sample Size Re-estimation (SSR) for Response-adaptive Randomized Clinical Trial and the Effect of Timing of SSR
11:45 AM-12:15 PM	Martha Cao (BridgeBio)	Win Ratio for Composite Endpoints
12:15-1:15 PM	**Lunch and Networking**	
12:45-1:15 PM	**Poster**	
1:15-2:15 PM	**Programming Session #1: Clinical Development Programming Bootcamp: Actionable Insights for Start-Up Leaders** Chairs: Gianna Huang (Gilead) and Nalin Tikoo (Alector)	
	Panel Discussion: Nalin Tikoo (Alector), Jenny Yuan, Zijie Yuan (Corcept), Laura Harris (Denali), Vijay Kumar (Kodiak), Tina Nagrani (CytomX), Houston Gilbert (HiBio)	
2:15-2:45 PM	**Poster Lightning Intro** Chair: Tuan Nguyen (Alector)	
2:45-3:00 PM	**Break**	
3:00-4:45 PM	**Career Session: Career Paths for Statisticians** Chair: Merrill Birkner (Gilead)	
3:00-3:25 PM	Fannie Mori (Kronos Bio)	From p-value to Program Strategy
3:25-3:50 PM	Barbara Elashoff (Pivotal Life Sciences)	Leaving Your Career Comfort Zone
3:50-4:15 PM	Howard Mackey (Genentech)	Opportunities Are Everywhere
4:15-4:45 PM	Panel Discussion: Fannie Mori, Barbrara Elashoff, Howard Mackey, Jean Feng, Stephen Ruberg, Peter Cimermancic	
4:45-5:00 PM	**Raffle**	
5:00-6:00 PM	**Mixer with Live Music**	

Day 2 (Part 1): October 25, 2023 (Wednesday) [Magellan Main Room Unless Otherwise Specified]

Time	Speaker	Topic	Speaker	Topic
8:00-8:45 AM	**Registration, Breakfast and Networking**			
8:45-9:00 AM	**Day 2 Opening Remarks**			
9:00-10:00 AM	**Keynote Speech: Participant-Powered Research – How Direct-to-Consumer Approaches Can Drive Scientific Discovery** Adam Auton (Vice President, Human Genetics, 23andMe)			
10:00-10:30 AM	**Break**			
10:30 AM-12:30 PM	**Statistical Session #2 (Parallel Track):** **Artificial Intelligence & Machine Learning** Chair: Yuan Ji (University of Chicago) and Tuan Nguyen (Alector)		**Programming Session #2 (Parallel Track):** **Data and Visualization** **[Syracuse Room]** Chair: Zijie Yuan (Corcept)	
10:30-11:00 AM	Li Wang (AbbVie)	Artificial Intelligence Demystified and How Can It Help Clinical Development	Gregory Alexander (FDA)	Statistical Challenges in the Evaluation of Emergent Health Technologies
11:00-11:30 AM	James Zou (Stanford)	Biomedicine in the Age of Generative AI	Gianna Huang (Gilead) & Nalin Tikoo (Alector)	The Rise of Biomarker Data in Drug Development; Are You Ready?
11:30 AM-12:00 PM	Jean Feng (UCSF)	Statistical Tools for Auditing Machine Learning Algorithms Across Subgroups and Time	Dony Unardi (Genentech)	Teal, Enabling Comprehensive Interactive Data Analysis and Exploration in R with an Open-Sourced Scalable Shiny Framework
12:00-12:30 PM	Peter Cimermancic (Verily/Tesorai)	Addressing Challenges in Processing and Analyzing Life Science Datasets	Aarka Shah (Acadia) & Tracy Sherman (Ephicacy)	Butterfly Plot Using SG Plot and GTL
12:30-2:00 PM	**Lunch and Networking**			
1:30-2:00 PM	**Poster**			
2:00-2:15 PM	**Poster Awards**			

Day 2 (Part 2): October 25, 2023 (Wednesday) [Magellan Main Room Unless Otherwise Specified]

Time	Speaker	Topic	Speaker	Topic
2:15-4:15 PM	**Statistical Session #3 (Parallel Track): Real World Evidence/Real World Data** Chair: Rita Lopatin (Grail)		**Programming Session #3 (Parallel Track): Emerging Trend in Data Sciences Within Pharma [Syracuse Room]** Chairs: Nalin Tikoo (Alector) and Jenny Yuan	
2:15-2:45 PM	Khaled Sarsour & Craig Meyer (Janssen)	Leveraging RWE for Label and Indication Expansion: Conceptual and Methodological Considerations	Lena Wang (Genentech)	Statistical Programming Workflow Automation
2:45-3:15 PM	Yu Deng (AbbVie)	BERTSurv: BERT-Based Survival Models for Predicting Outcomes of Trauma Patients	Diana Lam & Heng Wang (Genentech)	Introduction to Statistical Engineering Team at Roche
3:15-3:45 PM	Seagle Liu (Veracyte)	The Power of RWD with Clinical Outcome and Comprehensive Transcriptome Information on ~100k Prostate Cancer Patients	Sam Hume (CDISC)	CORE: The CDISC Open Rules Engine
3:45-4:15 PM	Anand Chokkalingam (Gilead)	Development of Real-World Evidence of Remdesivir's Effectiveness During the Global COVID-19 Pandemic	Tai Xie & Peng Zhang (CIMS Global)	Dynamic Monitoring of Ongoing Clinical Trials
4:15-5:00 PM	**Sponsor Talks/Raffle/Closing Remarks**			
5:00-6:00 PM	**Happy Hour with Live Music**			

Abbreviation: AI/ML = artificial intelligence/machine learning. CDISC = clinical data interchange standards consortium. NHS = national health service. R&D = research and development. RWD = real world data. RWE = real world evidence. SSR = sample size reestimation. UCSF = University of California at San Francisco.

Vendor Exhibits all day for both days.


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Loading Dock
Down Ramp
7' x 11'
Executive Tower
Crowne Club
7th Floor
Bayview
7th Floor
Princeton
2nd Floor
Exercise Room
4th Floor
Entrance
Alexandria III
Alexandria II
Alexandria I
87" w x 94" w
Magellan
Ballroom
Drake II
Drake I
Alexandria
Balboa
Columbus
Drake
Banquet Foyer
Banquet Office
Boardroom
Syracuse
Stanford
Restrooms
Waterfall
Marco Polo
Clubhouse Bistro
Back-stage
Ultra Lounge
Elevators
Café Florian
Pool & Hot Tub
Chit Chat Lobby Lounge
Lobby
Front Desk
Office
Japanese Restaurant
To Parking
Restrooms
Office
Yale
Business Center
Gift Shop
To Parking
Main Entrance

Keynote Talks

Stephen Ruberg (CEO, Analytix Thinking Consulting)

Topic: Does This Treatment Cause That Outcome? The Future of Inferring What is Likely to Be True

Abstract:
In 1925, Sir Ronald Fisher published his now VERY famous book Statistical Methods for Research Workers in which he posited, "The [test statistic] value for which P =.05, or 1 in 20, is 1.96 or nearly 2; it is convenient to take this point as a limit in judging whether a deviation is to be considered significant or not." With the later work by Jerzy Neyman and Egon Pearson in 1933 on what is now known as the Neyman-Pearson lemma, the foundations for statistical hypothesis testing (frequentist statistics) were laid and have predominated to the present day. Part 1 of this presentation will present concepts, arguments, and examples (some of which are novel) for why the Bayesian approach is a better answer to the title question.

In 1961, the University Group Diabetes Program (UGDP) was initiated to study the long-term cardiovascular outcomes of patients on anti-diabetic treatments. The UGDP adopted, somewhat controversially, the intent-to-treat approach to the statistical analysis. This became engrained in cardiovascular studies and other long-term outcome studies throughout the 1970's and 80's. ITT became the default approach for pharmaceutical drug development clinical trials with the issuance of ICH-E9: Statistical Principles for Clinical Trials (1998). In 2019, with the release of the ICH Addendum ICH-E9(R1): Estimands and Sensitivity Analysis in Clinical Trials, the door has been opened to other approaches and strategies for analyzing clinical trial data. Part 2 of the presentation will argue that in many situations, the ITT approach leads to an estimand (effect of initiating treatment) that is of less interest/value to patients and the clinical community than the direct treatment effect.

In 2023, the world of drug development and clinical medicine is vastly different than it was in 1925, or 1933 or 1961. The pharmaceutical industry is tackling new and varied diseases, and statistical/computing methods have made dramatic advances. It is time to step boldly into the future to answer the most fundamental question of drug development: Does This Treatment Cause That Outcome?

Bio:
Dr. Ruberg received a bachelor's degree in mathematics from Thomas More College, an MS in Statistics from Miami of Ohio, and a PhD in Biostatistics from the University of Cincinnati.

Dr. Ruberg was in the pharma industry for 38 years where he worked in all phases of drug development and commercialization – from R&D to Business Analytics. He retired from Lilly at the end of 2017. In his last 10 years at Lilly, he formed the Advanced Analytics Hub for which he was the Scientific Leader and ultimately the Distinguished Research Fellow. Since his retirement, he has formed his own consulting company, Analytix Thinking, which is dedicated to teaching good statistical principles and to consulting on analytical strategies for organizations. He is

also an Adjunct Professor of Statistics in the Department of Statistics at Purdue University.

He has been a Fellow of the American Statistical Association (ASA) since 1994, was given the Career Achievement Award by Quantitative Scientists in the Pharmaceutical Industry and was elected a Fellow of International Statistics Institute.

Dr. Ruberg has served in many leadership roles related to the pharmaceutical industry (e.g. PhRMA) and the statistical profession (e.g. ASA). He was on the Expert Working Group for ICH-E9 *Statistical Principles for Clinical Trials* and a co-author of that Guidance. He also served as the first Chairman of the Clinical Data Interchange Standards Consortium (CDISC) and received an FDA Commissioner Special Citation for contributions to standards development. Most notably, he served on a select Advisory Board to Secretary of Health and Human Services, Michael Leavitt, in the George W. Bush Administration for creating strategies involving the development and use of electronic medical records.

Dr. Ruberg has published and presented extensively on a wide variety of statistical topics related to preclinical and clinical drug development. Dr. Ruberg's current research interests include estimands, subgroup identification, Bayesian methods for clinical drug development, and digital medicine.

Adam Auton (VP, Human Genetics, 23andMe)

Topic: Participant-Powered Research - How Direct-to-Consumer Approaches Can Drive Scientific Discovery

Abstract:
Since 2006, 23andMe has not only connected people with their genetic heritage but also unlocked unprecedented insights into human health. With data from over 13 million customers and billions of phenotypic data points, it's established the world's largest consented, re-contactable database for genetic research. In this talk, I will provide an overview of research studies conducted at 23andMe, and outline how direct-to-consumer approaches offer a new, scalable paradigm for research. I will discuss the power of the 23andMe database for driving scientific discoveries that could lead to novel therapies in a wide range of diseases, and how 23andMe is working to power therapeutic discovery and development across the industry.

Bio:
Adam Auton is Vice President of Human Genetics at 23andMe. Adam joined 23andMe in 2015, and leads statistical genetics and computational biology teams focused on large-scale genetic analysis and algorithmic development for both drug discovery and consumer-facing products. Dr. Adam Auton is a widely recognised geneticist, noted for his work in population genetics and human evolution. Before joining 23andMe Adam held a central role within the 1000 Genomes Project, and developed approaches for analyzing large-scale genomic datasets that offered insights into human genetic variation and ancestry. Adam earned his DPhil in statistics from Oxford University, before completing his post-doctoral training at the Wellcome Trust Centre for Human Genetics at Oxford, and Cornell University.

BBSW2023 President

Whedy Wang, PhD (Alector)

Bio: Whedy has over 25 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 & Digital Science at Alector, a biotech company that is on a mission to slow the progression of neurodegenerative diseases and to one day prevent their occurrence. Prior to joining Alector, she held several senior positions including Vice President of Biometrics and Data Science at Theravance Biopharma, VP 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 the 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, Ann Arbor.

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 playing Animal Crossing with her daughters.

BBSW2023 President-Elect

Jing Huang, PhD (Veracyte)

Bio: 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 20 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 near ten thousand citations and is co-inventor of over 20 patent filings. Jing has been elected as a Fellow of American Statistical Association in 2023 to recognize her outstanding contributions to the medical research community in the field of statistics; for numerous statistical innovations in genomic tests; and for exemplary leadership and community service to the profession. Besides her daily work, she actively promotes data science through many of her volunteer activities: She is the founding president of DahShu, 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 was the general co-chair and local organization chair of the Fourteenth Asia Pacific Bioinformatics Conference (APBC 2016) as well as the DahShu 2017 Scientific Symposium on Computational Precision Health (CPH 2017).

Invited Talks

Gregory Alexander
Director, Division of Biostatistics
Office of Clinical Evidence & Analysis
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

Title: Statistical Challenges in the Evaluation of Emergent Health Technologies

Abstract: Artificial Intelligence (AI) and Machine-Learning (ML) models have been observed with increasing frequency in digital health-based products and software as a medical device (SaMD) submission. We discuss some general considerations for the validation study design of such devices and illustrate along with examples and challenges that arise in the evaluation of device performance and the assessment of benefit risk. One new area discussed is the evaluation of predetermined change control plans (PCCPs) which have the potential to accelerate introduction and release of device modifications without the need for a new regulatory submission.

Bio: Gregory Alexander, PhD has served as Director for the Division of Biostatistics within CDRH since August 2022. Dr. Alexander's current work in medical device regulation is preceded by over 20 years working in industry,applying statistical methodology for translational research, biomarker discovery, development of invitro assays and predictive algorithms. At GRAIL, LLC, a subsidiary of Illumina, his work focused on the development and validation of multi-cancer early detection diagnostic tests. Prior to that, at Genomic Health (acquired by Exact Sciences) his work included the development and validation of several LDT's which employed technologies such as multiplex PCR and IHC to aid disease prognosis, as well as NGS for molecular profiling of tumors from blood samples. At CareDx (formally XDx), his work centered on development of multi-gene expression assays used in non-invasive monitoring for acute rejection of organ transplants. At Cytokinetics, Inc., Dr. Alexander developed algorithms used in high-content image-based screening of small molecules for the potential treatment of cancer, cardiomyopathies, fungal and musculoskeletal diseases.

Martha Cao
Executive Director of Biostatistics, BridgeBio

Title: Win Ratio for Composite Endpoints

Abstract: In clinical trials, such as cardiovascular trials, hierarchical composite endpoints combining mortality and other non-fatal endpoints are often used. Different type of endpoints may be combined to measure the treatment effect.
The win ratio approach was introduced in 2012 (Pocock et al., 2012) as a new method for examining composite endpoints which compares patients in the treated group with those in the control group in a pairwise fashion. Compared to conventional methods for analyzing composite endpoints, the win ratio accounts for relative priorities of the components recognizing clinical importance of different components of the composite endpoint.

The win ratio approach has been widely adopted since introduction. During the presentation today, topics to be discussed will include application of the win ratio analysis in clinical trial design, components of the composite endpoints, implementation of intercurrent events handling rules, etc.

Bio: Dr. Martha Cao has 15 years of experience in design and statistical analysis of clinical trials. She currently serves as Executive Director of Biostatistics at BridgeBio, where she leads statistical and statistical programming teams. Prior to joining BridgeBio, Dr. Cao held positions of increasing responsibilities in BioMarin, Forest Laboratories (now AbbVie), and Quintiles. Dr. Cao obtained her PhD in Statistics from Colorado State University.

Anand Chokkalingam
Executive Director and Head, RWE Virology at Gilead Sciences
Associate Adjunct Professor, UC Berkeley School of Public Health

Title: Development of Real-World Evidence of Remdesivir's Effectiveness During the Global COVID-19 Pandemic.

Abstract: At the beginning of the COVID-19 pandemic, with daily mortality numbers quickly reaching into the thousands, an effective therapy for hospitalized patients was of the highest priority. Gilead's remdesivir, an RNA-dependent RNA polymerase inhibitor, was amongst the first antivirals put into clinical trials, including NIAID's ACTT-1 randomized placebo-controlled trial. With these trials still underway, there was intense interest to understand the potential effectiveness of remdesivir on COVID-19. Gilead sought to generate real world evidence, first to support the ongoing trials, and later to characterize effectiveness as desired outcomes and subgroups of interest evolved. Through investigation of outcomes in the compassionate use program, we were able to demonstrate effectiveness in general patients and develop evidence in both pediatric and pregnant patients. In addition, using an external comparator against a single-arm trial we characterized resmdesivir's effectiveness in subgroups with added statistical power. Later, as use of remdesivir increased and was captured in administrative data, we were able to demonstrate in several datasets a consistent reduction in mortality overall and in different subgroups of disease severity. The COVID-19 pandemic provided an opportunity to showcase the value of real world evidence in informing and accelerating decision-making about medicines.

Bio: Anand is Executive Director and Head of Real World Evidence for Gilead's Virology Therapeutic Area, encompassing HIV, viral hepatitis, and emerging infections including COVID-19. At Gilead he has also led Clinical Development teams for COVID-19 and HCV, and prior to that served as Head of the Epidemiology team for Gilead's Liver Disease portfolio. Anand is also an Associate Adjunct Professor of Epidemiology at the UC Berkeley School of Public Health. He came to Gilead in 2013 after eight years on faculty at UC Berkeley. He has worked previously for several biotech and molecular diagnostics companies including Syva/Syntex, Celera, and Tethys. He has a B.A. in Biochemistry from UC Berkeley and a Ph.D. in Epidemiology from the University of Maryland Baltimore, and completed post-doctoral training at the U.S. NCI's Division of Cancer Epidemiology and Genetics.

Peter Cimermancic
Co-founder of Tesorai

Abstract: Success in drug development hinges on the accuracy and efficiency of data processing and analytics workflows. Current data workflows are faced with three critical challenges that limit the inherent potential within generated datasets: (1) small size of labeled datasets, (2) difficulty of integrating multi-modal data, and (3) information loss during workflows. In my presentation, I'll showcase strategies to tackle these challenges by harnessing the latest AI/ML approaches.

Bio: Peter Cimermancic is a co-founder of Tesorai, a tech startup developing an AI platform to facilitate analyses of life science data. Most recently, he headed AI/ML and software teams for digital pathology at Verily, often collaborating with Google Brain and DeepMind teams. He co-authored the first paper on introducing deep learning to proteomics mass spectrometry data. Peter has completed his PhD at UCSF, applying AI/ML approaches to various life science areas, which led to several impactful contributions, including discovery of novel HIV-human protein interactions, a novel antibiotic class, determining structures of protein complexes using genetic interactions, and finding small molecule modulators of large protein complexes.

Yu Deng
Senior Research Statistician at AbbVie

Title: BERTSurv: BERT-Based Survival Models for Predicting Outcomes of Trauma Patients

Abstract: Survival analysis is a technique to predict the times of specific outcomes, and is widely used in predicting the outcomes for intensive care unit (ICU) trauma patients. Recently, deep learning models have drawn increasing attention in healthcare. However, there is a lack of deep learning methods that can model the relationship between measurements, clinical notes and mortality outcomes. In this paper we introduce BERTSurv, a deep learning survival framework which applies Bidirectional Encoder Representations from Transformers (BERT) as a language representation model on unstructured clinical notes, for mortality prediction and survival analysis. We also incorporate clinical measurements in BERTSurv. With binary cross-entropy (BCE) loss, BERTSurv can predict mortality as a binary outcome (mortality prediction). With partial log-likelihood (PLL) loss, BERTSurv predicts the probability of mortality as a time-to-event outcome (survival analysis). We apply BERTSurv on Medical Information Mart for Intensive Care III (MIMIC III) trauma patient data. For mortality prediction, BERTSurv obtained an area under the curve of receiver operating characteristic curve (AUC-ROC) of 0.86, which is an improvement of 3.6% over baseline of multilayer perceptron (MLP) without notes. For survival analysis, BERTSurv achieved a concordance index (C-index) of 0.7. In addition, visualizations of BERT's attention heads help to extract patterns in clinical notes and improve model interpretability by showing how the model assigns weights to different inputs. Paper for this project is already accepted: https://arxiv.org/abs/2103.10928

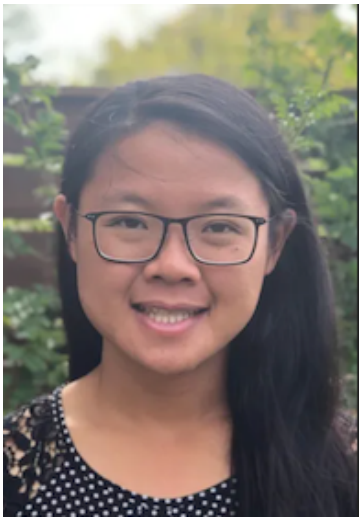
Bio: Dr. Deng is a senior research statistician of the Statistical Innovation Group at AbbVie. She received her PhD in Biomedical Informatics at Northwestern University. Her research interest includes machine learning, natural

language processing, and time series analysis with a focus on medical and clinical application. Dr. Deng has published more than 10 research papers. Currently, she serves on the ASA Houston Area Chapter committee.

Barbara Elashoff
Biostatistician at Pivoval Life Sciences

Title: Leaving Your Career Comfort Zone

Bio: Barbara Elashoff holds a master's in biostatistics from Harvard and has over 25 years of experience in clinical research in the pharma, diagnostic and medtech industries. She has led data science teams to validate algorithms for the world's first smart knee, created clinical trials AI software that Moderna used for the covid-19 vaccine studies, and was a regulatory expert at FDA reviewing new drugs. Barbara is currently a biostatistician at Pivotal Life Sciences, a venture capital firm, and a part-time lecturer at the UC Berkeley Extension school.



Jean Feng
Assistant Professor, Epidemiology and Biostatistics, University of California at San Francisco

Title: Statistical Tools for Auditing Machine Learning Algorithms Across Subgroups and Time

Abstract: Machine learning (ML) algorithms have the potential to derive insights from clinical data and improve patient outcomes. However, the performance of these highly complex systems often differs across patient subgroups and is sensitive to changes in the environment. Auditing these ML algorithms---both in pre-market and post-market settings---ensures their safety and effectiveness across diverse patient populations and over time. In this talk, we will explore how to audit for the fundamental safety requirement of strong calibration: for any subgroup, the average predicted probability should be close to its average event rate. Checking for strong calibration is challenging. Given the sheer number of possible subgroups, procedures are often underpowered after adjustment for multiple testing. Moreover, after a ML algorithm has been integrated into clinical practice, the ML algorithm modifies the medical decision making process and becomes a major source of bias in the data. In this talk, we illustrate how to address these challenges using tools from changepoint detection and causal inference.

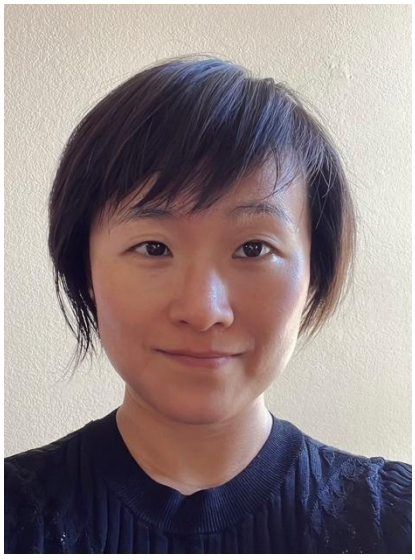
Bio: Dr. Feng is an Assistant Professor in the Department of Epidemiology and Biostatistics at the University of California, San Francisco and the UCSF-UC Berkeley Joint Program in Computational Precision Health. Her research interests include the interpretability and reliability of machine learning algorithms in medical devices and clinical decision support systems.

Haoda Fu
Associate Vice President, AI/Machine Learning, AADS

Title: Generative AI for Pharma R&D

Abstract: The realm of Pharma R&D is undergoing transformative changes with the integration of artificial intelligence. In this presentation, we will delve into the profound influence of generative AI on drug discovery and development processes. We'll explore its potential to revolutionize clinical innovative design and the promising prospects it brings to digital health. Furthermore, we will discuss how generative AI might pave the way for identifying novel endpoints, reshaping the future of pharmaceutical research and enhancing patient outcomes. Join us as we journey through the promising horizon of generative AI in Pharma R&D.

Bio: Dr. Haoda Fu is an Associate Vice President and an Enterprise Lead for Machine Learning, Artificial Intelligence, and Digital Connected Care from Eli Lilly and Company. Dr. Haoda Fu is a Fellow of ASA (American Statistical Association), and IMS Fellow (Institute of Mathematical Statistics). He is also an adjunct professor of biostatistics department, Univ. of North Carolina Chapel Hill and Indiana university School of Medicine. Dr. Fu received his Ph.D. in statistics from University of Wisconsin - Madison in 2007 and joined Lilly after that. Since he joined Lilly, he is very active in statistics and data science methodology research. He has more than 100 publications in the areas, such as Bayesian adaptive design, survival analysis, recurrent event modeling, personalized medicine, indirect and mixed treatment comparison, joint modeling, Bayesian decision making, and rare events analysis. In recent years, his research area focuses on machine learning and artificial intelligence. His research has been published in various top journals including JASA, JRSS, Biometrika, Biometrics, ACM, IEEE, JAMA, Annals of Internal Medicine etc.. He has been teaching topics of machine learning and AI in large industry conferences including teaching this topic in FDA workshop. He was board of directors for statistics organizations and program chairs, committee chairs such as ICSA, ENAR, and ASA Biopharm session. He is a COPSS Snedecor Awards committee member from 2022-2026, and will also serve as an associate editor for JASA theory and method from 2023.



Gianna Huang
Associate Director, Statistical Programming, Gilead Sciences

Title: The rise of biomarker data in drug development; are you ready?

Abstract: With advances in technology, biomarker data today plays a much more pivotal role in drug development than ever before , serving various purposes such as generating translational insights, regulatory submissions, and ongoing study or program level strategic decision making. However, using biomarker data through the clinical development lifecycle comes with challenges, including but not limited diversity of biomarker data (eg. imaging biomarkers, fluid biomarkers, digital biomarkers etc.), data standards that conform to regulatory standards, and yet the need for flexibility in supporting accessibility for deep scientific exploration. This presentation is to open a discussion on the nature of uncertainty in biomarker data, and challenges in clinical trials faced by statistical programmers, that involves CDISC standard data mapping, and data integration to enable data traceability and automated downstream analysis pipeline. In addition, the presentation will propose solutions on how to effectively manage

biomarker programming activities, grow, and develop statistical programmers in adopting challenges to yield maximum results.

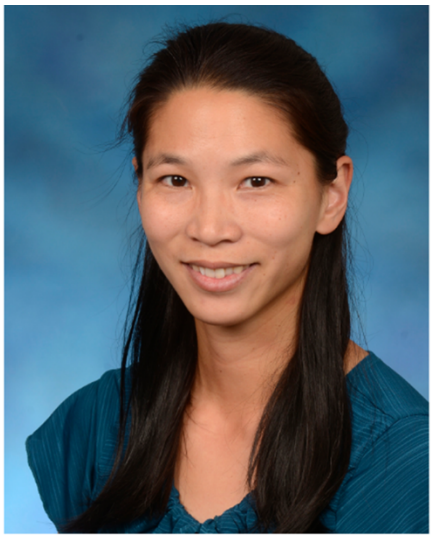
Bio: Gianna Huang is leading the biomarker statistical programming team in Gilead Sciences, supporting various therapeutic areas, including virology, inflammation, and oncology. Her current role is focused on biomarker statistical programming in clinical development for both exploratory and regulatory submissions. Gianna holds a Master of Science degree in Statistics, which she obtained before starting her career at Sanofi Aventis. There she contributed primary to late-phase clinical trials and data quality automation pipeline. Gianna is active in promoting data standardization and automation in biomarker data analysis. She engages with industry peers, and has presented at events such as PharmaSug, PHUSE, and internal company annual symposiums, sharing and promoting best practices. Gianna believes the value of continuous learning. She has pursued certifications such as business data analysis from Cornell University and clinical trial management from UC Berkeley Extension.

Sam Hume
Vice President, Data Science, CDISC

Title: CORE: The CDISC Open Rules Engine

Abstract: This presentation introduces the CDISC Open Rules Engine, or CORE, project and provides an overview of the new executable conformance rules as well as the software tools used to create and run the rules. The presentation provides the current state of the project, an overview of key stakeholder involvement, examples of current CORE usage, and highlights of future development plans.

Bio: Sam Hume leads the CDISC Data Science team who develops tools and standards that support clinical and translational research. Sam directs delivery of the CDISC Library, leads the Data Exchange Standards team, and serves as a leader of CORE. Additionally, he oversees the CDISC Open-Source Alliance (COSA), which supports CDISC-related open-source software projects.
Sam has 30 years' experience working in clinical research informatics and has held several senior-level technology positions in the biopharmaceutical industry. He holds a doctorate in Information Systems.



Diana Lam
Principal Data Scientist, Analytical Data Science (ADS) Enabling Platform, Product Development Data Sciences, Roche and Genentech

Title: Introduction to the Statistical Engineering team at Roche. (Co-present with Heng Wang)

Abstract: While biostatistics primarily focuses on the statistical aspects of clinical trials, statistical engineering extends these principles to create robust, reusable, and open-source software solutions for a broader range of analytical problems and novel data types such as biomarkers. Furthermore, the statistical engineering group helps incorporate statistical rigor into inherently ambiguous scenarios, such as those related to operations and decision-making. In this talk, we will discuss how the Statistical Engineering group operates at Roche/Genentech and give a brief overview of the types of projects we work on. No matter what group you belong to, we hope you will consider incorporating some aspects of the Statistical Engineering group, whether it be our agile methodology, or our fluid way of working.

Bio: Diana Lam joined Genentech in late 2018 as a Statistical Programming Analyst, and is currently part of the Analytical Data Science Enabling Platform. After graduating from the University of North Carolina, Chapel Hill, with a PhD in Biostatistics, she is glad to be back in California where she's from. Within Genentech, Diana has worked with the Non-Clinical Biostatistics, Methods Collaboration Outreach, and PHC Ophtha groups, in addition to hosting many git/GitLab trainings for the Data Science community.When not deploying shiny apps or collaborating on statistical packages, Diana enjoys biking around town and increasing her apple consumption to keep up with her apple tree.

Seagle Liu
Associate Director, Data Science & Data Engineering at Veracyte Inc

Title: The power of RWD with clinical outcome and comprehensive transcriptome information on ~100k prostate cancer patients

Abstract:
Importance: Although the prognostic significance of the Decipher prostate cancer genomic classifier (GC) has been largely established from analyses of archival tissue, less is known about the associations between results of Decipher testing and oncologic outcomes among patients receiving contemporaneous testing and treatment in the real-world practice setting.

Objective: To develop a novel linkage between the Decipher prostate genomic classifier (GC) and real-world patient data in the United States across payors and sites of care, and to assess the associations between the Decipher GC and risks of metastasis and biochemical recurrence (BCR) following prostate biopsy and radical prostatectomy (RP) among patients tested and treated in the real-world setting.

Design, Setting, and Participants: Clinical and transcriptomic data from clinical use of the Decipher prostate GC between 2013-2022 were anonymously linked through a de-identification engine using encrypted tokens (Datavant, San Francisco, CA) with real-world data aggregated from insurance claims, pharmacy records, and electronic health record (EHR) data. We developed and refined algorithms for identifying prostate cancer diagnoses, treatment timing, and clinical outcomes (biochemical recurrence, BCR, and prostate cancer metastases) in RWD using diagnosis, common procedural terminology (CPT) codes, pharmacy codes, SNOMED clinical terms and unstructured text. The association between the study outcomes, metastasis from prostate cancer and BCR after RP, and Decipher GC (continuous score and risk categories) were examined using Kaplan-Meier and Cox proportional hazards regressions adjusting for clinical and pathologic factors.

Results and Conclusion: A total of 92,976 of 95,578 (97.2%) patients with Decipher prostate GC were successfully linked to RWD, including 53,871 from biopsy and 39,105 from radical prostatectomy (RP) tests. The concordance of prostate cancer diagnoses between RWD and Decipher test records was 85.0%. Year of treatment was concordant in 98.5% of patients undergoing GC testing at RP, and 87.8% in patients with biopsy GC tests. A subset of 58,935 participants (33,379 biopsy and 25,556 RP) was identified to assess the association between Decipher GC and metastasis. The GC was independently associated with risk of metastasis among biopsy patient with hazard ratio (HR) of 1.21[1.16-1.27] (per 0.1 unit increase) and RP-tested patients of HR 1.20[1.17-1.24] after adjusting for baseline clinical and pathological risk factors and per 0.1 unit increase in GC. In addition, the GC was associated with risk of BCR among RP tested patients of HR 1.12 [1.10-1.14] in models adjusted for age and CAPRA-S. In conclusion, this real-world study of a novel transcriptomic linkage conducted at national scale demonstrates credibility of RWD and supports the prognostic validity of the Decipher GC among patients managed in contemporary practice.
Bio: Seagle is Associate Director of Data Science & Data Engineering at Veracyte Inc. He leads a team of data scientists and data engineers on large scale data analysis, machine learning and data pipeline development. He led

the ML development of many genomic signatures that resulted in improvements of three CLIA lab development tests, as well as a dozen of research-use-only signatures. Many of these genomic signatures are featured in publications on journals such as Nature, Clinical Cancer Research, JAMA Oncology etc. His team has also developed a fully scalable data processing system that hosts over 100 signatures and over 200K whole transcriptome genomic data. Prior to joining Veracyte Inc, Seagle obtained his master and PhD on statistics at UBC and worked as a data scientist intern at Google. Recently, he led the data linkage and analysis on Decipher Genomic Classifier data with real world data on over 93K patients, which will be featured in today's presentation.

Howard Mackey
People & Product Leader, Data & Statistical Sciences, Genentech/Roche

Title: Opportunities are Everywhere

Bio: Howie did his Ph.D. in Statistics under David Hinkley at UC Santa Barbara. After post-doctoral training in biostatistics at Johns Hopkins and working as a clinical biostatistician at Johnson & Johnson, he joined Genentech in 2005. Since then, he has worked on or managed projects in oncology, Alzheimer's Disease, autism, stroke, muscular dystrophy, and multiple sclerosis. In 2012, he took a two-year break from working as a biostatistician to lead the global development of Erivedge®, the first approved treatment for metastatic basal cell cancer. In his free time, he enjoys reading, surfing, and spending time with family.

Fannie Mori
Senior Director, Portfolio and Program Management at Kronos Bio

Title: From p-value to Program Strategy

Bio: Fannie Mori started her biopharmaceutical career at Amgen, where she was a statistical leader of functional and cross-functional teams for products in cardiovascular (Repatha®) and nephrology (Epogen®/Aranesp®) therapeutic areas; playing instrumental roles in multiple Cardio-renal Advisory Committee meetings and global marketing submissions. From there, Fannie joined Jazz Pharmaceuticals, where she was statistical lead for the Oyxbate franchise in the neuroscience therapeutic area, which achieved regulatory approvals for Xyrem® (pediatric narcolepsy) and Xywave® (narcolepsy). Jazz is where she also began her career pivot from biostatistics to a Chief of Staff role for the global head of R&D - in this role, Fannie provided influential leadership and strategic input to the executive leadership team to advance a large portfolio of programs across both neuroscience and oncology therapeutic areas. Currently, Fannie is a senior director in the portfolio and program management group at Kronos Bio where she serves as program team lead for a clinical stage molecule for acute myeloid leukemia. Fannie earned her BS in Applied Mathematics and MS in Biostatistics from UCLA. She is a Bay Area native and lives in San Mateo, CA with her plant babies and the rest of her family (husband and 2 kids). In her spare time, Fannie enjoys baking bread and anything that takes her outdoors (running, biking and hiking).

Khaled Sarsour
VP, Janssen R&D Data Science and Digital Health, RWE and Advanced Analytics

Title: Leveraging RWE for Label and Indication Expansion: Conceptual and Methodological Consideration
Presented with Craig S. Meyer, Principal Scientist, Data Science & Digital Health, Global RWE R&D at Janssen Pharmaceutical

Bio: In his role, Khaled is leading the Data Science and RWE technical and methodological excellence across Therapeutic Areas and Functions, focused on driving impact for the pipeline and patients. Khaled's RWE team is also executing the Janssen R&D Data Science RWE and advanced analytics agenda including the development and validation of RWE based endpoints, the study of the natural history of diseases, development and approval of external and hybrid control arms and use of RWD to enhance risk stratification, patient finding and clinical operations.
Khaled joined Janssen from the Genentech/Roche organization where he held a number of positions of successively increasing responsibilities. Most recently he was the Global Head of Data Science and Real-World Evidence (RWE) for Hematology, contributing to the functional mission, vision and strategy and leading a group of multidisciplinary scientists delivering RWE and insights in solid tumors and hematology programs.
Khaled is active in shaping the external environment on accepting RWD for decision-making. He is part of the Duke Margolis RWE Collaborative to advance the regulatory acceptability of RWE. He was also a member of the Pharmaceutical Research and Manufacturers of America (PhRMA) RWE Committee that seeks to engage with regulators on the acceptability of RWE. Khaled has authored or co-authored 43 peer-reviewed papers and many more conference abstracts in a range of therapeutic areas informing research and drug development decisions and investigating the safety and real-world effectiveness of treatments. He received a doctorate in epidemiology from the School of Public Health at the University of California, Berkeley.

Craig S. Meyer
Principal Scientist, Data Science & Digital Health, Global RWE R&D at Janssen Pharmaceuticals

Title: Leveraging RWE for Label and Indication Expansion: Conceptual and Methodological Consideration
Presented with Khaled Sarsour, VP, Janssen R&D Data Science and Digital Health, RWE and Advanced Analytics

Abstract: The use of real-world evidence (RWE) in drug development pre approval and post approval regulatory settings have been increasing. There have been several recent successes in leveraging RWE for label expansion in multiple therapeutic areas. This presentation offers a framework for using RWE for label expansion consisting of three steps: (1) Selecting the opportunity: an **evaluation framework** to assess and compare between relevant sets of opportunities. (2) Evidence strategy: **Coherent approach** to identify, generate, and integrate **evidence** and make the case for label expansion; and (3) Methodological considerations: outlining b**est practices** to outline a comprehensive and robust evidence package. Selecting the opportunity will be a function of the regulatory precedent, disease and drug characteristics, and data and methods. The presentation will offer a structured approach to guiding evidence and argument for regulatory

submission along with data quality and methodological considerations. The presentation will conclude with a discussion of three recent examples of using RWE for label expansion.

Bio: Dr. Meyer (PhD, MPH, MS) is a Principal Scientist in Data Science & Digital Health, Global Real-World Evidence R&D at Janssen Pharmaceuticals. He held previous roles as a Senior Data Scientist at Genentech, U.S. Medical Affairs, Evidence for Access, and Principal Biostatistician at the University of California San Francisco, San Francisco VA Medical Center, Department of Medicine. He completed his PhD in Epidemiology, MS in Biostatistics, and MPH in Environmental Health at the University of Minnesota School of Public Health.

Aarka Shah
Senior Director, Head of Statistical Programming at Acadia Pharmaceuticals

Title: Amazing Graph Series: Butterfly Graph Using SGPLOT and GTL
Presented with Tracy Sherman, Ephicacy Consulting Group, Inc., Kelowna, BC.

Abstract: Have you been tasked to create a butterfly graph? If so, you might be asking yourself, what is a butterfly graph and which SAS® procedure should I use to create one? Which procedure will be the most straight forward to learn but also has the flexibility for custom modifications? The two most common methods used to create these graphs are using the SGPLOT procedure and the GTL (graph template language). The documentation for these procedures to enhance the visual appearance of these graphs is lengthy and cumbersome. This paper will help you learn the syntax required and narrow the time it takes to produce high quality and amazing butterfly graphs which can be shared with upper management or in a conference presentation. In addition, the paper also compares the SAS 9.4 SGPLOT procedure and GTL so that you can choose which method fits well with your programming requirements.

Bio: Aarka Shar is currently Senior Director, Head of Statistical Programming at Acadia Pharmaceuticals. He has 19+ years of experience in the pharmaceuticals and medical device industries. In the past, he has worked at Neoleukin Therapeutics, Nektar Therapeutics, Pfizer, Medivation, Onyx Pharmaceuticals, Amgen, Abbott Vascular and PRA Health Sciences. He received his M.S. in Industrial Engineering from the University of Texas at Arlington and holds certification in PMP and SAS Advanced Programming.

Tracy Sherman
SAS Consultant at Acadia Pharmaceuticals

Title: Amazing Graph Series: Butterfly Graph Using SGPLOT and GTL
Presented with Aakar Shah, Acadia Pharmaceuticals Inc., San Diego, CA

Bio: Tracy Sherman is a SAS Consultant at Acadia Pharmaceuticals, with more than two decades of invaluable experience in the pharmaceutical research and development domain. A passionate and active participant in the industry, she is highly regarded for her contributions to PharmaSUG, where she shares her expertise and insights. Tracy's dedication to knowledge sharing and collaboration is evident in her extensive portfolio, having authored/co-authored over 15 papers that have made a significant impact in pharmaceutical research, data visualization and analytics.

Nalin Tikoo
Director of Analytical Programming, Alector

Title: The rise of biomarker data in drug development; are you ready?
Presented with Gianna Huang, Associate Director, Statistical Programming at Gilead Sciences

Bio: Originally from India, Nalin moved to the US to attend graduate school at the Fenn College of Engineering at Cleveland State University in Cleveland, Ohio. He has an M.S. degree in Chemical Engineering with a focus on biological systems modeling for his master's thesis.

After graduate school, he moved to the Bay Area and has since worked at different biotech companies including Gilead, BioMarin, Genentech & Roche Diagnostics. He is currently the Director of Analytical Programming at Alector which is a clinical stage Neuroscience company. At Alector, Nalin is responsible for Clinical Programming, Statistical Programming & Computational Infrastructure for Biometrics & Digital Science Organization.

Outside of work, Nalin loves spending time with his family. Building Lego & backyard grilling with his 11 y/o daughter are his favorites at home & hitting the slopes in winter & glamping in summers are his favorite outdoor activities.

Dony Unardi
Principal Data Scientist in the Product Development Data Sciences Enabling Platform Team at Roche/Genentech

Title: Revolutionize Clinical Trial Data Exploration with teal

Abstract: {teal} is an innovative open-source and scalable R-shiny based framework that has the potential to transform how clinical trial data is analyzed and visualized. It enables data scientists to streamline the creation of web applications, bringing data closer and faster to stakeholders, resulting in quicker insights and better-informed decisions. The framework's features, such as dynamic data filtering, code reproducibility and report generation, elevate the user experience and promote transparency in the data exploration process. With over 50 analysis templates and the ability to easily integrate customized modules for different analyses or data types, {teal} offers a comprehensive and extendable solution for clinical trial data exploration. In this talk, we will introduce the {teal} framework, highlight its key features, share how this has been adopted by hundreds of data scientists inside our organization and the experience on development collaboration across the pharmaceutical industry. For more information about {teal}, please visit https://insightsengineering.github.io/teal/

Bio: Dony Unardi is a Principal Data Scientist in the Product Development Data Sciences Enabling Platform team at Roche/Genentech. In the last five years, he has supported the adoption of R and implemented R solutions within his roles. He is currently the Engineering Team Lead, leading the development effort of the teal framework.

Heng Wang
Principal Data Scientist, Analytical Data Science (ADS) Enabling Platform, Product Development Data Sciences, Roche and Genentech

Title: Introduction to the Statistical Engineering team at Roche (Co-present with Diana Lam)

Abstract: While biostatistics primarily focuses on the statistical aspects of clinical trials, statistical engineering extends these principles to create robust, reusable, and open-source software solutions for a broader range of analytical problems and novel data types such as biomarkers. Furthermore, the statistical engineering group helps incorporate statistical rigor into inherently ambiguous scenarios, such as those related to operations and decision-making. In this talk, we will discuss how the Statistical Engineering group operates at Roche/Genentech and give a brief overview of the types of projects we work on. No matter what group you belong to, we hope you will consider incorporating some aspects of the Statistical Engineering group, whether it be our agile methodology, or our fluid way of working.

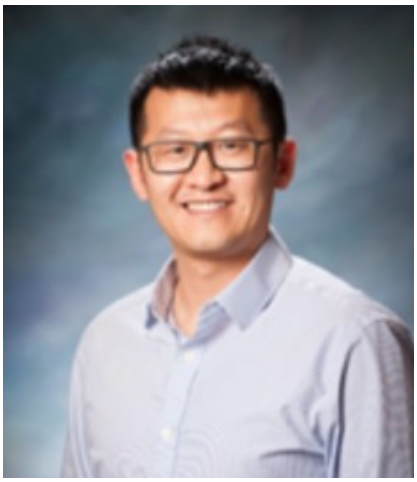
Bio: Heng Wang joined Roche in April 2016 after completing a PhD degree in Biostatistics. She is currently an Analytical Data Scientist based in South San Francisco. She has contributed to multiple Roche R packages (NEST packages) for clinical trial data analysis. Heng is also at the forefront of translating programming techniques into automation solutions for various problems in clinical trials such as automating presentation slides generation for topline results meetings. Outside of work, Heng enjoys gardening and growing everything edible.

Lena Wang
Principal Data Scientist, Data Science Acceleration (DSX) Enabling Platform, Product Development Data Sciences, Roche and Genentech

Title: A Genentech R package for streamlining generation of standard TLFs in both static and interactive formats

Abstract: As one of the NEST products, chevron package is designed to be a repository of TLF templates in R to create standard outputs used to analyze and report clinical trials data. Chevron enables generation of standard TLFs with minimal R code from end users. We also built an orchestration workflow around chevron to streamline the creation of a scalable number of outputs based on users configured metadata containing basic information regarding each output like filters, titles and footnotes. This orchestration workflow allows us to construct an automation pipeline that efficiently delivers standard TLFs for trials. In addition, with standardized TLF templates and orchestration workflow, we also plan to connect chevron with the NEST shiny framework to enable meaningful subgroup analysis in regulatory settings, which we envision to eventually support the delivery of CSR output under one harmonized framework, in both static and interactive formats (Shiny App).

Bio: Lena is from Roche Genentech DSX (Data Science Acceleration) team and an Analytical Data Scientist in I2O who joined Genentech in 2018. She worked on some I2O studies related to SLE(Systemic lupus erythematosus), COVID,etc. And now she's co-leading the COPD study. Lena is passionate about using R in different studies and is interested in learning about new tools we developed in our company.



Li Wang
Senior Director, Statistical Innovation Leader, Abbvie

Title: Artificial Intelligence Demystified and How Can It Help Clinical Development

Abstract: ML and AI are widely used in technology industry now and are finding their ways into drug development in pharmaceutical industry especially in manufacturing and discovery. In clinical development, how and where to appropriately apply ML/AI and what value it can bring to the business remain big questions without clear answers to researchers. For traditional clinical statisticians, it is not only a big challenge but also an exciting opportunity. AbbVie's statistical innovation group closely collaborated with different Development functions to leverage multiple data sources and deep learning methodologies to help make smarter decisions. Experiences and some use cases will be shared.

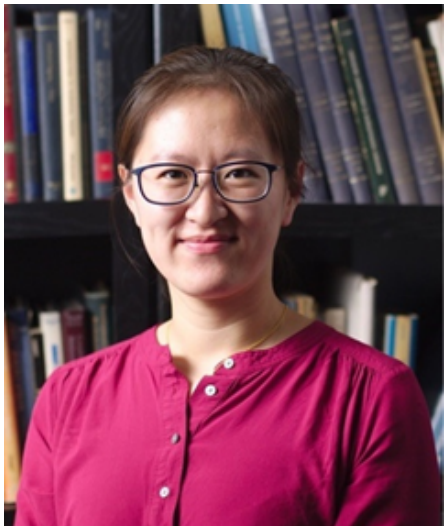
Bio: Li Wang, PhD, is currently Senior Director and Head of Statistical Innovation group in AbbVie. Li is leading Design Advisory which provides strategic and quantitative consulting as requested to all Clinical Development teams in all six Therapeutic Areas to facilitate innovative thinking and complex innovative design evaluation. Li also co-leads Development Advanced Analytics capability in AbbVie to drive Machine Learning and Advanced Analytics research and application in Development. Prior to this senior leadership role, he led Immunology and Solid Tumor statistical design and strategy discussions and multiple ML, RWE and Bayesian innovation projects, and contributed to and subsequently led several NDAs and SNDAs including blockbusters Eliquis, Onglyza and Rinvoq.

Tai Xie
CEO, CIMS Global

Title: Dynamic Data Monitoring for Ongoing Clinical Trials

Abstract: According to a recent report, nearly 70% Phase II trials failed to move forward to Phase III. Part of the reasons caused such high failure rate could be inefficient trial design and trial monitoring. In this talk, we introduce the concept of dynamic data monitoring (DDM) for ongoing clinical trials. We develop the principles and procedures for dynamically monitoring on-going clinical trials and demonstrate that the accumulative treatment effect can be automatically estimated and continuously accessible over the information time. Building on the adaptive group sequential (AGS) methods, and by taking the advantage of modern eClinical technologies, we developed a clinical trial "radar" system on which the Wald statistics, conditional power, trend, timing for sample size re-estimation, alerting of early stopping for efficacy and/or futility can be automatically displayed. Thus, the trail can be intelligently monitored. Through simulation, we demonstrate the power of DDM in guiding a promising trial to success or detecting a "hopeless" trial to stop. We provide an example of DDM application in the 1st remdesivir trial in Wuhan China.

Bio: Dr. Tai Xie is the founder and CEO of CIMS Global, an Innovative eClinical and Data Sciences company. He was the founder and CEO of Brightech which was successfully capitalized in 2022. Dr. Xie was an Adjunct Assistant Professor of Biostatistics Department, School of Public Health at the Rutgers University. He has extensive experience in innovative trial design and statistical analysis and reporting, data management, eClinical and eHealth, applying ML and A.I. to clinical trials. Dr. Xie is also an active researcher with a number of research papers published in distinguished journals on various topics including cancer prevention, adaptive design, dynamic data monitoring, survival analysis, personalized medicines and more.



Mengjia Yu
Manager, Statistical Innovation, Abbvie

Title: Sample size re-estimation (SSR) for response-adaptive randomized clinical trial and the effect of timing of SSR

Abstract: In confirmatory clinical trials which are often designed using assumed parameters or estimates from small scale trials, the observed treatment effect may vary, and it is desirable to perform interim analyses to reassess the assumptions and perform sample size re-estimation (SSR) such that the power is maintained at certain level. On the other hand, response-adaptive randomization (RAR) achieves various aims related to ethics and efficiency such as minimizing the total number of failures and maximizing the power by targeting different optimal allocation proportions. In this talk, we investigate the benefits of incorporating sequential monitoring of RAR and SSR. Furthermore, the effect from the timing of SSR is explored since it may affect the accuracy of interim assessment. We describe the method and provide extensive numeric studies for binary and continuous endpoints with evaluations on timing of SSR, power, parameter estimation bias, allocation ratio and total sample size.

Bio: Mengjia Yu joined Statistical Innovation Group at AbbVie in 2021. She obtained her PhD degree in Statistics from University of Illinois at Urbana Champaign, where she conducted research on change point analysis and advanced bootstrapping techniques in large sample theory. Her current research interests focus on developing novel statistical methods, advanced analytical modeling and designing analysis tools for adaptive designs in clinical trials. Specifically, Mengjia supports projects on group sequential designs, multi-arm multi-stage adaptive designs, sample size re-estimation, response adaptive design, adaptive hypothesis testing, Bayesian historical data borrowing, and machine learning and deep learning modeling. She also contributes software tools (R packages and R Shiny tools) in adaptive designs.

Ron Yu
Executive Director, Biostatistics, Gilead

Title: Generalized Pairwise Comparison as a Highly Versatile Approach to the Design and Analysis of Clinical Trials

Abstract: Generalized pairwise comparison (GPC) has been proposed as a novel statistical method to compare two groups of patients based on prioritized outcomes. This is an exciting area of research in clinical trials because of the versatility of comparing patient data in a pairwise manner. We show that the idea of GPC can go beyond prioritized outcomes or hierarchically combined endpoints for efficacy analysis and can answer other important questions. For example, the method enables quantifying benefit-risk and handling data that is missing not at random. We present a general sample size formula for clinical trials using GPC and give a flavor of other areas we are investigating such as a logrank version of GPC.

Bio: Ron Yu is currently the Head of Biostatistics Innovation Group and Executive Director of Biostatistics at Gilead Sciences. His team provides statistical consultation and training, develops statistical software, and supports functional and cross-functional initiatives at the company. Prior to joining Gilead, he spent close to a decade working as a project statistician on oncology clinical trials at Genentech. Aside from his day job, he has also been actively volunteering for local nonprofit organizations, such as BBSW and the San Francisco Bay Area Chapter of the American Statistical Association (SFASA). Ron received his bachelor's degrees in Mathematics and Electrical Engineering from Worcester Polytechnic Institute and his master's degree in Statistics and his PhD in Scientific Computing and Computational Mathematics, both from Stanford University.

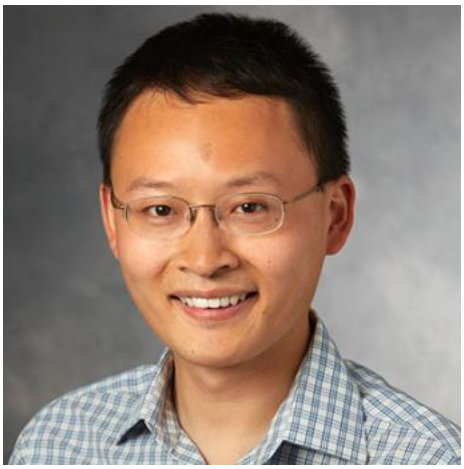
Peng Zhang
Manager, Innovative Data Sciences, CIMS Global

Title: Dynamic Data Monitoring for Ongoing Clinical Trials

Abstract: According to a recent report, nearly 70% Phase II trials failed to move forward to Phase III. Part of the reasons caused such high failure rate could be inefficient trial design and trial monitoring. In this talk, we introduce the concept of dynamic data monitoring (DDM) for ongoing clinical trials. We develop the principles and procedures for dynamically monitoring on-going clinical trials and demonstrate that the accumulative treatment effect can be automatically estimated and continuously accessible over the information time. Building on the adaptive group sequential (AGS) methods, and by taking the advantage of modern eClinical technologies, we developed a clinical trial "radar" system on which the Wald statistics, conditional power, trend, timing for sample size re-estimation, alerting of early stopping for

efficacy and/or futility can be automatically displayed. Thus, the trail can be intelligently monitored. Through simulation, we demonstrate the power of DDM in guiding a promising trial to success or detecting a "hopeless" trial to stop. We provide an example of DDM application in the 1st remdesivir trial in Wuhan China.

Bio: Dr. Peng Zhang is the manager of Innovative Data Sciences Department at CIMS Global. He graduated from Rutgers School of Public Health with Ph.D. in Biostatistics with research interest in adaptive design and statistical monitoring of clinical trials. He is the coauthor for the publication of dynamic data monitoring (DDM) and development lead of R package, R Shiny apps and software development. Dr. Peng Zhang has served as independent statistician for 30+ DSMB meetings and 10+ ongoing clinical trials from phase 2 to phase 3 for different therapeutical areas. He also facilitates the internal development of eDMC platform to incorporate previous DSMB experience, aiming to provide consistent and good practice for DSMB activities.



James Zou
Assistant Professor, Biomedical Data Sciences, Computer Science, and Electrical Engineering, Stanford University

Title: Biomedicine in the age of generative AI

Abstract: There have been tremendous advances in generative AI such as ChatGPT and DALLE2. Generative models can potentially expand researchers' creativity while balancing complex tradeoffs. I will illustrate this with applications of generative AI to pharma and biomedical research through two examples. First we will discuss how to use generative AI to design and experimentally validate novel drugs. Then we will demonstrate how to build multi-modal language models to index biomedical data.

Bio: James Zou is an assistant professor of Biomedical Data Science, CS and EE at Stanford University. He is also the faculty director of Stanford AI4Health. He works on both improving the foundations of ML by making models more trustworthy and reliable as well as in-depth scientific and clinical applications. Many of his innovations are widely used in tech and biotech industries. He has received a Sloan Fellowship, an NSF CAREER Award, two Chan-Zuckerberg Investigator Awards, a Top Ten Clinical Achievement Award, several best paper awards, and faculty awards from Google, Amazon, Tencent and Adobe.

Panelists

Jenny Yuan
Associate Director, Statistical Programming, BeiGene

Bio: Jenny Yuan joined BeiGene as Associate Director of Statistical Programming, on October 23, 2023. In this capacity, Jenny will serve as the People Manager for the US Statistical Programming with a focus on Hematology projects. Previously she was the Director, head of statistical programming at Bolt Biotherapeutics. Jenny provided both strategic leadership on statistical programming as well as hands-on programming activities to support the entire company pipeline.

She has 20 years of experience in multiple companies including Genentech, Amgen and BMS across multiple therapeutic areas.
At Amgen, Jenny established Spotfire packages for safety signal detection; At Genentech Jenny was compound lead programmer on multiple submissions and R Shiny App development.
Jenny holds a Master degree of Biostatistics from University of California, Los Angeles. Outside work, Jenny is a proud mother of two and lately ran a half marathon.

ZiJie Yuan
Associate Director, Statistical Programming, Corcept Therapeutics

Bio: Zijie Yuan is currently an Associate Director of Statistical Programming at Corcept Therapeutics, Inc. She has more than 11 years pharmaceutical experience as a Statistical Programmer across oncology, rheumatoid arthritis, liver, and rare disease therapeutic areas. She started her career as a study statistical programmer at Eli Lilly after graduating from the University of New Orleans, Louisiana, with a Masters of Statistics. Afterwards she continued her career and developed her interests and skills in CDISC data standards, programming, visualization and presentation to fsupport data analysis at Gilead and Corcept Therapeutics.

Laura Harris
Biostatistician, Denali Therapeutics

Bio: Laura is currently a Biostatistician at Denali Therapeutics. Before moving to clinical biostatistics at Denali, Laura built the Data Science and Statistical Programming group as an all-R programming group. She has 15+ years experience in small and large companies in the Biotech/Pharma industry as a Statistical Programmer and Biostatistician for various groups such as Biometrics, Clinical Pharmacology, and Biomarker Development. Her current interests include enabling Biometrics teams to master R and SAS, promoting the use of open-source statistical software in the Biostatistics community via public training and education, and methods to accelerate rare disease development.

Vijay Kumar
Senior Director, Statistical Programming, Kodiak Sciences

Bio: Vijay is a seasoned statistical programmer with 20 years of experience in Pharma/Biotech industry. He started his career at Glaxo Smithkline where he worked on developing applications to analyze ROI using sampling and detailing data. He spent majority of his career (12 year) at Gilead Sciences in various roles. After leaving Gilead, Vijay worked AImmune where he led submission and approval of Palforzia®.

He is currently at Kodiak sciences leading Statistical Programming and Data Science Team. Other than the routine data and TFL development tasks, Vijay like to build applications.
Vijay holds an MBA from Golden Gate University and MS in computer science from New Jersey Institute of Technology.

Outside of work, Vijay like spending time with his family. He enjoys nature. Whenever time permits, Vijay likes to go for hiking, and play pickleball.

Tina Nagrani
Head of Biometrics, CytomX

Bio: Tina Nagrani has been the acting head of Biometrics at CytomX since 2022. In this role she manages the Biostatistics, Data Management and Programming functions. Prior to that Tina led the Statistical Programming and Infrastructure group at CytomX for two years. Some of the highlights of the role at CytomX include creating a CRF part 11 compliant validated SAS server, develop statistical programming SOPs and work instructions, develop clinical and statistical programming expertise in-house to reduce dependency on CROs. Prior to CytomX, Tina worked at BeiGene for over three years where she led the first US and China submission for Brukinsa in Mantle Cell Lymphoma. She has led multiple supplemental filings

throughout her career in the biotech industry, some of which are Ibrutinib in cGVHD, Vectibix in CRC, Erlotinib in Pancreatic Cancer.

Tina has a master's in Pharmacy Administration which emphasis on epidemiology. She is currently taking courses in statistics and computer science at Foothill College.

Houston Gilbert
Vice President of Biometrics and Data Management, Human Immunology Biosciences (HI-Bio)

Bio: Houston Gilbert is Vice President of Biometrics and Data Management at Human Immunology Biosciences (HI-Bio). Houston began his career at Genentech, where he gained hands-on experience in nonclinical biostatistics, translational biostatistics, and early development oncology biostatistics, eventually overseeing part of the early development oncology biostatistics organization. Before joining HI-Bio, Houston was Vice President, Biometrics and Data Management at Arcus Biosciences, where he formally represented Arcus in strategic co-development partnerships with Gilead, AstraZeneca and other companies. Prior to Arcus, Houston led biostatistics efforts at Bellicum Pharmaceuticals, developing hematopoietic stem cell transplant and solid tumor CAR-T assets. Houston has over 15 years of industry experience and holds a BS in Biology from Harvey Mudd College as well as MPH and PhD degrees in Biostatistics from the University of California, Berkeley.

Session Chairs and Organizers

Haijun Ma, PhD (Exelixis)

Bio: Dr. Haijun Ma is the Head of Biostatistics at Exelixis Inc. Before joining Exelixis, she worked at Amgen Inc. and Nektar Therapeutics, where she had roles of increasing responsibilities. She worked in different therapeutic areas and drug development stages ranging from Phase I to post-marketing. She has experience with clinical trials and observational studies using real world data. She is active in promoting good statistical practices and developing statistical methods to tackle practical problems. Her current research interests are in study designs, statistical methods for oncology trials, Bayesian statistics and RWD/RWE. She has published peer reviewed manuscripts and book chapters. She earned her Ph.D. in biostatistics at the University of Minnesota – Twin Cities.

Tuan Nguyen, PhD (Alector)

Bio: Tuan Nguyen is currently a Director of Biostatistics at Alector. He has 12+ years of pharmaceutical industry experience in statistical methodologies and modeling in biomarker analyses supporting phase 1-3 clinical trials in Oncology, Liver, Respiratory and Neurodegenerative therapeutic areas. Before joining Alector, he had worked at Eli Lilly, Gilead, Nektar and Theravance, with special interest in data science/machine learning methods in the context of multivariate prediction and integrative analyses/data mining/subgroup identification. Tuan holds a Ph.D. in Statistics from Rice University.

Merrill Birkner, PhD, MPH (Gilead)

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 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.

Yuan Ji (University of Chicago)

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 hundreds of publications in peer-reviewed journals including across biomedical 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. He received Mitchell Prize in 2015 by the International Society for Bayesian Analysis. He is an elected fellow of the American Statistical Association.

Jeetu Ganju (Ganju Clinical Trials, LLC)

Bio: Jeetu is a clinical trials consultant with training in biostatistics. His focus with pharma companies is on speeding up timelines and collaborating with teams on preparing robust clinical development plans.

For the past few years, he has been working on designing better endpoints, quantifying benefit-risk, and handing data missing not at random.

Rita Lopatin (Grail)

Bio: Rita has 25 years of industry experience focusing on cancer screening, genomic test development in oncology and medical devices. She has led statistical activities on multiple phase 2, 3 and 4 studies, and provided strategic and operational input on the development of long range plans, product offerings and regulatory submissions.
Currently Rita is a Senior Director of Biostatistics at GRAIL, LLC, which is an industry leader in multi-cancer early detection. Rita leads statistical activities across several studies and supports regulatory, marketing and MSL interactions. She also leads a cross-functional team coordinating activities and resources across different programs and provides strategic input to lifecycle planning. Prior to Grail, Rita was a Lead Program Biostatistician (Director level) at Genomic Health, where she was a lead biostatistician on liquid biopsy program and led cross-functional teams for development of novel molecular tests in bladder, colon and renal cancer programs.

Rita received her BS in economic cybernetics from Novosibirsk State University (Russia) and MS in Statistics, minor in Biostatistics, from University of Minnesota. Outside of work, she enjoys hiking, kayaking and traveling around the world.

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With over 16 years of industry experience, we have pioneered the reshaping of clinical trials. CIMS is committed to revolutionizing the industry through our existing eClinical suite, and expertise in Dynamic Trial Design and Dynamic Data Monitoring. With our proprietary closed system, we empower pharmaceutical and biotech companies to expedite the drug development process, saving millions of dollars on clinical trials, and bringing life-saving therapies to patients faster.

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A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 40 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. Genentech has multiple therapies on the market for cancer & other serious illnesses. Please take this opportunity to learn about Genentech where we believe that our employees are our most important asset & are dedicated to remaining a great place to work. For more information, visit our Genentech Careers page, gene.com/careers. Connect with us - @Genentech on Twitter, Facebook or LinkedIn.

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ClinChoice is a global clinical CRO, with over 25 years' experience, dedicated to offering high-quality full clinical development services to Biopharmaceutical clients. ClinChoice has development centers across the US, Canada, China, Europe, India, Japan, and The Philippines with more than 2400 dedicated professionals worldwide. Our Biometrics team has over 600 employees worldwide with extensive experience in Data Management, SAS Programming, and Statistical Analysis services. We have successfully supported numerous development programs in different clinical trial phases and across all therapeutic areas, including NDA/BLA submissions and approvals around the world.

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Corcept Therapeutics, a Bay Area-based biotechnology company, has discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol. The company is committed to improving patient lives through the discovery and development of drugs that address serious unmet medical needs related to excess cortisol activity. To support this mission, Corcept collaborates with numerous basic scientists and clinical researchers. Through our collaborations with researchers around the world, more than 30 studies are underway to investigate the potential benefits GR antagonists may have in the treatment of serious and life-threatening diseases driven by cortisol dysregulation. Current clinical trials include studies evaluating potential treatments for patients with Cushing's syndrome, ovarian and adrenal cancer, weight gain caused by the use of antipsychotic medications and liver disease. Corcept's drug Korlym® was the first medication approved by the U.S. Food and Drug Administration for the treatment of patients with Cushing's syndrome.

Cytel enables decision-makers in the life sciences to unlock the full potential of their products. From navigating uncertainty to proving value, Cytel's 30 years of global expertise in consulting, data-driven analytics, and industry-leading software helps biotechs and pharmaceuticals transform intelligence into confident decisions. We have an uncompromising commitment to scientific rigor and high standards of operational excellence, which are channeled through our locations in North America, Europe, the United Kingdom, and Asia. Together, we enable our clients to deliver the therapies that propel us forward.

DuBu Research ("DuBu") is a biometrics-focused contract research organization (CRO) providing a range of expertise-based statistical services to biotech companies. DuBu was founded by a group of biostatisticians with decades of clinical trial experience in the pharmaceutical/CRO industry. We strongly believe that a highly effective collaboration between a biotech company and a specialized CRO can greatly improve the drug development process. We are customer-focused and believe in quality and efficiency. As your biostatistics CRO, our

biostatisticians work together with your team to determine the best methods for collecting, analyzing, and presenting your data, all in compliance with regulatory guidelines. Our experienced team will provide creative thinking and keen analysis optimized for your unique study design.Contact us today (email: Info@DuBuResearch.com; phone: 929-900-3828 [929-900-DuBu]) to learn how DuBu can provide the best statistical services for your next project.

Everest Clinical Research is a full service contract research organization (CRO) with longstanding and major clinical data management and biostatistics and programming capabilities, stemming from 20 years of supporting North American and global pharmaceutical, biotechnology, and medical device companies in delivering their clinical development programs. Since our company's inception in 2004, Everest has built a strong foundation as a statistical and data management center of excellence, operating primarily in North America with additional subsidiary offices in Shanghai and Taipei. Our high quality and niche focus allows us to deliver industry leading biometrics services, with many pharma and biotechnology clients relying on us as their trusted centralized data and analytical partner.

Building on our customer focused, flexible and data-driven approach, Everest has continuously expanded our service offerings to provide full service clinical trial execution, while still driving significant growth in our foundational biometrics services. We truly support our partners by acting as a proactive and experienced extension of their team, providing timely delivery of routine and complex projects, and bringing templates and libraries to help improve quality and accelerate timelines. A dynamic, people-focused organization with an entrepreneurial origin, Everest continues to drive forward in providing industry-leading clinical research services to companies around the world.

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The 2023 BBSW workshop is sponsored by the American Statistical Association's Biopharmaceutical Section.

Clinvia LLC is a data science company providing services to growing Biotech and Pharma Companies. Clinvia aims to leverage modern AI/ML technologies and provides best in class services to support and transform the clinical trial development landscape. Specifically, we aim to bring faster insights for drug development by creating end-to-end real-time analytics solutions for your customers, improving data quality, and reducing cost of data handling. Please take this opportunity to learn about Clinvia LLC and the services we offer. For more information, please visit Clinvia webpage https://clinvia.com/ or email us at info@clinvia.com.

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Denali Therapeutics is dedicated to defeating neurodegenerative diseases by breaking through historical barriers in scientific research and clinical development with the goal of delivering safe and effective medicines to patients and families. Our scientific approach is based on three core principles: rigorous assessment of genetic targets, engineering brain delivery, and using biomarkers to guide development.

We invite you to learn more at www.denalitherapeutics.com

Our team thrives in a work environment that is scientifically driven, impact-focused, supportive, and collaborative. Our ability to have a positive impact on people's lives is directly related to the trust we have in each other and our ability to unify our diverse backgrounds and experience behind our purpose to defeat degeneration.

Founded in 1994, Exelixis is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Following early work in model system genetics, we established a broad drug discovery and development platform that has served as the foundation for our continued efforts to bring new cancer therapies to patients in need. Our discovery efforts have resulted in four commercially available products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib), COTELLIC® (cobimetinib) and MINNEBRO® (esaxerenone), and we have entered into partnerships with leading pharmaceutical companies to bring these important medicines to patients worldwide. Supported by revenues from our marketed products and collaborations, we are committed to prudently reinvesting in our business to maximize the potential of our pipeline. We are supplementing our existing therapeutic assets with targeted business development activities and internal drug discovery — all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer.

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Pharmapace, a subsidiary of WuXi Clinical, is a Biometrics CRO offering consulting and outsourcing services in statistical planning and analysis, clinical data management, and statistical programming to deliver exceptional quality and value to clinical development, regulatory submissions, medical affairs, safety surveillance, and outcomes research programs. We combine deep statistical expertise with efficient data management and programming capabilities to deliver exceptional quality and value to your clinical trials.

Wu Consulting, Inc. (WCI) was founded in 1996, based in King of Prussia, PA and San Francisco, CA. It specializes in providing statistical support to its pharmaceutical clients in its expertise's area of Biostatistics, SAS Programming, and Data Management. Its FSP team has been recognized as top-notched stat and SAS experts in the pharmaceutical industry.

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SFASA, the San Francisco Bay Area Chapter of the American Statistical Association (ASA), is non-profit organization run by dedicated volunteers. SFASA organizes activities and events for the local community such as: local social gatherings, seminars, student travel awards, activities for K-12 Students, short course, and more.

For more information http://sfasa.net

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