About the Symposium

Where will the AI revolution take Pharmaceutical Science?

The Pfizer/ Northeastern/ASA Symposium on Risks and Opportunities of AI in Pharmaceutical Medicine (AIPM) is an event jointly sponsored by Pfizer Inc., the Roux Institute at Northeastern University and the American Statistical Association (ASA).

Our world increasingly relies on data and computing to create knowledge, to make critical decisions, and to better predict the future. Data science has emerged to support these data-driven activities by integrating and developing ideas, concepts, and tools from computer science, engineering, information science, statistics, and domain fields. Data science now drives fields as diverse as biology, astronomy, material science, political science, and medicine—not to mention vast tracts of the global economy, key government activities, and quotidian social and societal functions.

The pharmaceutical enterprise has been slower to respond, especially to the rapid developments in AI, but tectonic shifts are underway in approaches to the discovery, development, evaluation, registration, monitoring, and marketing of medicines for the benefit of patients and the health of the community.

While there is much discussion about the potential of AI and modern machine learning tools to transform the drug development paradigm, there is a growing recognition of the paucity of research about the opportunities, inevitable pitfalls and unintended consequences of the digital revolution in this important area of application. As we move toward personalized and truly evidence-based medicine, the use of AI and machine learning to optimize drug deployment raises a whole different set of challenges.

This forum is, therefore, expected to serve as a platform for distinguished statisticians, data scientists, regulators, and other professionals to address the challenges and opportunities of AI

in pharmaceutical medicine; to foster collaboration among industry, academia, regulatory agencies, and professional associations; and to propose recommendations with policy implications for proper implementation of AI in promoting public health.

Co-Chairs

David Madigan, Ph.D., **Provost and Senior Vice President for Academic Affairs, Northeastern University**

David Madigan, Ph.D., came to Northeastern from Columbia University, where he served as executive vice president for arts and sciences and dean of the Faculty of Arts and Sciences. In those roles, he oversaw five schools with 27 departments and some 50 research centers and institutes. He led successful initiatives to expand lifelong learning programs, and to make Columbia's faculty and student body more diverse. Notably, he spearheaded a program to ensure that Columbia's first-generation students would have the mentoring and support they needed to succeed in a highly demanding academic environment.

At Columbia and in his previous position as Rutgers University's Dean of Physical and Mathematical Sciences, Madigan developed new interdisciplinary learning and research collaborations, and forged industry partnerships to support student and faculty innovation. Under his leadership as department chair, Columbia's statistics faculty ascended to the ranks of the nation's top 10.

A Fellow of the American Association for the Advancement of Science, Madigan has long been a leading researcher at the intersection of Big Data with healthcare innovation. While serving on the statistics faculty at the University of Washington, he was a member of the world-renowned Fred Hutchinson Cancer Research Center.

Madigan also brings a strong global perspective to Northeastern. A native of Ireland, he has led large-scale global collaborations involving academic and pharmaceutical company researchers and government regulators in the U.S. and Europe. Beyond the halls of academia, he has experience as an entrepreneur, innovation leader, researcher, and consultant, both in the U.S. and Ireland. He earned his BA and PhD from Trinity College Dublin.

Demissie Alemayehu, Ph.D., is Vice President of Biostatistics and Head of Statistical Research and Data Sciences (SRDC) in Global Biometrics and Data Management (GBDM) at Pfizer Inc. Demissie has over 25 years of leadership experience in the pharmaceutical industry and has supported projects in almost all therapeutic areas. Demissie has also been influential externally, with decades of research and teaching experience at major institutions. He has co-authored three monographs and published numerous manuscripts in peer-reviewed journals. In addition, he has held important offices at key professional societies, and has served on editorial boards of major journals. He is an elected *Fellow* of the American Statistical Association, and holds a Ph.D. degree in Statistics from the University of California at Berkeley.

Steering Committee

Asieh Golozar, Ph.D., **Vice President, Global Head of Data Science, Odysseus Data Services, Inc.**

Asieh Golozar, Ph.D., is a physician-epidemiologist and biostatistician with more than 20 years of experience in health services research, real-world evidence generation, and evaluation of healthcare interventions within government, academia, and industry. She holds a PhD in epidemiology from the Johns Hopkins University School of Public Health and a Master of Health Sciences in biostatistics from JHU, supported by a postdoctoral research fellowship award with the National Cancer Institute's Division of Cancer Epidemiology and Genetics. She earned her medical degree from the Tehran University of Medical Sciences.

After receiving her PhD, Golozar joined the faculty at the JHU Department of Epidemiology, where she focused on cancer and diabetes epidemiology, the application of epidemiologic and statistical methods for robust synthesis of evidence from epidemiologic data, and applying evidence-based findings to strengthen public heath infrastructure and policies. In 2017, she moved into industry roles at Bayer AG, AstraZeneca, and Regeneron, where she led lifecycle

management and real-world evidence generation activities in oncology, women's health, and other therapeutic areas.

As a professor of the practice, Golozar brings a comprehensive knowledge of healthcare systems to Northeastern. She also has the skills in research methodology and statistics required for addressing safety and effectiveness outcomes and risk assessment, and for generating high quality real-world evidence (RWE) from real-world data. She has played leading roles in large-scale private-public partnerships, including the Innovative Medicines Initiative (IMI) Big Data for Better Outcomes project and the IMI PIONEER Prostate Cancer Study-a-thon.

Since 2018, Golozar has led the OHDSI Oncology Working Group, endeavoring to extend the OMOP common data model to support oncology use cases and advance oncology real-world evidence research. In 2021, Golozar received an OHDSI Titan Award for Clinical Application. In addition to her role at Northeastern, Golozar is an adjunct faculty member at the JHU School of Public Health and vice president of data science at Odysseus Data Services, a leading RWE technology vendor.

Kannan Natarajan, Ph.D., **Senior Vice President, Head of Data Sciences & Analytics, Pfizer Inc.**

Kannan Natarajan, Ph.D., Kannan is Senior Vice President, Head of Data Sciences & Analytics (DSA) and is a leadership team member in the Chief Medical Office at Pfizer Inc. The DSA organization consists of Statistics, Statistical Data Sciences & Analytics and the Advanced Quantitative Data Sciences functions. Each of the functions within DSA support end-to-end development from non-clinical to market access and medical affairs and contributes to the global clinical development and regulatory strategy across all of Pfizer's product portfolio. Prior to this role, Kannan was Senior Vice President, Head of Global Biometrics and Data Management (GBDM).
Kannan is a registered board member of Pfizer Healthcare India Pvt Ltd (PHIPL). PHIPL consists of colleagues in India supporting global Pfizer Research & Development, including product manufacturing. In his role as a PHIPL board member, Kannan represents over 600 Clinical Development colleagues located in the Chennai and Mumbai offices.

He has been in the pharmaceutical industry for over 30 years, working across various therapeutic areas. Prior to joining Pfizer in 2016, he was Senior Vice President and Global Head of Oncology Biometrics and Data Management at Novartis Pharmaceuticals. Kannan holds a Masters in Statistics from the Indian Statistical Institute, Kolkata, India, and a PhD. in Statistics from the University of Florida, Gainesville. Kannan is an elected Fellow of the American Statistical Association.

Ron Wasserstein, Ph.D., **Executive Director, American Statistical Association**

Ronald L. (Ron) Wasserstein, Ph.D., is the executive director of the American Statistical Association (ASA). Wasserstein assumed the ASA's top staff leadership post in August 2007.
In this role, Wasserstein provides executive leadership and management for the association and is responsible for ensuring that the ASA fulfills its mission to promote the practice and profession of statistics. He also is responsible for a staff of 36 at the ASA's headquarters in Alexandria, Va. As executive director, Wasserstein also is an official ASA spokesperson.

Prior to joining the ASA, Wasserstein was a mathematics and statistics department faculty member and administrator at Washburn University in Topeka, Kan., from 1984–2007. During his last seven years at the school, he served as the university's vice president for academic affairs.

Wasserstein is a longtime member of the ASA, having joined the association in 1983, and prior to becoming Executive Director had been active as a volunteer in the ASA for more than 20 years. He was a member of the ASA Board of Directors from 2001–2003.

Wasserstein is a Fellow of the ASA and of the American Association for the Advancement of Science. He was presented the John Ritchie Alumni Award and Muriel Clarke Student Life Award from Washburn University, the Manning Distinguished Service Award from the North American Association of Summer Schools, and the George Mach Distinguished Service Award from Kappa Mu Epsilon National Mathematics Honor Society. For his community service, he received the Champion of Character Award from the Fairfax County Athletic Council and the Administrator of the Year Award from the Virginia Youth Soccer Association.

Ron and his wife, Sherry, live in northern Virginia and enjoy traveling, movies, binge-watching TV series, live theater, audio books, and doting on their children and grandchildren.

Key Details

Conference Co-Chairs

Demissie Alemayehu, Pfizer Inc.

David Madigan, Northeastern University

Date & Time

June 9-10, 2025

Day 1: 12:00 pm-5:00 pm EDT

Day 2: 8:00 am-7:30 pm EDT

Location

Ocean Gateway

14 Ocean Gateway Pier

Portland, Maine 04101

Hotel

AC Hotel Portland Downtown/Waterfront, ME

158 Fore Street Portland, Maine, 04101

Contact Us

For program-related queries, please reach out to:

Demissie Alemayehu demissie.alemayehu@pfizer.com

Program Committee Members

- Demissie Alemayehu, Pfizer Inc.
- Javier Cabrera, Rutgers University
- Margaret Gamalo, Pfizer Inc.
- Larry Han, Northeastern University
- Nareen Katta, AbbVie
- Tania Konry, Northeastern University
- Hana Lee, US Food and Drug Administration
- Subha Madhavan, Pfizer Inc.
- David Madigan, Northeastern University

- Kristin Mohebbi, ASA
- Tristan Naumann, Microsoft
- Malaikannan Sankarasubbu, SAAMA
- Elizabeth Stuart, Johns Hopkins University
- Suzanne Taranto, Pfizer Inc.
- Bingzhi Zhang, Sanofi

Keynote Speaker 1

Robert Califf, M.D., MCAA
Former Commissioner
Food and Drug Administration
Professor of Medicine
Duke University School of Medicine

Robert M. Califf, MD, MACC, was the Commissioner of Food and Drugs from February 2016 to January 2017 and from February 2022 to January 2025. He is currently Instructor in Medicine at Duke University School of Medicine. Between his two stints at FDA, Dr. Califf was the head of medical policy and strategy for Alphabet's subsidiaries Verily and Google Health. Previously, Dr. Califf served as the FDA's Deputy Commissioner for Medical Products and Tobacco from February 2015 until his appointment as Commissioner in February 2016.

Prior to joining the FDA, Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with more than 1,200 publications in peer-reviewed literature.

Dr. Califf became a Member of the National Academy of Medicine (formerly known as the Institute of Medicine (IOM)) in 2016, one of the highest honors in the fields of health and medicine. Dr. Califf has served on numerous IOM committees, and he has served as a member of the FDA Cardiorenal Advisory Panel and FDA Science Board's Subcommittee on Science and Technology. Dr. Califf has also served on the Board of Scientific Counselors for the National Library of Medicine, as well as on advisory committees for the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Environmental Health Sciences and the Council of the National Institute on Aging.

While at Duke, Dr. Califf led major initiatives aimed at improving methods and infrastructure for clinical research, including the Clinical Trials Transformation Initiative (CTTI), a public-private

partnership co-founded by the FDA and Duke. He also served as the principal investigator for Duke's Clinical and Translational Science Award and the NIH Health Care Systems Research Collaboratory coordinating center.
Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco and a fellowship in cardiology at Duke.

Keynote Speaker 2

Jeremy Forman
Pfizer Inc
Vice President
Research & Development AI, Data, & Analytics

Jeremy Forman is the Vice President, R&D AI, Data, and Analytics at Pfizer Inc. Jeremy brings over 25 years of expertise in data-driven innovation and artificial intelligence. His career is marked by strategic leadership roles where he has harnessed the power of AI and data to drive business growth, enhance customer and employee experiences, and foster a culture of innovation and responsible use of technology. Jeremy's experience extends beyond the corporate world into academia, where he shares his knowledge as an Adjunct Professor at the Tippie School of Business, University of Iowa. His work at the Bill & Melinda Gates Foundation, Oracle Corporation, and Los Alamos National Laboratory further underscores his global perspective, strategic thinking, and commitment to sustainability and social responsibility.
Jeremy lives in Seattle with his wife, Bernadette, dogs Axel and Piper, and with his two grown children nearby. When not working Jeremy can be found on his bike, playing guitar, or enjoying the food and wine of the Pacific Northwest.

Program

Day 1 (June 9, 2025)
All times are in Eastern Time.

11:00 AM – 12:00 PM	**Registration**
12:00 PM – 5:00 PM	**Tutorials** (Coordinators, Nareen Katta, AbbVie; Margaret Gamalo, Pfizer Inc.)
12:00 PM – 2:00 PM	**Tutorial 1:** Large Scale Processing and Analysis of Wearable Device Data. Yiorgos Christakis, Pfizer Inc and Lukas Adamowicz, Pfizer Inc.
2:00 PM – 2:15 PM	**Break**
2:15 PM – 5:00 PM	**Tutorial 2:** TMLE in Drug Development. Susan Gruber, TL Revolution, Hana Lee, U.S. Food and Drug Administration, and Mark van der Laan, UC Berkeley

Day 2 (June 10, 2025)
All times are in Eastern Time.

7:00 AM – 8:00 AM	**Registration and Breakfast**
8:00 AM – 8:05 AM	**Welcome:** David Madigan, Northeastern University; Kannan Natarajan, Pfizer, Inc; and Ron Wasserstein, American Statistical Association.
8:05 AM – 9:00 AM	**Keynote Address,** Jeremy Forman, Pfizer Inc., Moderator, Demissie Alemayehu, Pfizer Inc.
9:00 AM – 10:40 AM	**Plenary Session 1,** Chair, Bingzhi Zhang, Sanofi "AI and digital health for drug discovery and development". Tommaso Mansi, Johnson and Johnson. "Targeted Learning, HAL, and Causal Inference for Generating Real-World Evidence in Drug Development". Mark van der Laan, UC Berkeley "Using Statistical Foundations to Demonstrate Effectiveness of AI/ML Algorithms for Clinical Utility". Charmaine Demanuele, Pfizer Inc. "Transforming Pharmacovigilance with AI: A Roadmap". Hussein Ezzeldin, FDA
10:40 AM – 10:50 AM	**Break/Posters**
10:50 AM – 12:30 PM	**Plenary Session 2**, Chair, Javier Cabrera, Rutgers University "Safety First: Systematic Approaches to Hallucination Mitigation in Clinical AI". Malaikannan Sankarasubbu, Saama Technologies "Stage-Aware Learning for Dynamic Treatments". Annie Qu, UC Irvine "Leveraging the power of AI/ML to enhance statistical inference in clinical trials: opportunities and learnings". Scott McClain, SAS "Testing and decision making with e-values". Aaditya Ramdas, Carnegie Mellon

12:30 PM – 2:00 PM	**Lunch**
2:00 PM – 3:00 PM	**Fireside Chat** with Robert M. Califf, former U.S. Commissioner, Food and Drug Administration; Duke University School of Medicine Moderator, David Madigan, Provost, Northeastern University
3:00 PM – 4:00 PM	**Panel Discussion** on "Statistics/Data Science Leadership in the Era of AI /ML in Pharma". Biopharma Statistics Leadership Consortium. Moderator, Kannan Natarajan, Pfizer Inc. Panelists: Matt Austin, Amgen Jingyi Liu, Eli Lilly and Company Surya Mohanty, Johnson and Johnson Melanie Poulin-Costello, Roche
4:00 PM – 4:15 PM	**Break**
4:15 PM – 5:25 PM	**Keynote Panel**: "Responsible AI in Medical Research", Moderator, Subha Madhavan, Pfizer Inc. Panelists: Tala Fakhouri, Food and Drug Administration Andy Houseman, Sanofi Suchi Saria, Johns Hopkins University Ayan Paul, Northeastern University Ajay Yekkirala, Superluminal Medicines Inc.
5:25 PM – 5:30 PM	Closing Remarks and Acknowledgments, Demissie Alemayehu, Pfizer Inc.
5:30 PM – 7:30 PM	**Networking Reception** Roux Institute, Northeastern University 100 Fore Street, Portland, ME 04101

Speakers

Our distinguished speakers represent the forefront of AI innovation in pharmaceutical medicine, bringing together leading experts from top research institutions, pharmaceutical companies, and regulatory agencies. From pioneering data scientists to experienced industry practitioners, these thought leaders will drive critical discussions about AI's transformative potential in healthcare.

Matt Austin, M.S.
Executive Director
Amgen

Matt Austin, M.S., currently leads a Data Science team in Clinical Development at Amgen. He has over 25 years of industry experience including time in biostatistics before forming his current team. He enjoys collaborating with groups across Clinical Development to identify key issues and find solutions to help optimize our performance. His team mixes engineering and data science roles to effectively move from prototypes to production and has projects in production using advanced statistical techniques, AI/ML, and GenAI approaches.

Charmaine Demanuele, Ph.D.
Executive Director
AI/ML Quantitative and Digital Sciences
Global Biometrics and Data Management
Pfizer Inc.

Dr. Charmaine Demanuele, Ph.D., is Vice President of R&D Data Science & Digital Health for Neuroscience at Johnson & Johnson Innovative Medicine. She leads efforts to transform neuroscience drug discovery and development by integrating multiomics, real-world evidence, and novel digital endpoints. Before joining J&J, Charmaine was Executive Director in Pfizer's AI/ML Quantitative and Digital Sciences group within the Global Biometrics & Data Management organization, where she developed new digital endpoints across therapeutic areas, and advanced efficient, patient-centric clinical trials using approaches such as Bring-Your-Own-Device and decentralized trials. Charmaine holds a PhD in Neuroscience and conducted postdoctoral research in psychiatric neuroimaging at the Bernstein Center for Computational Neuroscience in Germany and at Harvard Medical School. A recognized thought leader, Charmaine actively drives the cross-industry adoption of AI and digital health technologies, contributing to global consortia, regulatory initiatives, and academic programs that are shaping the future of digital medicine and clinical research.

Hussein Ezzeldin, Ph.D.
Associate Director for Advanced Technologies
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Biostatistics and Pharmacovigilance
Dr. Ezzeldin, Ph.D., is the Associate Director for Advanced Technologies in the Office of Biostatistics and Pharmacovigilance (OBPV), in the Center for Biologics Evaluation and Research (CBER). Dr. Ezzeldin supported multiple programs in previous roles, for example, leading the digital health technology review team, and leading the natural history study for metachromatic leukodystrophy, HOME, among other initiatives. Currently, Dr. Ezzeldin leads the Biologics Effectiveness and Safety Innovative Methods Initiative (BEST IM), which aims to develop new and innovative methods for a semi-automated adverse events (AEs) reporting system for CBER-Regulated Biological Products.

Tala H. Fakhouri, Ph.D., MPH
Associate Director for Policy Analysis
Food and Drug Administration
Tala H. Fakhouri, Ph.D., MPH, is the Associate Director for Policy Analysis at the Food and Drug Administration. Dr. Fakhouri manages a team tasked with developing, coordinating, and implementing medical policy with a focus on the use of Artificial Intelligence (AI) in drug development. She also contributes to the development of medical policy related to real-world evidence (RWE) for medical product development. In 2023, She was selected by the Office of Management and Budget to serve on the Federal Committee for Statistical Methodology for her expertise in statistical methods. Prior to joining FDA, Dr. Fakhouri served as Chief Statistician for the CDC's flagship population survey, the National Health and Nutrition Examination Survey (NHANES), which is recognized as the premier source of nationally representative data on the health of the nation. Prior to NHANES, she served as an Epidemic Intelligence Service Officer with the CDC, and deputy lead for health surveys at ICF-Macro International. Dr. Fakhouri published over 30 government reports, peer-reviewed papers, and book chapters.

Dr. Fakhouri earned a Ph.D. in Oncological Sciences from The Huntsman Cancer Institute at the University of Utah, an MPH in Epidemiologic and Biostatistical Methods from the Johns Hopkins University School of Public Health, and a postdoctoral fellowship in molecular biology and genetics from Harvard University, and holds a BSc Medical Technology from the Jordan University of Science and Technology.

Andy Houseman, Ph.D.
Senior Project Leader
Statistical Innovation Hub
Sanofi

Andy Houseman, Ph.D., is a Senior Project Leader / Team Leader in the Statistical Innovation Hub at Sanofi. He has been at Sanofi for almost three years [as of June 2025], before which he held biomarker statistics positions at GSK. In the more distant past, he held faculty positions (research faculty at Harvard and Brown, tenured at Oregon State) before pivoting his career to work in the pharmaceutical industry. He has published extensively in Biostatistics, Bioinformatics, and subject matter areas that utilize biostatistical methods.

Jingyi Liu, Ph.D.
Associate Vice President
Head of the Cardio-Metabolic Health Statistics
Eli Lilly and Company

Dr. Jingyi Liu, Ph.D., serves as Associate Vice President and Head of the Cardio-Metabolic Health Statistics group at Eli Lilly and Company. In this role, he leads a global team of over 100 statisticians supporting early- and late-phase clinical development, medical affairs, and commercialization initiatives.

Dr. Liu earned his Ph.D. in Statistics from the University of California, Davis, and joined Eli Lilly in 2009. Over the years, he has held numerous leadership and technical positions across multiple therapeutic areas, including oncology and immunology.

A recognized leader in the field, Dr. Liu is actively engaged with the American Statistical Association (ASA). He is the founder of the STATBOLIC working group, which brings together industry, academic, and regulatory stakeholders to address statistical challenges in metabolic

disease research. Additionally, he serves as co-chair of the Covariate Adjustment Working Group under the ASA Biopharmaceutical Section.
Dr. Liu has also been instrumental in advancing Artificial Intelligence initiatives within the drug development lifecycle, further contributing to innovation and efficiency in pharmaceutical research.

Subha Madhavan, Ph.D.
Vice President and Head
AI/ML, Quantitative and Digital Sciences, Research and Development
Pfizer Inc.

Subha Madhavan, Ph.D., is a dynamic and results-driven leader with a strong track record of excellence in organizations that operate at the nexus of science, technology and business. She has initiated and successfully directed several productive clinical research and development programs at the Georgetown Lombardi Comprehensive Cancer Center, MedStar hospital network, FDA, NIH and BioPharma industry. She was co-leader of the FDA's Center for Excellence in Regulatory Science and worked with the oncology and vaccine teams. She was an advisory member to the Biden Foundation's Cancer Moonshot Program and advised on pre-competitive data sharing initiatives across pharma, health tech companies and research organizations to drive innovation. She has been recognized for her work through several awards including the Service to America award in the Science and Environment category (2005), Research Acceleration Award by AACR and Pancreatic Cancer Action Network (2015), and Women in Tech Global award (2021). She is currently the Head of Clinical AI/ML & Digital Sciences at Pfizer worldwide R&D where she leads a team focused on advancing precision therapies across multiple treatment areas including Anti-Infectives, Oncology, Immunology & Inflammation among others.

Tommaso Mansi, Ph.D.

VP of AI/ML and Digital Health

The Janssen Pharmaceutical Companies of Johnson & Johnson

Tommaso Mansi, Ph.D., is a member of the IEEE and received his Ph.D. degree from INRIA Sophia Antipolis in 2010. He is currently serving as the VP of AI and Digital Health at Janssen: Pharmaceutical Companies of Johnson and Johnson. He then worked at Siemens Healthineers, prior to joining Janssen. His research focuses on artificial intelligence, medical imaging, computational physiology, and image-guided therapy, with the goal to develop solutions to enable next generation treatments. He is currently an AIMBE Fellow. He and his team have been honored of multiple awards, in particular the Siemens Inventor of the Year 2020, the MICCAI Young Scientist (2011, 2013, and 2018), and the NJ Thomas Alva Edison Patent Award (2015 and 2019).*(Based on document published on 19 January 2022).* https://www.tmansi.net/

Scott McClain, Ph.D.

Principal Industry Consultant

SAS Life Sciences

Scott McClain, Ph.D., brings 33 years of experience in toxicology, biotechnology, and product safety risk assessment. His academic background is environmental and molecular toxicology with a focus in quantitative risk assessment. He received his advanced degrees from Miami University of OH. Career industry experiences ranges across immunology combined with cellular genetics, disease model research and analytics/statistics. More recently, the focus has been on regulatory safety data communications and analytic process development with global regulatory agencies. He currently serves as strategic advisor to the Health and Life Science practice at SAS Institute, Inc.

Surya Mohanty, Ph.D.
Head of Translational Medicine and Early Development Statistics (TMEDS)
Johnson & Johnson

Surya Mohanty, **Ph.D.**, heads Translational Medicine and Early Development Statistics (TMEDS) at Johnson & Johnson. He leads a team of statistical scientists who provide strategic and statistical leadership in drug discovery and early-stage research. With a Ph.D. in Mathematical Statistics from Yale University, his career spans roles at IBM Research and several biopharmaceutical companies, including Bristol-Myers Squibb and Johnson & Johnson. His work has significantly contributed to drug development, regulatory submissions, and innovative statistical methodologies.

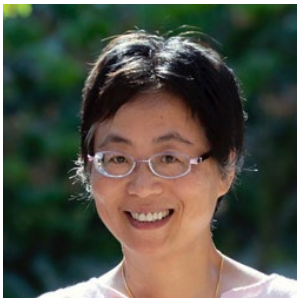
Ayan Paul, Ph.D.
Research Scientist
The Institute of Experiential AI
Northeastern University

Ayan Paul, Ph.D., is the PI of the Neural Dynamics Lab at the Institute for Experiential AI, Northeastern University. Paul's research focuses on RNA biology, and Protein structure and function prediction and evolution, which includes understanding transcriptome and protein diversity, cell differentiation, and disease-causing genetic variants through the use of graph neural networks and large language models. The goal of his work is to develop targeted therapeutics for complex diseases such as chronic obstructive pulmonary disease and small-cell lung cancer. His work also covers understanding immune cell biology for personalized immunotherapy using single-cell function-to-omics methods.
Paul's academic journey includes a doctorate in theoretical particle physics from the University of Notre Dame, followed by positions as a postdoctoral fellow at INFN in Rome, a Fellow at DESY, and a senior scientist at Humboldt Universität zu Berlin before joining the Institute for Experiential AI in 2022. His research spans a range of fields including particle physics, quantum field theory, mathematical epidemiology, computational socioeconomics, interpretable machine learning, genetics, and proteomics.
Among his notable scientific achievements, Paul contributed to the theoretical predictions that led to the discovery of CP violation in charm mesons, which stands as the second most significant discovery at CERN after the Higgs Boson. During the COVID-19 pandemic, he made

significant contributions to understanding disease spread and highlighted why automated contact tracing would fail without population-wide participation, which led to further scientific contributions in mathematical epidemiology funded by the Volkswagen Foundation and the German Ministry of Education and Research.

Beyond academic research, Paul has ventured into entrepreneurship as co-founder of two companies. At CoVis Inc., he developed algorithms for individual disease risk prediction that powered an app for pandemic mitigation across Germany, Austria, Belgium, and the United States. As Chief Scientific Officer of KarmaV Inc., he developed algorithmic implementations of diversity, equity, and inclusion solutions for workforce transformation and recruitment.

Paul also demonstrates strong commitment to service and leadership, serving on the Steering Committee for the Asian Faculty and Staff affinity group at Northeastern University, leading DE&I initiatives in both Germany and the United States, and holding a leadership position in sustainability initiatives within the High Energy Physics and Scientific Computing community.



Annie Qu, Ph.D.
Chancellor's Professor
Department of Statistics
University of California, Irvine

Annie Qu, **Ph.D.,** is Chancellor's Professor, Department of Statistics, University of California, Irvine. She received her Ph.D. in Statistics from the Pennsylvania State University in 1998. Qu's research focuses on solving fundamental issues regarding structured and unstructured large-scale data and developing cutting-edge statistical methods and theory in machine learning and algorithms for personalized medicine, text mining, recommender systems, medical imaging data, and network data analyses for complex heterogeneous data. The newly developed methods can extract essential and relevant information from large volumes of intensively collected data, such as mobile health data. Her research impacts many fields, including biomedical studies, genomic research, public health research, social and political sciences. Before joining UC Irvine, Dr. Qu was a Data Science Founder Professor of Statistics and the Director of the Illinois Statistics Office at the University of Illinois at Urbana-Champaign. She was awarded the Brad and Karen Smith Professorial Scholar by the College of LAS at UIUC and was a recipient of the NSF Career award from 2004 to 2009. She is a Fellow of the Institute of Mathematical Statistics (IMS), the American Statistical Association, and the American Association for the Advancement of Science. She is also a recipient of IMS Medallion Award and Lecturer in 2024. She serves as

Journal of the American Statistical Association Theory and Methods Co-Editor from 2023 to 2025 and as IMS Program Secretary from 2021 to 2027.
Qu Lab website: https://faculty.sites.uci.edu/qulab/

Aaditya Ramdas, Ph.D.
Associate Professor
Department of Statistics and Data Science
Machine Learning Department
Carnegie Mellon University

Aaditya Ramdas, Ph.D., is an Associate Professor in the Department of Statistics and Data Science and the Machine Learning Department at Carnegie Mellon University, as well as a visiting academic at Amazon Research. His work has been recognized by the Sloan fellowship, the IMS Peter Hall Early Career Prize, the inaugural COPSS Emerging Leader Award, the Bernoulli New Researcher Award, the NSF CAREER Award, faculty research awards from Google and Adobe, and discussion papers at *JASA* and *JRSSB*.

Malaikannan Sankarasubbu
Chief Technology Officer
Saama Technologies

Malaikannan Sankarasubbu, is the Chief Technology Officer at Saama Technologies, where he leads initiatives to accelerate clinical trials through advanced artificial intelligence and analytics. With over 15 years in software product development, Malaikannan is dedicated to "bringing certainty to uncertainty" in AI research and life sciences, helping streamline clinical trials for faster, more reliable outcomes. As a seasoned entrepreneur, he has founded companies and built high-performance teams that drive innovation in healthcare.
His research spans Natural Language Understanding, uncertainty bounds, and Explainable AI, contributing to transparent and effective AI applications in precision medicine. With numerous peer-reviewed publications in major conferences, [available on Google Scholar] (https://scholar.google.com/citations?user=znWv6tUAAAAJ&hl=en), Malaikannan is a thought leader advancing AI's role in life sciences, bringing new insights and efficiency to clinical research.

Suchi Saria, Ph.D.

John C. Malone Associate Professor of Computer Science at the Whiting School of Engineering and of Statistics and Health Policy at the Bloomberg School of Public Health

John Hopkins University

Suchi Saria, Ph.D. is the founder and president of Bayesian Health, the most scientifically advanced clinical AI platform company that augments care teams by bringing together state of the AI/ML technology combined with responsible AI best practices to dramatically improve quality while saving clinicians' time. She is also an AI Professor at Johns Hopkins where she holds the John C. Malone endowed chair and is the Director of AI and health lab.

Dr. Saria's work in AI over the last two decades has led to foundational advances in technology, best practices around translation, and AI policy. She has written several seminal papers in AI/ML around issues of learning robust models, detecting drifts, monitoring and learning from messy real-world datasets. Her applied research has built on these technical advances to develop novel next generation diagnostic and treatment planning tools that use AI/ML to individualize care. Her work has been funded by leading organizations including the NSF, DARPA, FDA, NIH and CDC and she regularly serves as a scientific advisor to leading Fortune 500 companies.

Dr. Saria completed her PhD in AI at Stanford, her BSc in Physics, Computer Science and Statistics at Mount Holyoke. She's a Sloan Research Fellow, named by IEEE to "AI's 10 to Watch", Modern Healthcare's Top 25 Innovators, World Technology Forum' Technology Pioneer, and her work was recognized as one of TIME's Best Inventions in 2023. Her work with Bayesian has also received FDA Breakthrough Designation. She is a co-founder and on the board of directors for Coalition of Health AI (CHAI) and serves on the National Academy of Medicine AI Code of Conduct.

Mark Van Der Laan, Ph.D.
Jiann-Ping Hsu/Karl E. Peace Professor
Biostatistics and Statistics
University of California, Berkeley

Mark Van Der Laan, Ph.D., is Jiann-Ping Hsu/Karl E. Peace Professor of Biostatistics and Statistics at UC Berkeley, co-Director of the Center for Targeted Machine Learning and Causal Inference (CTML) Research Center, Director of the Computational Biology core of the UC Berkeley Superfund Research Program and co-founder of TL Revolution. He developed Targeted Learning, TMLE, and super learning based on decades of research on causal inference, survival analysis, censored data, multiple testing, machine learning, and semiparametric models. Dr. van der Laan has been awarded numerous research grants and prestigious awards, including the Presidents' Award of the Committee of Presidents of Statistical Societies, the Mortimer Spiegelman Award and the van Dantzig Award.

Ajay Yekkirala, Ph.D.
Co-Founder and SVP, Head of Discovery
Superluminal

Ajay Yekkirala, Ph.D., is an experienced drug hunter who is also a serial entrepreneur and inventor. As Co-founder and Head of Discovery and Development at Superluminal, Ajay directs scientific and experimental efforts across various programs. Prior to Superluminal, Ajay founded Blue Therapeutics to develop non-addictive painkillers and before that had trained with Philip Portoghese at the University of Minnesota for his PhD and completed postdoctoral training with Clifford Woolf at Harvard Medical School. He has authored several papers published in high-impact, peer-reviewed journals, including book chapters and invited reviews. Ajay is also an expert KOL advising various committees at the NIH – including EPPIC-NET at NINDS and Medication Development Research Committee at NIDA.

Bingzhi Zhang, Ph.D.
Biostatistical Team Leader
Sanofi

Bingzhi Zhang, Ph.D., is the Biostatistical Team Leader at Sanofi. Her work is dedicated to bridging the gaps between project execution and innovative study design and decision-making approaches, making use of emerging sources for evidence generation. Her research interests include study designs utilizing external/historical data, master protocols and AI/ML-powered study design. She received her Ph.D. in Biostatistics from Columbia University.

Tutorial Instructors, Poster Coordinators, and Poster Presenters

Lukas Adamowicz, M.S.
Senior Data Scientist
Pfizer Inc.

Lukas Adamowicz, M.S, has an MS in Mechanical Engineering from the University of Vermont. He has been with Pfizer for approximately five years and works with wearable inertial sensor data, implementing and improving algorithms for extracting novel digital endpoints, as well as the deployment of those algorithms at scale. He published the open-source SciKit Digital Health package, a collection of these algorithms. In his spare time, he enjoys biking, running, and skiing outside in Vermont.

Javier Cabrera, Ph.D.
Professor
Department of Statistics, Department of Medicine
Rutgers University

Javier Cabrera, Ph.D., is a Professor in the Department of Statistics and the Department of Medicine, Rutgers University, and a member of the Cardiovascular Institute of New Jersey and the Institute of Quantitative Biomedicine. He is a winner of the 2010 SPAIG award of the American Statistical Association, a Fulbright Fellow, and a Henry Rutgers Fellow. He was Director of the Institute of

Biostatistics at Rutgers University and the chief co-editor of the journal, *Computational Statistics and Data Analysis*. Professor Cabrera has numerous publications and books in Statistics and Biostatistics on diverse topics, including, Big Data for medical research, functional genomics, analysis of genomic data, statistical computing, graphics, and computer vision. He received his PhD from Princeton University.

Yiorgos Christakis, M.S.
Associate Director of Data Science
Pfizer Inc.

Yiorgos Christakis, MS, is an Associate Director of Data Science at Pfizer, Inc., where he has been contributing since 2018. With a background in Biomedical Engineering and Computer Science, Yiorgos specializes in developing and deploying novel digital endpoints in clinical trials. He also works on developing algorithms for wearable data and building scalable cloud pipelines.
Yiorgos holds a BS in Biomedical Engineering from Boston University and an MSc in Computer Science with a focus on Machine Learning from Georgia Institute of Technology.

Mingshi Cui
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Mahan Dastgiri
Department of Statistics
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Susan Gruber, Ph.D., M.P.H., M.S.

Co-Founder TL Revolution

Founder of Putnam Data Sciences

Dr. Susan Gruber, **Ph.D., M.P.H., M.S.**, is a biostatistician and computer scientist who founded Putnam Data Sciences, a statistical consulting firm specializing in causal inference and predictive modeling and co-founded TL Revolution with Dr. van der Laan. She is the former Director of the Biostatistics Center, Department of Population Medicine at Harvard Pilgrim Health Care and Harvard Medical School, and former Senior Director of the IMEDS Methods program at the Reagan Udall Foundation for the FDA. Dr. Gruber is an expert on targeted learning who developed the first open-source R package for TMLE and has an extensive record of publications, presentations, and training sessions on Targeted Learning.

Larry Han, Ph.D.

Assistant Professor of Health Sciences

Department of Health Sciences

Bouvé College of Health Sciences

Northeastern University

Larry Han, **Ph.D.**, develops novel statistical and machine learning methodology to synthesize real-world data and integrate information from heterogeneous data sources to improve decision-making in clinical medicine and public health. His research interests include causal inference, conformal prediction, federated learning, transfer learning, surrogate markers, quality measurement, healthcare operations, and sensitivity analysis. His applied interests include clinical trial design and the safe, efficient, and robust use of observational study data such as electronic health records. In addition to his methodological research, he has experience leading epidemiological studies in disease areas such as COVID-19, cardiology, dementia, and infectious diseases (e.g., HIV, STIs, malaria).

Nareen Katta, M.B.A, M.S.

Head, Data Science & Analytics

AbbVie

Nareen Katta, M.B.A, M.S., works as the Head of Data Science and Analytics at AbbVie. Nareen has over 20 years of experience in the pharmaceutical industry. In his current role, Nareen is responsible for building and executing the advanced analytics strategy, that covers both Scientific and Business Operations, across Clinical Development Continuum, Geostrategy and Study start-up, Centralized and Risk Based Monitoring, Site Engagement, Business Performance, Precision Medicine, Patient Safety and R&D. In addition, Nareen is actively engaged in evaluating the opportunities created by the technology trends like big data, automation, machine learning and AI, digital health etc. and strategically instantiating them at AbbVie to drive organizational transformation. Nareen has an MBA from The University of Chicago Booth School of Business and a MS in Electrical Engineering from University of Texas at Arlington.

Hana Lee, Ph.D., M.S.

Senior Staff Fellow

U.S. Food and Drug Administration

Hana Lee, Ph.D., is a Senior Statistical Reviewer of the Office of Biostatistics (OB) in the CDER, FDA. She leads and oversees various FDA-funded projects intended to support development of the agency's Real-World Evidence (RWE) program. She's been leading the RWE scientific working group of the ASA Biopharmaceutical Section, which is a public private partnership with FDA involving scientists from FDA, academia, and industry to advance the understanding of RWD/E to support regulatory decision-making. Dr. Lee has been recognized for her outstanding contributions to the field with numerous awards from FDA. Most recently, she received the prestigious FDA Scientific Achievement Award, which honors FDA scientists who have made exceptional advancements in regulatory science and contributed significantly to FDA's mission of protecting public health.

Melanie Poulin-Costello, MSc

Director of Biostatistics

Roche

Melanie Poulin-Costello, MSc, is a Director of Biostatistics at Roche, focusing on solid tumor oncology drug development. With over two decades of experience in the pharmaceutical industry, including roles at Amgen and Bayer, she has observed and contributed to industry advancements that expedite drug delivery to patients. Her extensive expertise encompasses the design, execution, analysis, and interpretation of clinical trials across all phases and therapeutic areas.

Melanie is a strategic leader who actively participates in cross-functional initiatives. Her focus areas include the application of external controls, pragmatic trials, the use of real-world data in trial design, and AI regulation through a Regulatory Policy rotation. She is also an adjunct professor in Biostatistics at the Dalla Lana School of Public Health at the University of Toronto.

Bonnie Smith

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Johns Hopkins University

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Janmejay Vyas
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Ph.D. Candidate
Khoury College of Computer Sciences
Northeastern University

Abstracts

2025 Annual Symposium on Risks and Opportunities of AI in Pharmaceutical Medicine

Day 1 Tutorial 1

Title:

"Large Scale Processing and Analysis of Wearable Device Data"

Lukas Adamowicz, Pfizer Inc.

Yiorgos Christakis, Pfizer, Inc.

Abstract:

This tutorial will cover the use of Scikit Digital Health (SKDH) as a comprehensive framework for setting up scalable processing pipelines for wearable device data. Wearable devices generate vast amounts of data that require efficient processing and analytics to extract digital measures of health (e.g., metrics of physical activity, sleep, gait, etc.). SKDH provides a robust and flexible library of tools to handle this data at scale, enabling researchers and practitioners to streamline their workflows. Participants will learn how to leverage SKDH to load, preprocess, and analyze wearable data, with practical examples. By the end of this tutorial, attendees will be equipped with the knowledge to implement scalable data processing pipelines using SKDH, enhancing their ability to derive digital measures of health from wearable device data.

Day 1 Tutorial 2

Title:

"TMLE in Drug Development"

Susan Gruber, TL Revolution

Hana Lee, Food and Drug Administration

Mark van der Laan, UC Berkeley

Abstract:

Artificial intelligence and machine learning (AI/ML) is transforming the field of medical product development and evaluation. AI/ML tools are driving innovative solutions to accelerate processes, improve efficiency, and reduce costs, however naive use could result in biased

findings that yield low quality evidence. The U.S. Food and Drug Administration (FDA) has developed regulatory frameworks and guidances to ensure the safe and effective integration of AI/ML. Targeted Learning provides a particularly useful framework for integrating AI/ML in the planning, design, and analysis of randomized controlled trials (RCTs) and real-world evidence (RWE) studies.

This course will first provide an overview of FDA's perspectives on the use of AI/ML for drug development and evaluation, describing various uses of AI/ML across the full spectrum of drug development processes, landscape assessment of regulatory submissions, and available guidance and resources from FDA along with other FDA initiatives.

Targeted Learning (TL), a subfield of statistics that combines statistical theory, ML, and causal inference, provides a framework for addressing the many challenges to efficient unbiased estimation in a regulatory context. The course will present the Targeted Learning (TL) estimation roadmap for causal inference, with applications to both RCTs and RWE studies. The roadmap offers step-by-step guidance to specifying key design components including the target causal estimand, statistical estimand and identifying assumptions, required data, estimation, sensitivity analysis and interpretation. AI/ML solutions can be incorporated throughout, e.g., for outcome identification, power calculations, and setting tuning parameters for pre-specified analyses of primary and secondary outcomes.

Targeted maximum likelihood estimation (TMLE) is an efficient, double robust estimator that is suitable for analyses of point treatment, longitudinal, and survival data. TMLE is combined with super learning (SL), an ensemble of various ML algorithms, to provide superior causal inference when compared with traditional parametric methods, or the use of AI/ML alone. TMLE+SL provides valid statistical inference while preserving transparency, interpretability, and replicability to meet regulatory recommendations.

Case studies will be presented that illustrate the application of the TL roadmap and TMLE+SL in challenging areas of medical product development, such as evaluating point treatment effects and survival analysis in rare disease settings.

Day 2 Plenary Session 1

Title:

"Targeted Learning, HAL, and Causal Inference for Generating Real-World Evidence in Drug Development", Mark van der Laan, UC Berkeley

Abstract:

Targeted Learning follows a general causal roadmap for 1) accurately translating the real world into a formal statistical estimation problem in terms of causal estimand, a corresponding

statistical estimand, and statistical model; 2) a corresponding template for construction of a targeted maximum likelihood estimator (TMLE) of the statistical estimand; and finally 3) a sensitivity analysis addressing the possible causal gap. The TMLE represents an optimal plug-in machine learning based estimator of the estimand combined with formal statistical inference. The three pillars of TMLE are super-learning, Highly Adaptive Lasso (HAL), and the TMLE-update step, where the latter has various choices such as CV-TMLE/C-TMLE, and the recently developed adaptive TMLE (Lars van der Laan et al., 2023). Through super-learning it can incorporate high dimensional and diverse data sources such as images, NLP features, and state-of-art algorithms tailored for such data sources. To optimize finite sample performance, the precise specification of TMLE can be tailored towards the precise experiment and statistical estimation problem in question, while being theoretically grounded, optimal, and benchmarked. We provide a motivation, explanation, and overview of targeted learning; the key role of super-learning and HAL; discuss some of the key choices and considerations in specifying the TMLE-step; and discuss (a priori specified) SAP construction based on targeted learning, incorporating outcome-blind simulations to choose the best specification of the SAP. We will also discuss various case studies including a Sentinel and FDA RWE demonstration project of targeted learning demonstrating SAP specification on real data.

Title:

“Using Statistical Foundations to Demonstrate Effectiveness of AI/ML Algorithms for Clinical Utility”, Charmaine Demanuele, Pfizer Inc.

Abstract:

AI presents significant opportunities for improving healthcare, especially in disease diagnosis (e.g., COVID-19) and prognosis (e.g., sepsis or acute kidney injury). However, many clinical predictive algorithms (CPAs) remain unused, exhibit bias, or fail to generalize across different populations and hospital platforms. This issue stems from two key factors. First, there is an overreliance on the area under the receiver operating characteristic curve (AUC) as the main measure of CPA quality, which does not consider the prevalence of the target characteristic, limiting the understanding of the CPA’s positive and negative predictive value. We advocate for a comprehensive approach to optimizing CPA development, akin to the methodologies employed in bioanalytical diagnostic tests and biologic biomarkers. Secondly, there is a lack of robust clinical trials to quantify the benefits and risks of implementing CPAs. To address this, we propose a fit-for-purpose, sequential clinical development approach, similar to the process used in evaluating new medicinal products and biomarkers, with potential oversight from regulatory agencies. By embracing these recommendations, the benefits and risks associated with CPAs

will become clearer, fostering increased credibility, transparency, and utility. This will enable our healthcare system to fully harness the potential of digital medicine and AI learning demonstrating SAP specification on real data.

Title:

“Transforming Pharmacovigilance with AI: A Roadmap”, Hussein Ezzeldin, FDA

Abstract:

Since its inception in the mid-19th century, Pharmacovigilance (PV), the science of detecting, assessing, and understanding adverse drug events, has undergone profound transformation. Over the decades, PV has evolved from paper-based systems, such as the UK Yellow Card scheme, to automated processing of electronic health records enabled by advancements in natural language processing, machine learning, and data interoperability. This presentation traces the trajectory of PV, highlighting key historical milestones from its origins to the application of large language models for safety signal detection, case summarization, and adverse events adjudication. Concluding with a forward-looking perspective, we explore the future of PV, where the integration of diverse datasets and emerging technologies converge to advance public health and foster the development of safer, more effective treatments.

Day 2 Plenary Session 2

Title:

“Safety First: Systematic Approaches to Hallucination Mitigation in Clinical AI”,

Malaikannan Sankarasubbu, Saama Technologies

Abstract:

Large Language Models (LLMs) are increasingly being deployed in healthcare settings, promising to revolutionize clinical workflows and decision support systems. However, their tendency to hallucinate – generating plausible but factually incorrect information, poses unique challenges in medical contexts where accuracy is paramount.

This talk presents a comprehensive examination of hallucinations in medical LLMs, grounded in real-world deployment experiences from clinical settings. We analyze actual cases where hallucinations impacted clinical workflows and discuss the implemented safeguards.

The presentation covers cutting-edge research in hallucination detection and mitigation, including recent advances in knowledge-grounded generation and semantic consistency checking specifically tailored for medical contexts. We share our novel contributions to this field, including a proposed framework for real-time hallucination detection in clinical applications and automated verification systems integrated with medical knowledge bases.

Looking ahead, we explore emerging approaches for building more reliable medical LLMs and

discuss the critical balance between innovation and safety in healthcare AI deployment. This talk bridges the gap between theoretical research and practical implementation, offering valuable insights for both researchers and healthcare technology practitioners.

Title:

“Stage-Aware Learning for Dynamic Treatments”, Annie Qu, UC Irvine

Abstract:

Recent advances in dynamic treatment regimes (DTRs) provide powerful optimal treatment searching algorithms, which are tailored to individuals’ specific needs and able to maximize their expected clinical benefits. However, existing algorithms could suffer from insufficient sample size under optimal treatments, especially for chronic diseases involving long stages of decision-making. To address these challenges, we propose a novel individualized learning method which estimates the DTR with a focus on prioritizing alignment between the observed treatment trajectory and the one obtained by the optimal regime across decision stages. By relaxing the restriction that the observed trajectory must be fully aligned with the optimal treatments, our approach substantially improves the sample efficiency and stability of inverse probability weighted based methods. In particular, the proposed learning scheme builds a more general framework which includes the popular outcome weighted learning framework as a special case of ours. Moreover, we introduce the notion of stage importance scores along with an attention mechanism to explicitly account for heterogeneity among decision stages. We establish the theoretical properties of the proposed approach, including the Fisher consistency and finite-sample performance bound. Empirically, we evaluate the proposed method in extensive simulated environments and a real case study for COVID-19 pandemic.

Title:

“Leveraging the power of AI/ML to enhance statistical inference in clinical trials: opportunities and learnings”, Scott McClain, SAS

Abstract:

Predicting both drug efficacy and safety, as well as model modes of actions using historical atomic level descriptors is a sort of “holy grail.” The what-if scenario is “what if I had the ability to predict the next new drug, its parameters of dose and expected adverse effects with fewer pre-clinical animal studies, much earlier in the pipeline?” There are vast amounts of hidden value in the years’ worth of animal and in vitro data, and we now have an ability to stack thousands of metrics for the drug chemistry. The tactical question is how to access the historical to train for a drug’s future performance. But it is not clear that black-box AI/ML modeling pointed at this data is a straightforward or better answer. In fact, it’s argued that with the advent of big data, data

itself is a hindrance. We will discuss access to key approaches for a blended world of chemistry and biology: feature extraction, data reduction and clustering. Newer generative and predictive techniques, such as adversarial networks, will also be examined. Getting a view of stitching traditional and new techniques together to support trusted modeling is our objective in reviewing risks and key opportunities in a generative AI drug development world.

Title:

“Testing and decision making with e-values”, Aaditya Ramdas, Carnegie Mellon

Abstract:

This talk will describe an approach towards sequentially testing hypotheses and estimating functionals that is based on games. In short, to test a (possibly composite, nonparametric) hypothesis, we set up a game in which no betting strategy can make money under the null (the wealth is an “e-value” under the null). But if the null is false, then smart betting strategies will have exponentially increasing wealth. Thus, hypotheses are rewritten as constrained games, the statistician is a gambler, test statistics are derived from betting strategies, and the wealth obtained is directly a measure of evidence which is valid at any data-dependent stopping time (an e-value). The optimal betting strategies are typically Bayesian, but the guarantees are frequentist. This “game perspective” provides new statistically and computationally efficient solutions to many modern problems, with particular importance for an open-ended meta-analysis that can be updated on the fly.