PROGRAMME OF THE EIGHTY-FIRST ANNUAL DEMING CONFERENCE ON APPLIED STATISTICS

Sponsored by
Deming Conference Organization
AMERICAN STATISTICAL ASSOCIATION: Biopharmaceutical Section

December 7 – December 11, 2026: Three-Day Conference plus Two-Day Short Course

Tropicana Casino and Resort, Havana Tower, Atlantic City, NJ

Three Keynotes on December 7-9, 2026

Statistics and AI Capabilities in Accelerating Drug Development, Pandurang M Kulkarni and **Jingyi Liu**, Eli Lilly
From Real-World Data to Regulatory-Grade Evidence: What Statisticians Need to Know About External Controls in Oncology, **Jonathan Kish**, Flatiron
Bayesian Adaptive Clinical Trials: From Bandit Problems to Real-World Innovation, **Prof. Don Barry**, MDACC

Twelve Sessions of Tutorials on December 7-9, 2026, and Two Short Courses on December 10-11, 2026

Short Course 1. Master Protocol Clinical Trials for Evidence Generation
by **Prof. Don Berry**, MDACC, **Ruixiao Lu**, Alumis, **Cindy Lu**, AstraZeneca, **and Jingjing Ye**, BeOne

Short Course 2. Clinical Trials in the Era of Real-World Evidence
by **Jie Chen**, Taimei Intelligence, **Naitee Ting**, Veramed, **and Feinan Lu**, IMPACT Therapeutics

A $5,000 college scholarship will be awarded to an undergraduate spouse, child, stepchild, or grandchild of a registrant

The registration will start at 7:00 AM Monday December 7th through Thursday December 10th.

RECEIPTS and a CERTIFICATE OF ATTENDANCE will be distributed at the conference. Register and pay for both the conference and the hotel online as early as possible at www.deming-conference.org. This gives you instant email acknowledgement. Payment must be paid by credit card.

We are soliciting abstract proposals for posters. The Poster Presentation forum allows participants to submit their research concepts and issues of relevance for peer review in the area of biostatistics. Poster sessions, which will be held on all 3 days of the conference, allow attendees to discuss the specifics of an abstract with the author in a small group setting. Accepted poster abstracts will be published on both the website and in the transactions. Submissions will be accepted through Saturday, October 15, 2026. Full details and tips for presentation are on our website. We will hold poster sessions, providing a forum to attendees to present concepts and issues of relevance to their peers. Poster abstracts can be submitted online for consideration. Students pursuing a doctorate degree in Biostatistics/Statistics may apply to receive a student scholar award and present a poster on their doctoral thesis at the conference. For further information, please contact the student scholar chair at Spaul@syros.com

Meeting facilities are in Tropicana's Havana Tower state-of-the-art complex with 502 nonsmoking rooms where attendees stay in soundproof climate-controlled rooms with direct-dial phones, cable TV, coffee makers, hairdryers, refrigerators, safe, iron and board, complimentary wireless internet and gorgeous views of the Atlantic City skyline.

- **There is a guest check-in desk on the 3rd floor of the Havana Tower and meeting facilities are on the 4th floor.**
- **One of the largest NJ hotels, with 5 hotel towers and more than 2,200 hotel rooms, elegant public areas, exclusive retail shops and fine dining.**
- **The resort features an indoor pool in the South Tower for hotel guests**
- **It has free Wi-Fi in the rooms and conference floor. The casino is in a separate building connected by a bridge.**
- **A free Trop Advantage Card can offer rewards based on your play and may offer dining and show discounts.**

The Tilton Fitness Atlantic City is a fully equipped fitness facility located in the Havana Tower. Access to the fitness center is completely free as it is covered under the resort fee for registered hotel guests (ages 21 and older).
Parking is available in the Tropicana Garage adjacent to the Havana Tower.

Eighty First (81st) Annual Deming Conference on Applied Statistics
Tropicana Casino and Resort, Havana Tower, Atlantic City, NJ
Sponsored by the Biopharmaceutical Section of the ASA and the Deming Conference Organization

Monday December 7, 2026 Registration: 7:00 ⇒ 8:00 AM and Hot Breakfast 7:00 ⇒ 7:50 AM

December 7, 8:00 ⇒ 9:00 AM Keynote: Statistics and AI Capabilities in Accelerating Drug Development, Pandurang M Kulkarni and Jingyi Liu, Eli Lilly
Moderator: Ivan F. Chan

Session A	Session B
Towards an AI-First Workflow for Clinical Development and its Analysis and Reporting Yilong Zhang, Meta, and Pingye (Eric) Zhang, Eikon Therapeutics Moderator: Bill wang	**LLM-assisted RWE analysis in R** Garrett Grolemund, Posit, Phil Bowsher, Posit, and Esteban Jenkins, Organon Moderator: Wenjin Wang

Lunch (On Your Own) 12:00 ⇒ 2:00 PM

Session C♣	Session D ♣
Opportunities and Challenges in the AI Age: Concrete Examples from Statistics, Science, and Beyond Mark Chang and Niya Xiong, Boston University Moderator: Din Chen	**Selected Topics of Statistics in Clinical Drug Development: A Statistical and Regulatory Perspective** Dacheng Liu, Boehringer Ingelheim Moderator: Naitee Ting

December 7, 2026 6:00 – 9:00 PM Deming Banquet Dinner: Statistical Talent in the AI Era, Hongtu Zhu, UNC, and Christine Gause, Merck & Co.

Tuesday December 8, 2026 Registration: 7:00 ⇒ 8:00 AM and Hot Breakfast 7:00 ⇒ 7:50 AM

December 8, 8:00 ⇒ 9:00 AM: Keynote: From Real-World Data to Regulatory-Grade Evidence: What Statisticians Need to Know About External Controls in Oncology, Jonathan Kish, Flatiron
Moderator: Sofia Paul

Session E ♣	Session F ♣
Navigating the Complexities of Platform Trials: Design and Simulation Kyle Wathen, Cytel Inc Moderator: Jingjing Ye	**Statistical Issues in the Development of Response Biomarkers for use in "First in Class" Clinical Development** Scott Chasalow and James Rogers, Metrum Research Group. Moderator: Naitee Ting

Lunch (On Your Own) 12:00 ⇒ 2:00 PM

Session G	Session H
Responsible Use of AI for Decision-Making in Drug Development Mat Soukup, FDA, BIOP AI-NEXUS, Tarek Hammad, Takeda, Jianchang Lin, BMS, Hongtu Zhu, UNC, and Judy Li, Astra Zeneca, BIOP AI-NEXUS Moderator: Kalyan Ghosh	**Evidence-Based Clinical Trial Design: When the Power of AI Meets Statistical Rigor** Will Ma, HopeAI Moderator: Jerry Li

Wednesday December 9, 2026 Registration: 7:00 ⇒ 8:00 AM and Hot Breakfast 7:00 ⇒ 7:50 AM

December 9, 8:00 ⇒ 9:00 AM: Keynote: Bayesian Adaptive Clinical Trials: From Bandit Problems to Real-World Innovation, Prof. Don Barry, MDACC
Moderator: Bill Wang

Session I ♣	Session J ♣
Master Protocol Trials: From Strategic Consideration to Real Case Implementation Don Berry, MDACC, Ruixiao Lu, Alumis, and Cindy Lu, AZ Moderator: Jingjing Ye	**Adaptive Designs in Clinical Trials** Vlad Dragalin, J&J Moderator: Ivan S. F. Chan

Lunch (On Your Own) 12:00 ⇒ 2:00 PM

Session K	Session L
Digital Pathology and AI: Building the Next Generation of Biomarker Discovery Talia Muram, Zhaohua Lu, and Li Liu, Daiichi Sankyo Inc. Moderator: Li-An Xu	**From Exploratory to Confirmatory: Designing and Executing Master Protocol for Meaningful Decision-Making** Robert Beckman, Georgetown University, Cong Chen, and Lan Luo, Merck & Co. Moderator: Bill Wang

Thursday December 10, 2026 Registration: 7:00 ⇒ 8:00 AM and Hot Breakfast: 7:00 ⇒ 7:50 AM

Short Course 8:00⇒9:30 Lecture / **9:30⇒9:50** *Break* / **9:50⇒11:20 Lecture** / **11:20⇒12:40** *Lunch on Your Own* / **12:40⇒2:10 Lecture** / **2:10⇒2:30** *Break* / **2:30⇒4:00 Lecture** / **4:00⇒4:20** *Break* / **4:20⇒5:00 Lecture**

Master Protocol Clinical Trials for Evidence Generation 🕮	Clinical Trials in the Era of Real-World Evidence 🕮
Don Berry, MDACC, Ruixiao Lu, Alumis, Cindy Lu, AstraZeneca, and Jingjing Ye, BeOne Moderator: Bill Wang	Jie Chen, Taimei Intelligence, Naitee Ting, Veramed, and Feinan Lu, IMPACT Therapeutics Moderator: Alfred Balch

Friday December 11, 2026 Hot Breakfast: 7:00 ⇒ 7:50 AM

Short Course (Continued) 8:00 - 9:30 Lecture / **9:30 - 9:50** Break / **9:50 - 11:20 Lecture** / **11:20 - 11:40** Break / **11:40 - 1:10 Lecture**

All tutorial and short course titles, presenters and moderators from 1970 onwards are on www.demingconference.org

🕮 Session is based on a recently published text that is available either for a discounted price or is included in the price of the short course registration

♣ Sessions will have their breaks extended by 15 minutes for Poster Presentations

TRAVEL TO THE DEMING CONFERENCE

AIR:
The nearest airports are Atlantic City International Airport (ACY) and Philadelphia International Airport (PHL). PHL generally offers the greatest number of flight options and is approximately 60 miles from Atlantic City, while ACY is closer to the conference venue. Ground transportation options from either airport include rental cars, taxis, rideshare services, shuttle services, and public transportation. Attendees are encouraged to compare airfare, schedules, and total travel time when selecting an airport.

RAIL:
Atlantic City is served by NJ Transit rail service, with connections available through Philadelphia and other Northeast Corridor destinations. Travelers arriving by train can continue to Tropicana via taxi, rideshare, jitney, or other local transportation options. Please consult NJ Transit and Amtrak websites for current schedules and fares.

BUS:
Multiple intercity bus providers offer service to Atlantic City from major cities throughout the Northeast. Attendees should check directly with bus operators for current routes, schedules, and fares. Local transportation is readily available from the Atlantic City Bus Terminal to the Tropicana.

DRIVING:
The Tropicana Atlantic City is conveniently accessible via the Atlantic City Expressway and major regional highways. Attendees driving to the conference should follow GPS directions to:

Tropicana Atlantic City
2831 Boardwalk
Atlantic City, NJ 08401

The Havana Tower can be accessed through the Tropicana parking facilities. Parking rates and policies are subject to change; attendees should consult the hotel website or conference communications for the most current parking information.

LOCAL INFORMATION:
Atlantic City offers a variety of entertainment, dining, shopping, and recreational opportunities. The Tropicana is located directly on the Boardwalk and within walking distance of numerous attractions, restaurants, and retail shops. Additional visitor information can be found through Atlantic City tourism resources.

MEALS AND NETWORKING:
Conference registration includes a full hot breakfast each morning, as well as morning and afternoon refreshment breaks. A welcome reception on Sunday evening provides an opportunity to meet fellow attendees and speakers. Additional conference meals and social events will be described in the final conference program.

Committee Members

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Conference Speakers Biography

Robert A. Beckman is Professor of Oncology and of Biostatistics, Bioinformatics, and Biomathematics at Georgetown University Medical Center and Scientific Advisor to the Vice President for Research. He is an oncology clinical researcher and mathematical biologist specializing in cancer evolution, precision medicine, and innovative clinical trial design. Dr. Beckman has held leadership roles in oncology clinical research across multiple pharmaceutical companies, contributing to bringing numerous therapies into development and to market, and has co-invented novel biomarker-driven and adaptive trial strategies.

Donald A. Berry is a leading biostatistician and pioneer of Bayesian methods in medicine, widely recognized for his contributions to adaptive clinical trial design. At MD Anderson, he served as the founding Chair of the Department of Biostatistics (1999–2010) and played a central role in advancing the use of Bayesian approaches for innovative oncology trials. He founded Berry Consultants in 2000, a scientific consulting firm specializing in Bayesian and adaptive clinical trial design and implementation for pharmaceutical and medical device development. Dr Berry has designed and led numerous innovative trials, including platform trials evaluating multiple therapies simultaneously, including the landmark I-SPY 2 adaptive platform trial in breast cancer. He has published hundreds of scientific papers and multiple books in statistics and biostatistics.

Mark Chang, PhD, is the founder of AGInception. He is a Fellow of the American Statistical Association with over 25 years of experience as a statistician in both the biopharmaceutical industry and academia, having held positions ranging from Scientific Fellow to Senior Vice President. As an adjunct professor at Boston University, Dr. Chang has supervised PhD students on research topics such as adaptive clinical trial design and artificial intelligence. His broad research interests span adaptive clinical trials, AI, the principles of scientific methods, paradoxes, and various issues in modern biostatistics and software development. Dr. Chang has published 15 books, including most recently Artificial Intelligence for Drug Development, Precision Medicine, and Healthcare (2020); Foundation, Architecture, and Prototyping of Humanized AI (2023); and Critical Thinking and Creative Analogies in Statistics, Science, and Technology—Essential Skills for the AI Era (2025). He served on editorial boards of several statistical journals and is the Series Editor of the Chapman & Hall/CRC Biostatistics Book Series. He is also the co-founder of the International Society for Biopharmaceutical Statistics and has served as co-chair of the BIO Adaptive Clinical Trial Design Working Group.

Scott Chasalow joined Metrum Research Group in 2025 as a Principal Scientist in Statistical Bioinformatics, contributing more than three decades of experience in applied statistics, bioinformatics, and translational science. He holds an M.A. in Biochemistry and a Ph.D. in Biostatistics from the University of California, Berkeley.

Scott's early work focused on statistical genetics and genomics in plant breeding, where he helped advance data-driven strategies for crop science. He later shifted his focus to human health, joining Bristol Myers Squibb, where he spent 21 years in statistical and bioinformatics leadership roles across clinical and non-clinical research. At BMS, he established and led the Translational Bioinformatics Methodology group, delivering expertise in experimental design, advanced statistical analysis, and development of novel approaches to biomarker discovery and evaluation. At Metrum RG, Scott collaborates across disciplines to integrate statistical, bioinformatic, and pharmacometrics insights - accelerating the development of meaningful biomarkers and enabling more informed, data-driven decisions in drug development.

Cong Chen is Scientific Associate Vice President (AVP) in Early Development Statistics at Merck & Co., Inc., leading statistical strategy for oncology early and transitional development programs. He specializes in innovative clinical trial design and decision-making strategies and has supported major oncology programs, including playing a key role in the development and regulatory acceleration of pembrolizumab (KEYTRUDA). Dr. Chen is a Fellow of the American Statistical Association, a leader in industry working groups on innovative design, and has published extensively on clinical trial methodology with over 100 papers and book chapters

Jie Chen, PhD, is the Chairman & Chief Scientific Officer in Taimei Intelligence Biopharma R&D, Inc. Dr. Chen has over 30 years of experience in biopharmaceutical research, development, and life-cycle management. He has contributed to the design, conduct, analysis, and regulatory submission of more than 50 new drug clinical trials, leading to regulatory approvals of over 10 drugs across diverse therapeutic areas. His primary research interests focus on adaptive trial design, multiple comparisons, Bayesian methods, drug safety evaluation, and the application of real-world evidence (RWE), artificial intelligence/machine learning, and causal inference to support medical product development and regulatory decision-making. He has co-authored or edited three books: Medical Product Safety Evaluation—Biological Models and Statistical Methods (Chapman & Hall/CRC, 2019), Real-World Studies—From Real-World Data to Real-World Evidence (China Medical Technology Publishing House, 2025), and Clinical Trials in the Era of Real-World Evidence (Wiley, 2026). Dr. Chen has published more than 60 peer-reviewed papers. He is a Fellow of the American Statistical Association.

Vlad Dragalin is a Vice President, Scientific Fellow in Quantitative Sciences at Janssen Pharmaceutical Companies of Johnson & Johnson. Vlad is the Head of QS Consulting and is chairing the QSTEPS (QS Technical Excellence and Program Strategy) Advisory Committee. He joined Janssen in 2014 as the Head of the Adaptive Clinical Trial Center of Excellence. Vlad is a well-known adaptive design expert with 35 years of experience in developing the statistical methodology of adaptive designs and with more than 20 years of experience in pharmaceutical industry, including positions of increasing responsibilities at GlaxoSmithKline, Wyeth, Pfizer, Quintiles, and Aptiv Solutions. Vlad is a PhRMA representative on ICH E9(R1) Expert Working Group and on ICH E20 Expert Working Group. He is a member of PhRMA Clinical Development Workgroup. Vlad is a Fellow of the American Statistical Association and an Associate Editor of the Journal of Biopharmaceutical Statistics and Statistics in Biopharmaceutical Research.

Christine Gause is currently Vice President of Biostatistics at Merck, leading a group of ~300 that encompasses Late Development Statistics, Clinical Safety Statistics and Scientific Communications and Information Sciences. In this role, she is responsible for overseeing end-to-end statistical support for the entire late development pipeline across therapeutic areas, partnering with colleagues in clinical, regulatory, and other quantitative groups. Prior to her current role, Christine led the late development oncology statistics group where she supervised a team of more than 70 statisticians focusing on critical project strategy, data analysis and interpretation, fit-for-purpose novel study design, and innovative statistical methodology for multiple high-profile oncology products. Throughout her career, Christine has held positions of increasing responsibility in statistics across several therapeutic areas including vaccines, biosimilars, diabetes, and oncology, and has contributed to multiple regulatory submissions, statistical publications and presentations.

Garrett Grolemund is a Director of Learning, Posit PBC (formerly RStudio). Garrett Grolemund is the Co-Author of R for Data Science, the creator of the Lubridate R package, and an ASA award-winning educator. For over a decade, he has helped data scientists learn to analyze data with R's Tidyverse and build interactive apps with R's Shiny framework.

Tarek Hammad is VP & Head of Medical Safety for Marketed Products at Takeda Pharmaceuticals, is a renowned expert in drug safety, benefit-risk assessment, and pharmacoepidemiology. With extensive experience at major pharmaceutical companies like Sanofi and Merck, as well as a distinguished 13-year career at the US FDA, he has received numerous awards for his contributions. Dr. Hammad is a sought-after speaker, actively involved in industry initiatives and has held several academic appointments. He has authored over 80 peer-reviewed articles, book chapters, and letters to the editor, offering valuable insights in the field.

Esteban Jenkins is an Associate Director of Data Science and AI/ML, Organon. Esteban Jenkins is Associate Director on Organon's Enterprise Data and Analytics team, leading the Advanced Analytics area where he focuses on building modern data science and machine learning capabilities and use cases to deliver value across the various business functions.

Jonathan Kish is VP and Head of Research Sciences at Flatiron, an epidemiologist and designer of novel research approaches to demonstrate real-world effectiveness, safety and patient impact of pharmaceuticals in oncology, immunology, neurology and rare diseases.

Pandu Kulkarni is the Chief Analytics Officer / Vice President of Biometrics and Advanced Analytics Organization leading an organization of nearly 700 people comprising of Statisticians from discovery to commercialization, Medical writing, and Data Standards and Technology. He obtained his Ph.D. in Statistics at the LaTrobe University, Melbourne, Australia. He taught and did research in statistics at the University of South Alabama for 10 years where he attained tenure and full professorship. He received several grants from the Air Force for the development of techniques to evaluate and study the effects of environmental contaminants such as dioxin on humans. He also received grants from NASA to study the effects of microgravity to see the effectiveness of exercise countermeasures in minimizing the effects of microgravity on astronauts.

Dacheng Liu is a Highly Distinguished Therapeutic Area and Methodology Statistician at Boehringer Ingelheim, with nearly two decades of experience in the pharmaceutical industry. He provides leadership in driving the statistical quality and fostering innovation of companywide clinical development programs across all therapeutic areas. He represents Boehringer Ingelheim in industry-wide groups and leads collaborations with US partners from both industry and academia. Before his current role, Dacheng held positions as the Global Head of Clinical Data Sciences and the US Head of Statistics, where he led both US and global teams in clinical drug developments of the company pipeline. He has extensive experience leading early and late-phase development in multiple disease areas, including landmark studies, regulatory submissions, and FDA advisory committee meetings. He has over 40 publications in areas of clinical research, trial design, statistical methodologies, and machine learning.

Jianchang Lin, PhD, FASA, is Vice President and Head of Oncology Biostatistics at Bristol Myers Squibb. He is a statistical and quantitative sciences leader with broad experience across Oncology, Neuroscience, Cell Therapy, Immunology, and Rare Diseases, and has contributed to numerous global regulatory approvals and commercial launches. Dr. Lin is recognized for advancing innovative methodologies in clinical development, including digital twins, novel trial designs, real-world evidence, and AI/ML applications. He has authored over 80 publications, edited two Springer books, serves in leadership roles across ASA and ICSA, is an ASA Fellow, and received the 2026 RSS/PSI Statistical Excellence in the Pharmaceutical Industry Award.

Jingyi Liu, PhD, is Vice President of Global Statistics and Head of Cardiometabolic Health Statistics at Eli Lilly and Company. He also takes the leadership role of AI for Lilly's statistics, data, and analytics organization through Next Generation Analytics (NGA), which moves AI ideas from concept to scalable impact. Within the ASA Biopharmaceutical Section, he co-chairs the Covariate Adjustment Working Group and founded STATBOLIC, a cross-sector working group advancing statistical innovation in cardiometabolic drug development. Dr. Liu was elected an ASA Fellow in 2026. He holds a PhD in Biostatistics from UC Davis.

Judy Li, PhD, MBA is Executive Director and Head of Hematology Strategy, Late Oncology Statistics at AstraZeneca. Previously she held senior statistical leadership positions at Bristol Myers Squibb/Celgene, Regeneron, and the U.S. FDA. She is recognized for leadership in oncology and hematology drug development, Bayesian methods, benefit-risk assessment, safety statistics, multi-regional clinical trials, and AI applications in pharmaceutical development. She serves in leadership roles within the American Statistical Association BIOP Section and was elected 2026 Chair-elect. Judy was selected as Fellow of American Statistical Association in 2026. Dr Judy Li is the founding chair of the ASA BIOP AI-NEXUS Task Force.

Li Liu is Head of the Precision Medicine Biostatistics Group at Daiichi Sankyo, leading statistical strategy and support for biomarker, translational science, and companion diagnostic (CDx) development activities. She led the statistical strategy and execution for the successful global regulatory submissions and approvals of quizartinib by the FDA, EMA, and PMDA. Prior to joining Daiichi Sankyo, Li held biostatistics positions at Sanofi and Pfizer, where she assumed roles of increasing responsibility across early- and late-phase oncology and hematology development programs. She has extensive experience in clinical trial design and execution, statistical strategies for translational science and CDx development, PK/PD modeling, and the application of innovative statistical methodologies to support precision medicine and oncology drug development.

Chengxing (Cindy) Lu is a senior director of Oncology Biometrics in AstraZeneca, where she leads a team of statisticians dedicated to early-phase immunology and radioconjugate oncology development. Throughout her extensive career in drug discovery and development, her work has spanned the full spectrum of the field, encompassing early- and late-stage clinical development as well as post-marketing, medical affairs, reimbursement, and commercial strategies. Cindy is deeply committed to driving innovation and enhancing efficiency through multidisciplinary collaborations. She is actively engaged with the professional community through organizations such as the American Statistical Association (ASA), DahShu, DIA, and the International Society of Biopharmaceutical Statistics (ISBS), where she serves as the working group leads

Feinan Lu is Director of Biometrics at IMPACT Therapeutics. She has over 10 years of experience in biopharmaceutical research and drug development. She has extensive expertise in clinical trial design, statistical analysis, and global regulatory submissions across major health authorities, including the NMPA, FDA, and EMA, with experience spanning more than 10 pivotal clinical trials.

Her primary research interests focus on oncology clinical trial design, including adaptive designs, single-arm trials, and centralized statistical monitoring. Feinan has been an invited speaker at industry conferences and has co-authored multiple publications on oncology trial design and single-arm studies. She is also a co-author of the book *Clinical Trials in the Era of Real-World Evidence* (Wiley, 2026).

Ruixiao Lu is a recognized leader in the biotech and biopharma industry, currently as Vice President and Head of Biostatistics and Statistical Programming at Alumis Inc. She has held senior leadership roles where she led end-to-end data science and analytical teams to support product development, regulatory submissions and approvals, medical affairs, and enterprise strategic initiatives. She is dedicated to advancing statistics and data science through professional organizations, as an elected Fellow and Board Director of of the American Statistical Association (ASA) (2020-2023, 2026–2028), elected President and Board Director of BBSW (2024–2026), and co-founder of DahShu (2015–present). She is widely engaged in cross-disciplinary collaborations, with a proven record of success in promoting scientific excellence and improving public health outcomes, including her leadership role at the 2023 FDA-AACR-ASA Overall Survival Workshop.

Zhaohua Lu is an Associate Director of Biostatistics at Daiichi Sankyo and a Ph.D.-trained statistician with more than 16 years of experience in statistical modeling, data science, and the design and implementation of clinical trials. Prior to joining Daiichi Sankyo, he served as a faculty member in the Department of Biostatistics at St. Jude Children's Research Hospital and as a Principal Data Scientist at DiDi. His research and professional expertise span the analysis of large-scale imaging, genomic, and natural language data, with particular interests in machine learning, Bayesian methods, statistical computing, and innovative clinical trial methodology. He has authored or co-authored more than 70 peer-reviewed clinical and methodological publications.

Will Ma is the founder and CEO of HopeAI, a Mayo Clinic Platform_Accelerate company on a mission to bring hope to patients through AI-accelerated clinical development. HopeAI has developed AI teammates that combine clinical insights with statistical innovations, enabling faster and more precise clinical trials. Prior to founding HopeAI, Will had over 10 years of experience in clinical development, including working as a statistician at Sanofi and BMS, and serving as a faculty member at Moffitt Cancer Center. Will is also a serial entrepreneur who co-founded Learnta, an AI learning company, and grew it to over 1,600 learning centers.

Talia Muram is currently Daiichi Sankyo's executive director and head of translational pathology.

Jim Rogers is the Vice President of Statistics in the Quantitative Sciences Business Unit at Metrum Research Group. After receiving his doctorate in statistics from The Ohio State University in 2001, Jim worked for two years on genomic and metabonomic analyses for biotechnology companies, followed by five years at Pfizer Global Research and Development where he worked initially as a nonclinical statistician and later as a clinical biostatistician. In 2008, Jim joined Metrum Research Group in order to work in closer collaboration with quantitative biologists and pharmacometricians. Over the course of his 15 years at Metrum RG, Jim has worked on decision-making informatics across a wide range of therapeutic areas and therapeutic modalities. Recurring areas of focus have included problems related to dose selection and dose optimization, as well as platform development based on disease progression models and clinical trial simulation. From a methodological perspective, Jim's focus in recent years has centered on the role of causal inference concepts in evidence integration. Jim believes that scientists trained in statistics can revolutionize the discipline of pharmacometrics and that scientists trained in pharmacometrics can revolutionize the discipline of statistics.

Mat Soukup, Ph.D., is a mathematical statistician with more than twenty years of experience in drug regulatory science at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER). He received his Ph.D. in Biostatistics from the University of Virginia, joining FDA/CDER in 2004. Dr. Soukup began his FDA career in the Office of Biostatistics (OB) supporting the Division of Dermatology and Dental Products. In 2010, he joined the Division of Biometrics VII (DBVII), where as a Team Leader he led pioneering efforts in the design and analysis of safety outcome trials, the application of meta-analytic methods to evaluate key safety signals, and the statistical representation of safety findings at numerous advisory committee meetings. Dr. Soukup was appointed Deputy Division Director of DBVII in 2016 and Division Director in 2024, contributing to numerous cross-disciplinary initiatives including efforts to standardize safety assessment across the Office of New Drugs and contributing to multiple CDER guidance documents. Dr Mat Soukup is the co-chair of the ASA BIOP AI-NEXUS task force.

Naitee Ting is a Fellow of American Statistical Association (ASA). Naitee is the recipient of the prestigious Mentoring Award of ASA in 2025. He is currently Vice President of Veramed. Naitee is also an Adjunct Professor of Department of Statistics at University of Connecticut, Adjunct Professor of Department of Biostatistics at Columbia University. He joined Veramed in 2025. Before Veramed, Naitee has been with Boehringer Ingelheim Pharmaceuticals, Inc. (BI) for 15 years, and he was working at Pfizer Inc. for 22 years (1987-2009). Naitee received his Ph.D. in 1987 from Colorado State University (major in Statistics). He has an M.S. degree from Mississippi State University (1979, Statistics) and a B.S. degree from College of Chinese Culture (1976, Forestry) at Taipei, Taiwan. Naitee published articles *in Technometrics, Statistics in Medicine, Drug Information Journal (Therapeutic Innovation and Regulatory Science), Journal of Statistical Planning and Inference, Journal of Biopharmaceutical Statistics, Biometrical Journal, Statistics and Probability Letters, Statistics in Biosciences, Statistics in Biopharmaceutical Research,* and *Journal of Statistical Computation and Simulation.* His book "*Dose Finding in Drug Development*" was published in 2006 by Springer, and is considered as the leading reference in the field of dose response clinical trials. The book "*Fundamental Concepts for New Clinical Trialists*", co-authored with Scott Evans, was published by CRC in 2015. Another book "*Phase II Clinical Development of New Drugs*", co-authored with Chen, Ho, and Cappelleri was published in 2017 (Springer). Naitee has been an active member of both the ASA and the International Chinese Statistical Association (ICSA).

Kyle Wathen brings experience from a diverse background in academia, consulting, and the life sciences industry to his tutorial. Working on the development and application of novel Bayesian methodology for adaptive clinical trial designs, he is involved in each step of developing new adaptive clinical trial designs, starting from initial concept development through software development/trial simulation and completing with trial conduct and data collection. Kyle has over 25 years of experience in the design of innovative clinical trials such as Bayesian approaches, platform trials and other adaptive approaches. He has been involved in many innovative clinical trials, especially platform trials, in various disease areas including oncology, neuroscience, infectious diseases, cardiovascular and inflammation. He has released several software packages besides OCTOPUS. Kyle received his M.S. in statistics from Texas A&M University and M.S. and Ph.D. in Biostatistics from the University of Texas: Graduate School of Biomedical Sciences.

Niya Xiong is a PhD candidate in Biostatistics at Boston University. Before entering the PhD program, she spent five years as a statistician at the Dana-Farber Cancer Institute, where she was the primary statistician on more than 15 Phase I/II gynecologic oncology trials, including NCI-sponsored multi-site studies, and collaborated with nurse scientists on patient-reported outcomes and treatment decision-making research. She works under the supervision of Prof. Mark Chang, with a research focus on digital twins and artificial intelligence in clinical trial design. She developed PREDCOVA, a covariate-adjustment method for randomized trials that combines a digital-twin prognostic score with a treatment-effect modifier. She has co-authored more than 25 peer-reviewed publications, including clinical trial reports in the Journal of Clinical Oncology, JAMA Oncology, and Clinical Cancer Research. From 2021 to 2024, she served on the Dana-Farber Scientific Review Committee, and she is a peer reviewer for Nature Medicine, Nature Cancer, Nature Communications and Journal of Clinical Oncology.

Jingjing Ye is a biopharmaceutical executive and former senior FDA regulatory leader with more than 20 years of experience spanning global industry R&D and a decade at the U.S. Food & Drug Administration, specializing in digital transformation, advanced analytics, and data-driven drug development. Her expertise covers the whole patient's journey from diagnosis, treatment to living with the disease. She is a proven leader in building and scaling global organizations and translating complex science and data into regulatory, operational, and portfolio-level impact. Dr. Ye is an elected Fellow of the American Statistical Association (ASA). As a founder and principal consultant of DataDoctor LLC, Dr. Ye is driven by a commitment to improving patient outcomes and is passionate about multidisciplinary collaboration to advance innovations in drug development.

Eric Zhang is a Director of Biostatistics at Eikon Therapeutics, where he supports oncology programs spanning early to late-stage clinical development. He earned his Ph.D. in Biostatistics from the University of Southern California and began his career at Merck, where he served as the lead statistician for late-stage oncology trials and played a pivotal role in the regulatory filing and approval of pembrolizumab (KEYTRUDA) for RCC and HN cancer. Following his time at Merck, Eric worked at BeiGene and Gilead Sciences. In addition to his project work, Eric is also an active participant in scientific discussions across industry and regulatory bodies, and has published extensively in both statistical and medical journals.

Yilong Zhang is a Health Quantitative Scientist at Meta. He previously worked as a statistician at Merck & Co., Inc. on late-stage clinical trial development. His interests include developing AI workflow, R and Python packages to improve clinical trial analysis, reporting, and regulatory submission. Yilong has published over 25 peer-reviewed articles and holds a PhD in Biostatistics from New York University.

Hongtu Zhu, PhD, is the Kenan Distinguished Professor of Biostatistics at the University of North Carolina at Chapel Hill. An internationally recognized expert in statistical learning, medical imaging, precision medicine, artificial intelligence, and big-data analytics, he has published more than 345 papers in leading scientific and statistical journals. Dr. Zhu is a Coordinating Editor of the *Journal of the American Statistical Association* and recipient of the 2025 COPSS Snedecor Award and the 2019 INFORMS Daniel H. Wagner Prize. He previously served as Chief Scientist of Statistics at DiDi Chuxing and held the Endowed Bao-Shan Jing Professorship in Diagnostic Imaging at MD Anderson Cancer Center.

Monday December 7, 2026 9:00 – 12:00 PM

Session A

Towards an AI-First Workflow for Clinical Development and its Analysis and Reporting

Yilong Zhang, Meta, and Pingye (Eric) Zhang, Eikon Therapeutics

Moderator: Bill wang

Abstract

As AI adoption accelerates across the biopharmaceutical industry, the challenge for organizations has shifted from "if" to "how." To remain competitive, leaders must transition from ad-hoc AI usage to AI-First strategies, where AI serves as the default starting point. This requires a rigorous definition of workflows where humans are strategically positioned on-the-loop for oversight and experts are in-the-loop for complex edge cases.

In this short course, we provide publicly available examples and hands-on exercises for implementing selected AI-First processes around deliverables for Biometrics organizations including clinical trial design, analysis and reporting. The short course is structured into three key modules:

1. **The AI Evolution:** Mapping the journey from AI-adoption to AI-first, and ultimately to **AI-native** organizational structures.
2. **Strategic Use Cases:** Deep-diving into AI-first processes for study design, clinical analysis, and reporting with focus on reducing human review burden.
3. **Applied AI Agent Skills:** Hands-on exercises in developing and evaluating Agent Skills for biometrics use cases using modern, publicly available AI agents and clinical development tools.

Session B

LLM-assisted RWE analysis in R

Garrett Grolemund, Posit, Phil Bowsher, Posit, and Esteban Jenkins, Organon

Moderator: Wenjin Wang

Abstract

Large Language Models (LLMs) can help you quickly write code, draft reports, and build interactive applications. In this hands-on workshop, you'll use an LLM to do a preliminary analysis of real-world evidence (RWE) data and to build three deliverables: a written report, an HTML dashboard, and an interactive app with a built-in AI chatbot for querying the data and findings.

Working in R within Positron (a fork of VS Code built for data scientists), participants will solve a common and important question: Is there enough data, in the right subgroups, to support the study we want to design? Along the way, we'll cover practical skills that matter beyond the workshop itself: writing effective LLM prompts, tracking token usage, and monitoring code execution so that LLM-assisted work stays methodologically sound and reproducible.

Basic familiarity with R is recommended; no prior LLM experience is needed. We'll provide a cloud-based compute environment, pre-provisioned with AI API keys, so participants can get straight to work on the day of the workshop. We will rely solely on Positron's Posit Assistant client, which is designed to use any model provider on the backend, so you can reproduce the lessons of the workshop *as is,* with the model providers you are permitted to use.

Outline

- The motivating example. How can we tell whether enough RWE data exists across subgroups to support a study design built around those subgroups?
- A quick review of R. A refresher to make sure everyone has the footing they need.
- Writing R with an LLM. Use an LLM to write R functions and scripts.
- From analysis to report. Use an LLM to write a Quarto report, then render it into an HTML dashboard.
- Building an app. Use an LLM to build a Shiny app around the analysis.
- Adding a chat interface. Use Querychat to add an LLM-powered chat session to the Shiny app.
- Sharing the work. Publish the Shiny app and configure it to communicate with an LLM in production.

Monday Lunch (On Your Own) 12:00 PM - 2:00 PM

2:00 - 5:00 PM

Session C ♣

Opportunities and Challenges in the AI Age: Concrete Examples from Statistics, Science, and Beyond

Mark Chang and Niya Xiong, Boston University

Moderator: Din Chen

Abstract

This tutorial explores both the opportunities and challenges of the AI era through a collection of concrete examples drawn from pharmaceutical statistics, clinical development, scientific discovery, philosophy of science, and human reasoning. On the opportunities side, participants will learn how AI and machine learning can improve clinical trial efficiency, enable precision medicine, support adaptive designs, and generate innovative frameworks such as PROCOVA, PREDCOVA, and Split-Cross PROCOVA for traditional and adaptive designs. The tutorial will also illustrate how statistical thinking, randomization, and game-theoretic reasoning can rescue seemingly failed development programs and create new pathways for innovation. The tutorial concludes by discussing the future relationship between humans and AI, including the concepts of Humanized AI, large-data versus small-data learning paradigms, and the role of human judgment in an increasingly AI-driven world.

Opportunities in Pharmaceutical Statistics and Beyond

- PROCOVA: A Regulatory-Embraced AI-Assisted ANCOVA Framework.
- PREDCOVA: Precision-Medicine-Based PROCOVA with Similarity-Based Machine Learning.
- Split-Cross PROCOVA: A Further Enhanced PROCOVA Framework.
- AI-Enabled Adaptive Clinical Trial Designs.
- The Power of Randomization in Rescuing Failed Drug Development Programs.
- Game-Theoretic Approaches to Clinical Development Programs (CDPs).

Challenges and Controversies in Statistics, Science, and Beyond

- Intransitivity in Rank-Based Decision Making.
- Hierarchical Evolution and the Identity Paradox: When One Entity's Evolution Is Another Entity's Devolution—and the Circular Definitions of Survivorship and Fitness.
- Can Mathematics Be 100% Reliable? Proof by Contradiction and the Limits of Certainty.
- Discovery versus Invention: Which Drives Scientific Progress?
- The Multi-Faceted Objective World: Causal Determinism versus Free Will.
- The Nature of Understanding, Meaning, and Emotion.
- Humanized AI: Large-Data-Based versus Small-Data-Based Models.

Session D ♣

Selected Topics of Statistics in Clinical Drug Development: A Statistical and Regulatory Perspective

Dacheng Liu, Boehringer Ingelheim

Moderator: Naitee Ting

Abstract

Clinical drug development is a complex process that involved years of investment and high failure rate. There are many areas that statistics can contribute to improve the efficiency of drug development, ranging from early phase dose finding to confirmatory trial designs. Novel statistical approaches have been implemented in recent years to improve this process. There have been notable shift in the regulatory landscape supporting these approaches, such as the FDA complex innovative design (CID), model informed drug development (MIDD) programs. In this short course, we will provide a broad perspective of how such statistical innovations contribute to clinical drug development. We will discuss relevant regulatory guidance. Topics to be covered include early phase dose finding, dose ranging, confirmatory adaptive designs, multiplicity, covariate adjustment, Go/NoGo decision making, Bayesian borrowing, estimand and missing data. We will provide examples from recent trials and drug reviews/approvals.

Deming Banquet Dinner: Statistical Talent in the AI Era, Hongtu Zhu, UNC, and Christine Gause, Merck.

Monday December 7, 2026 6:00 – 9:00 PM

Tuesday December 8, 2026 9:00 – 12:00 PM

Session E ♣

Navigating the Complexities of Platform Trials: Design and Simulation

Kyle Wathen, Cytel Inc
Moderator: Jingjing Ye

Abstract

Adaptive platform trials offer substantial advantages over traditional clinical trial designs, including greater flexibility, improved efficiency, and the ability to evaluate multiple interventions within a single, evolving framework. Their operational and statistical complexity, however, makes careful planning and comprehensive simulation essential. This 3-hour tutorial provides a practical introduction to the design and simulation of adaptive platform trials using OCTOPUS (https://kwathen.github.io/OCTOPUS/), an R package developed for simulating platform trials.

The tutorial begins with a concise overview of platform trial design, including core design features, common sources of complexity, and the situations in which platform approaches may offer meaningful advantages. It then focuses on why it is important to simulate the actual trial intended for implementation, including key real-world features such as the addition or removal of treatment arms over time and other sources of variability that can materially affect operating characteristics and trial performance. A hands-on worked example will help participants to develop a simulation plan for a hypothetical platform trial and implement it in OCTOPUS. Using this example, the tutorial will demonstrate how to specify design assumptions, run simulations, and interpret outputs relevant to trial decision-making. The tutorial will additionally introduce the concept of patient-level simulation, including examples of custom patient simulators and approaches that extend beyond the standard analyses available in OCTOPUS.

Take-Home Learnings

After completing the tutorial, participants will leave with:

- A practical framework for thinking about the design and simulation of adaptive platform trials.
- Hands-on experience using OCTOPUS to build and run a platform trial simulation.
- A clearer understanding of how perpetual features, such as adding or dropping treatment arms, can affect trial behavior.
- Experience interpreting results from simulated trial scenarios to inform design decisions.
- Reusable ideas and code patterns for setting up simulations and producing visual summaries in R.

Session F ♣

Statistical Issues in the Development of Response Biomarkers for use in "First in Class" Clinical Development

Scott Chasalow and James Rogers, Metrum Research Group.
Moderator: Naitee Ting

Abstract

Recent draft ICH and FDA guidance suggests that mechanistic evidence increasingly will be prioritized in drug efficacy evaluations (e.g., the "model-informed drug development" framework of ICH M15 and the more recent "plausible mechanism framework" for rare genetic disorders). This likely will include an increasing role for response biomarkers in decision making. These developments are particularly relevant to biomarker research for "First in Class" settings, where historical meta-analysis methods are not directly applicable. In this tutorial, we provide an overview of statistical issues relevant in this setting, emphasizing opportunities for statistical influence even in the development of "mechanistic" evidence.

Tuesday Lunch (On Your Own) 12:00 AM - 2:00 PM

2:00 - 5:00 PM

Session G

Title: Responsible Use of AI for Decision-Making in Drug Development

Mat Soukup (FDA, BIOP AI-NEXUS), Tarek Hammad (Takeda), Jianchang Lin (BMS), Hongtu Zhu (UNC), and Judy Li (Astra Zeneca, BIOP AI-NEXUS)
Moderator: Kalyan Ghosh

Abstract

Artificial intelligence (AI) is rapidly transforming drug discovery and development, creating unprecedented opportunities to improve efficiency, accelerate evidence generation, and enhance decision-making across the product lifecycle. At the same time, widespread adoption of AI introduces important scientific, regulatory, and governance considerations that must be addressed to ensure trustworthy and responsible use.

This three-hour short course brings together leaders from industry, academia, and regulatory science to examine both the promise and challenges of AI implementation in biopharmaceutical research and development.

- The session will begin with an overview of the ASA BIOP section AI-NEXUS initiative, (led by Dr Mat Soukup, US FDA and Dr Judy Li, Astra Zeneca), highlighting findings from recent landscape assessments, industry surveys, FDA and other emerging regulatory guidance, and key insights from recent professional discussions.
- To provide specific context and examples, Dr Jianchang Lin (BMS) and Dr Tarek Hammad (Takeda) will then present their award-winning work on digital twins (2026 RSS Statistical Excellence Award Announcement) and on AI for safety evaluation. These examples will illustrate how AI-enabled approaches can support decision-making while emphasizing the importance of causal reasoning, transparency, validation, and human oversight.
- To further deep dive into the responsible use of AI, Professor Hongtu Zhu (UNC) will introduce Causal Generalist Medical AI (CGM-AI) with a case study, which combines AI, causal inference, and a disease-centric knowledge graph to transform fragmented biomedical evidence into actionable clinical knowledge.

The course will conclude with an interactive panel discussion on scalable AI adoption, regulatory expectations, workforce development, and the future role of statisticians and data scientists in an AI-driven environment. Attendees will gain practical perspectives and actionable principles for implementing AI responsibly to support high-quality scientific and regulatory decisions throughout drug development.

Session H

Title: Evidence-Based Clinical Trial Design: When the Power of AI Meets Statistical Rigor

Will Ma, HopeAI
Moderator: Jerry Li

Abstract

Clinical trial design decisions — from endpoint selection to sample size estimation to comparator arm construction — are only as good as the evidence informing them. Yet in practice, development teams often face fragmented literature, incomplete data, and limited access to patient-level information from prior studies, leading to designs built more on convention than on evidence.

This talk presents a framework where AI and statistical rigor converge to enable truly evidence-based clinical trial design. The approach, developed at HopeAI, integrates three core capabilities: (1) systematic, human-curated synthesis of clinical outcome data across indications through the PURE Evidence platform; (2) generation of synthetic individual patient data (SynthIPD) from published aggregate results, enabling trial-level simulations grounded in real-world evidence; and (3) agentic AI tools — including an AI Clinician and an AI Statistician — that work alongside biostatisticians to translate synthesized evidence into actionable design parameters.

We illustrate this framework through oncology case studies, demonstrating how AI-curated evidence and synthetic patient-level data can inform adaptive designs, optimize randomization strategies, and strengthen regulatory submissions by grounding design assumptions in a more complete evidence base. Critically, each AI-generated output is validated through established statistical methods — ensuring that AI amplifies, rather than replaces, statistical judgment.

When AI meets statistical rigor, the result is clinical trial designs that are both innovative and defensible — built on evidence, not convention.

Wednesday December 9, 2026 9:00 – 12:00 PM

Session I ♣
Master Protocol Trials: From Strategic Consideration to Real Case Implementation

Don Berry, MDACC, Ruixiao Lu, Alumis, and Cindy Lu, AZ
Moderator: Jingjing Ye

Abstract

This half-day tutorial provides a focused yet comprehensive exploration of the science, strategy, and practical implementation of master protocol trials. It is designed to give participants both a conceptual framework and a deep-dive into a real-world case study on how these complex trial designs function in modern drug development.

The tutorial begins with an introduction to the fundamental concepts and framework of master protocols, followed by an overview of the evolving regulatory landscape, including recent guidance and increasing regulatory acceptance of such innovative trial designs. Participants will also examine trends in the adoption of master protocols across therapeutic areas and development settings, as well as the key challenges that continue to limit broader implementation, including operational complexity, stakeholder alignment, governance structures, statistical considerations, data sharing, and regulatory uncertainty.

Using I-SPY2 as the central and unifying case study, the tutorial illustrates how platform trials have transformed clinical research by enabling more efficient, flexible, and patient-centered development pathways. In particular, the course highlights how Bayesian adaptive design principles, biomarker-driven decision making, and the ability to evaluate multiple investigational agents within a single, continuously evolving protocol can substantially accelerate learning and improve clinical outcomes. Participants will gain insight into both the methodological innovations and the practical considerations that made I-SPY2 a landmark example in the field.

By combining conceptual discussions with concrete examples and lessons learned, the tutorial equips participants with actionable knowledge to critically assess, design, or contribute to master protocol trials within their own organizations and research settings.

Session J ♣
Adaptive Designs in Clinical Trials

Vlad Dragalin, J&J
Moderator: Ivan S. F. Chan

Abstract

Adaptive clinical trials offer powerful opportunities to improve decision-making, efficiency, and ethical conduct in drug development by using accumulating data to modify a study in a pre-specified and scientifically justified manner. When well designed and carefully implemented, adaptive approaches can support earlier stopping for futility or success, sample size re-estimation, treatment or dose selection, population enrichment, multi-arm multi-stage strategies, and seamless Phase 2/3 development, while preserving the validity and interpretability of trial results.

This half-day course will provide a practical overview of adaptive clinical trial design, moving from foundational concepts to implementation considerations that are essential for regulatory-ready studies. The session will review key classes of adaptive designs, including group sequential designs, adaptations based on combination tests or the conditional error principle, sample size reassessment, adaptive treatment selection, enrichment designs, and designs involving multiple treatments, endpoints, or patient subgroups. Attention will be given to the role of simulation in evaluating operating characteristics, including type I error control, power, estimation reliability, and the consequences of design choices under realistic clinical development scenarios.

The presentation will also discuss the evolving regulatory framework for adaptive designs, with emphasis on the principles reflected in ICH E20: adequacy of the design within the broader development program, the importance of prospective planning, control of erroneous conclusions, reliability of estimation for benefit-risk decisions, and maintenance of trial integrity through appropriate blinding, information flow, and independent oversight. Both frequentist and Bayesian perspectives will be considered, including how Bayesian decision rules may be calibrated to frequentist error-rate requirements and how hybrid approaches can be used to combine flexibility with regulatory confidence.

By the end of the course, participants will have a structured understanding of when adaptive designs may add value, what statistical and operational risks must be addressed, and how to design adaptive trials that are efficient, reliable, and suitable for regulatory evaluation. The presentation is intended for statisticians, clinical development scientists, regulatory colleagues, and decision-makers interested in translating adaptive design methodology into sound clinical development practice.

Wednesday Lunch (On Your Own) 12:00 AM - 2:00 PM

2:00 - 5:00 PM

Session K
Digital Pathology and AI: Building the Next Generation of Biomarker Discovery

Talia Muram, Zhaohua Lu, and Li Liu, Daiichi Sankyo Inc.
Moderator: Li-An Xu

Abstract

Digital Pathology (DP) and multiplex immunohistochemistry (IHC) are rapidly transforming biomarker discovery, patient stratification and selection, and clinical trial efficacy assessment in the pharmaceutical industry. However, translating massive, high-dimensional image data into robust predictive models requires a deep understanding of both the underlying biology and the complex data processing pipelines. This tutorial is aimed to bridge the gap between tissue biology and data science. We will provide practical frameworks, pharmaceutical case studies, and actionable best practices for handling DP data—from the moment a slide is scanned to the final predictive model. Attendees will learn how to navigate the unique statistical challenges of spatial data, effectively manage pre-processing artifacts, and apply advanced machine learning and AI techniques to extract meaningful, actionable biomarker signatures.

This first part of the tutorial sets the stage by framing the evolution of tissue-based biomarkers. We will explore the transition from traditional, semi-quantitative IHC scoring by pathologists to modern, fully digitized Whole Slide Imaging (WSI) and multiplexing technologies.

The biological context of the data, current regulatory perspectives, and the future trajectory of DP in clinical development frameworks will be discussed.

The second part of the tutorial will focus on image processing and pre-data processing in DP. The quality of downstream statistical analysis is entirely dependent on the upstream image processing. This session demystifies the "black box" of translating pixels into structured datasets.

Approaches and challenges in cell segmentation, tissue phenotyping, and spatial coordinate generation will be discussed. We will share practical frameworks and best practices for quality control (QC), handling artifacts, and ensuring high-fidelity data preparation.

The third part of the tutorial will provide the statistical frame on how to analyze DP data to build predictive biomarkers. It will cover study design, data quality evaluation, the core analytical challenge in digital pathology lies in translating highly complex, spatially resolved single-cell data into clinically actionable patient-level predictions. This session dives deep into the specialized statistical and machine learning frameworks required to navigate high-dimensional tissue datasets without falling into common overfitting traps. We will showcase real-world pharmaceutical examples of using AI applications and predictive modeling to identify predictive biomarker signatures for drug efficacy and patient response.

The key takeaways of this tutorial session:

- A clear conceptual framework of the end-to-end Digital Pathology pipeline.
- Best practices for quality control and pre-processing of spatial and image-derived tabular data.
- Concrete examples of applying machine learning and spatial statistics to DP data for clinical trial decision-making

Session L
From Exploratory to Confirmatory: Designing and Executing Master Protocol for Meaningful Decision-Making

Robert Beckman, Georgetown University, Cong Chen and Lan Luo, Merck & Co..
Moderator: Bill Wang

Abstract

Master protocol trials can markedly improve the efficiency of oncology and rare disease drug development by evaluating a therapy across multiple molecularly defined cohorts or/and evaluating multiple therapies for the same disease within a single protocol. While their benefits are well established conceptually, the next frontier is scaling these advantages to broader, high-impact scenarios through rigorously designed trials in both exploratory and confirmatory settings with the right context. This tutorial will translate conceptual frameworks into practical know-how, covering design choices, statistical operating characteristics, operational execution, the trial results interpretations, and the considerations for maximizing regulatory acceptance. Both frequentist and Bayesian frameworks will be elaborated in different design settings.

What you will learn:

- Core concepts and taxonomy: Understand the differences between exploratory versus confirmatory basket and platform trials, histology-agnostic versus histology-restricted cohorts, and single-arm versus randomized designs.
- Design elements for master protocol trials: Learn how to select cohorts, the recommended number of cohorts in the baskets, and set early stopping rules; compare tumor-agnostic decision frameworks, Bayesian versus frequentist approaches in information borrowing, multiplicity control for platform trials and usage of non-concurrent controls for platform trials.
- Statistical rigor for decision-making: Understand methods to ensure robust inference: type I error control, operating characteristics, hierarchical modeling and partial pooling, pre-specification of decision rules to fit different decision-making scenarios.
- Path to confirmatory evidence and regulatory considerations: Explore how to transition from signal detection to confirmatory trials. Identify the right development context for randomized confirmatory master protocol trials, the potential concerns from regulatory and mitigations to the potential regulatory risks.
- Case studies and pitfalls: Examine case studies illustrating efficient signal detection and a simulated case study in the confirmatory setting, successful real-world examples and discuss common pitfalls and how to avoid them. Provide tips and techniques for practical considerations regarding the case studies.

By the end of the session, participants will be able to design fit-for-purpose master protocol trials, articulate when and how to introduce randomization and controls for both basket and platform settings and implement statistical and operational practices that maximize patient benefit while generating robust evidence for meaningful decision-making.

TWO SIMULTANEOUS SHORT COURSES THURSDAY AND FRIDAY, DECEMBER 10-11, 2026

Registration includes a hot breakfast, and two refreshment breaks each day; No registration will be accepted without payment in full. We will refund full tuition if courses are canceled due to insufficient registration.

Thursday Schedule 8:00⇒9:30 Lecture / 9:30⇒9:50 *Break* **/ 9:50⇒11:20 Lecture / 11:20⇒12:40** *Lunch on Your Own* **/ 12:40⇒2:10 Lecture / 2:10⇒2:30** *Break* **/ 2:30⇒4:00 Lecture / 4:00⇒4:20** *Break* **/ 4:20⇒5:00 Lecture**

Friday Schedule 8:00 - 9:30 Lecture / 9:30 - 9:50 Break **/ 9:50 - 11:20 Lecture / 11:20 - 11:40** Break **/ 11:40 - 1:10 Lecture**

Master Protocol Clinical Trials for Evidence Generation 🕮

Instructors: Don Berry, MDACC, Ruixiao Lu, Alumis, Cindy Lu, AstraZeneca, and Jingjing Ye, BeOne

Moderator: Bill Wang

Abstract

Drug development faces mounting pressure to deliver faster, more reliable evidence while controlling costs. Master protocols — umbrella, basket, and platform trials — have emerged as a transformative framework that enables the simultaneous evaluation of multiple therapies, biomarker-defined subpopulations, or disease subtypes within a single, integrated infrastructure. Demonstrated across oncology, COVID-19, and rare diseases, these designs improve efficiency, reduce patient exposure to ineffective treatments, and accelerate the path from evidence generation to regulatory decision-making.

This two-day short course offers a multidisciplinary immersion into the science, strategy, and practice of master protocol trials. The course is based on a newly published book: Master Protocol Clinical Trials for Evidence Generation (Chapman & Hall/CRC Biostatistics Series) https://www.amazon.com/Protocol-Clinical-Evidence-Generation-Biostatistics/dp/103254452X.

Day 1 Morning: Strategic Foundations, Statistical Innovation and Inspiration. The opening session examines the evolving regulatory landscape across FDA and global agencies, the economic value proposition of platform trials in both single-sponsor and multi-sponsor settings, and holistic decision-making frameworks that integrate clinical, statistical, and patient-centric considerations into a unified governance approach.

The session then turns to I-SPY2 as a defining case study. Launched in breast cancer, I-SPY2 was the first trial to carry the adjective "platform" and incorporated numerous innovations for efficiently evaluating multiple investigational agents in parallel. Its Bayesian design — including response-adaptive randomization (RAR) and the "time machine" methodology — enabled more rapid decision-making about therapies while delivering better treatment to patients in the trial. Participants will explore the inspiration behind these statistical innovations, their operational implementation in I-SPY2, and their broader implications for the field of adaptive trial design.

Day 1 Afternoon: Statistical Design and Methodology, Impact to Clinical Benefit. The afternoon provides a deep dive into biomarker-based platform trial design and the resulting clinical benefit with success case studies such as I-SPY2. The session then broadens to additional statistical considerations including estimands and multiplicity, multi-regional master protocol strategies, use of external data and real-world evidence, tumor agnostic design and safety and benefit-risk assessment.

Building on these foundations, the session reviews and explores how master protocol designs — both basket and platform trials — can be extended from exploratory to confirmatory settings, examining fit-for-purpose design elements, information borrowing strategies, regulatory and HTA considerations, and common pitfalls to maximize evidence generation for regulatory decision-making. We will invite Dr. Robert Beckman (Georgetown University) and Dr. Cong Chen (Merck) as special guests and panel members to share their experiences.

Day 2 Morning: Implementation and Case Studies. The session addresses the operational realities of running master protocols — globalization of master protocol, data monitoring committee establishment and operation, regulatory and IRB/ethics committee interactions, and software tools for trial design and simulation. It then turns to patient engagement and representation in master protocols before concluding with in-depth case studies from landmark trials: BRAF V600E basket trials, and the RECOVERY trial. These case studies illustrate how the design principles, regulatory strategies, and statistical methods from the preceding sessions play out in practice, with candid discussion of challenges and lessons learned.

Day 2 Afternoon: Panel Discussion and Q&A. The course concludes with a multidisciplinary panel bringing together perspectives from statisticians, regulators, clinical investigators, and industry practitioners. Participants are invited to pose questions, discuss emerging challenges, and explore how master protocol approaches can be applied to their own programs. This interactive session is designed to bridge the course material to participants' real-world needs and foster cross-disciplinary dialogue on the future of master protocol trials.

Designed for clinical trialists, biostatisticians, regulatory scientists, drug developers, and industry professionals, this course bridges theory and practice to equip participants with the knowledge needed to design, evaluate, and implement master protocol trials in modern drug development.

Professor Donald A. Berry is a leading biostatistician and pioneer of Bayesian methods in medicine, widely recognized for his contributions to adaptive clinical trial design. At MD Anderson, he served as the founding Chair of the Department of Biostatistics (1999–2010) and played a central role in advancing the use of Bayesian

Clinical Trials in the Era of Real-World Evidence 🕮

Instructors: Jie Chen, Taimei Intelligence, Naitee Ting, Veramed, and Feinan Lu, IMPACT Therapeutics

Moderator: Alfred Balch

Abstract

In new drug development, the goal is to generate the strongest possible evidence—most often through rigorously designed clinical trials such as randomized controlled trials (RCTs)—to support regulatory approval. Alongside these trials, external data sources—such as real-world data (RWD) from insurance claims, electronic health records, and longitudinal observational studies—and real-world evidence (RWE) generated from RWD are increasingly used to support the design, conduct, and evidence synthesis of clinical trials.

This short course aims to provide systematic and integrated approaches for use of RWD and RWE throughout the clinical development of medicinal products, effectively bridging the methodologies of traditional RCTs and modern RWE studies. While grounded in the general statistical concerns of clinical trials within regulatory frameworks, the course incorporates innovative concepts—such as single-arm trials, externally controlled trials, rare disease drug development, and treatment switching—and modern tools—including digital health technologies, artificial intelligence, and machine learning—to address emerging trends in the design and conduct of clinical trial methodologies.

Outline of the short course:

Day 1 Morning:

- Introduction
- A brief history and critical components of clinical trials
- Clinical development process of a new drug

Day 1 Afternoon:

- Design considerations for Phase III confirmatory trials
- Regulatory submission and approval
- An overview of the use of RWD & RWE in regulatory setting
- Single-arm trials

Day 2 Morning:

- Externally controlled trials
- Master protocols
- Drug development for rare diseases
- Time to event analysis with treatment switching

Day 2 Afternoon:

- Precision medicine
- Sensitivity analysis in clinical trials
- Estimands in RWE studies
- Artificial intelligence in clinical studies

Jie Chen, PhD, is the Chairman & Chief Scientific Officer in Taimei Intelligence Biopharma R&D, Inc. Dr. Chen has over 30 years of experience in biopharmaceutical research, development, and life-cycle management. He has contributed to the design, conduct, analysis, and regulatory submission of more than 50 new drug clinical trials, leading to regulatory approvals of over 10 drugs across diverse therapeutic areas. His primary research interests focus on adaptive trial design, multiple comparisons, Bayesian methods, drug safety evaluation, and the application of real-world evidence (RWE), artificial intelligence/machine learning, and

approaches for innovative oncology trials. He founded Berry Consultants in 2000, a scientific consulting firm specializing in Bayesian and adaptive clinical trial design and implementation for pharmaceutical and medical device development. Dr Berry has designed and led numerous innovative trials, including platform trials evaluating multiple therapies simultaneously, including the landmark I-SPY 2 adaptive platform trial in breast cancer. He has published hundreds of scientific papers and multiple books in statistics and biostatistics.

Dr. Ruixiao Lu is a recognized leader in the biotech and biopharma industry, currently as Vice President and Head of Biostatistics and Statistical Programming at Alumis Inc. She has held senior leadership roles where she led end-to-end data science and analytical teams to support product development, regulatory submissions and approvals, medical affairs, and enterprise strategic initiatives. She is dedicated to advancing statistics and data science through professional organizations, as an elected Fellow and Board Director of of the American Statistical Association (ASA) (2020-2023, 2026–2028), elected President and Board Director of BBSW (2024–2026), and co-founder of DahShu (2015–present). She is widely engaged in cross-disciplinary collaborations, with a proven record of success in promoting scientific excellence and improving public health outcomes, including her leadership role at the 2023 FDA-AACR-ASA Overall Survival Workshop.

Dr. Chengxing (Cindy) Lu is a senior director of Oncology Biometrics in AstraZeneca, where she leads a team of statisticians dedicated to early-phase immunology and radioconjugate oncology development. Throughout her extensive career in drug discovery and development, her work has spanned the full spectrum of the field, encompassing early- and late-stage clinical development as well as post-marketing, medical affairs, reimbursement, and commercial strategies. Cindy is deeply committed to driving innovation and enhancing efficiency through multidisciplinary collaborations. She is actively engaged with the professional community through organizations such as the American Statistical Association (ASA), DahShu, DIA, and the International Society of Biopharmaceutical Statistics (ISBS), where she serves as the working group leads.

Dr. Jingjing Ye is a biopharmaceutical executive and former senior FDA regulatory leader with more than 20 years of experience spanning global industry R&D and a decade at the U.S. Food & Drug Administration, specializing in digital transformation, advanced analytics, and data-driven drug development. Her expertise covers the whole patient's journey from diagnosis, treatment to living with the disease. She is a proven leader in building and scaling global organizations and translating complex science and data into regulatory, operational, and portfolio-level impact. Dr. Ye is an elected Fellow of the American Statistical Association (ASA). As a founder and principal consultant of DataDoctor LLC, Dr. Ye is driven by a commitment to improving patient outcomes and is passionate about multidisciplinary collaboration to advance innovations in drug development.

causal inference to support medical product development and regulatory decision-making. He has co-authored or edited three books: *Medical Product Safety Evaluation—Biological Models and Statistical Methods* (Chapman & Hall/CRC, 2019), *Real-World Studies—From Real-World Data to Real-World Evidence* (China Medical Technology Publishing House, 2025), and *Clinical Trials in the Era of Real-World Evidence* (Wiley, 2026). Dr. Chen has published more than 60 peer-reviewed papers. He is a Fellow of the American Statistical Association.

Naitee Ting is a Fellow of American Statistical Association (ASA). Naitee is the recipient of the prestigious Mentoring Award of ASA in 2025. He is currently Vice President of Veramed. Naitee is also an Adjunct Professor of Department of Statistics at University of Connecticut, Adjunct Professor of Department of Biostatistics at Columbia University. He joined Veramed in 2025. Before Veramed, Naitee has been with Boehringer Ingelheim Pharmaceuticals, Inc. (BI) for 15 years, and he was working at Pfizer Inc. for 22 years (1987-2009). Naitee received his Ph.D. in 1987 from Colorado State University (major in Statistics). He has an M.S. degree from Mississippi State University (1979, Statistics) and a B.S. degree from College of Chinese Culture (1976, Forestry) at Taipei, Taiwan. Naitee published articles *in Technometrics, Statistics in Medicine, Drug Information Journal (Therapeutic Innovation and Regulatory Science), Journal of Statistical Planning and Inference, Journal of Biopharmaceutical Statistics, Biometrical Journal, Statistics and Probability Letters, Statistics in Biosciences, Statistics in Biopharmaceutical Research,* and *Journal of Statistical Computation and Simulation*. His book "*Dose Finding in Drug Development*" was published in 2006 by Springer, and is considered as the leading reference in the field of dose response clinical trials. The book "*Fundamental Concepts for New Clinical Trialists*", co-authored with Scott Evans, was published by CRC in 2015. Another book "*Phase II Clinical Development of New Drugs*", co-authored with Chen, Ho, and Cappelleri was published in 2017 (Springer). Naitee has been an active member of both the ASA and the International Chinese Statistical Association (ICSA).

Feinan Lu is Director of Biometrics at IMPACT Therapeutics. She has over 10 years of experience in biopharmaceutical research and drug development. She has extensive expertise in clinical trial design, statistical analysis, and global regulatory submissions across major health authorities, including the NMPA, FDA, and EMA, with experience spanning more than 10 pivotal clinical trials. Her primary research interests focus on oncology clinical trial design, including adaptive designs, single-arm trials, and centralized statistical monitoring. Feinan has been an invited speaker at industry conferences and has co-authored multiple publications on oncology trial design and single-arm studies. She is also a co-author of the book *Clinical Trials in the Era of Real-World Evidence* (Wiley, 2026).

THREE KEYNOTES

(Monday, Tuesday, and Wednesday Morning, December 7-9, 2026, 8-9am)

Keynote 1:
Statistics and AI Capabilities in Accelerating Drug Development

Pandurang "Pandu" Kulkarni and Jingyi Liu, Eli Lilly
Moderator: Ivan F. Chan

Abstract

Artificial intelligence, machine learning, and advanced analytics are rapidly reshaping the way medicines are discovered, developed, and delivered to patients. In this presentation, we will discuss

- Evolving role of statistics and data science across the development continuum
- Evolution of innovation in analytical and AI capabilities to accelerate drug development
- Importance of science and statistical rigor/capabilities

Keynote 2:
From Real-World Data to Regulatory-Grade Evidence: What Statisticians Need to Know About External Controls in Oncology

Jonathan Kish, Flatiron
Moderator: Sofia Paul

Abstract

In this keynote, I will discuss how real-world evidence is moving from a promising concept to a practical component of regulatory and clinical development strategy, with a particular focus on externally controlled trials and oncology evidence generation. The talk will be designed for a statistical audience that already understands the analytic methods, but may be less familiar with the full end-to-end process required to make real-world data usable, credible, and potentially regulatory-grade. I will walk through how a real-world evidence package begins: identifying the right clinical question, determining whether an external control is scientifically appropriate, assessing data fit-for-purpose, developing the protocol and statistical analysis plan, defining cohorts and endpoints, and pressure-testing the design against bias, missingness, confounding, and sensitivity to assumptions. The goal is to move beyond buzzwords and show what it actually takes to generate robust evidence from real-world data: where the data come from, how they are curated and validated, what statisticians need to know before analysis begins, how regulators are thinking about these approaches, and how sponsors can build evidence packages that are not only analytically rigorous but also clinically meaningful and reviewable. Drawing on Flatiron's experience working across pharma, biotech, academic, and regulatory contexts, the keynote will offer a practical view of where real-world evidence is already helping drug development, where caution is still warranted, and what statisticians can do to shape the next generation of credible, decision-ready evidence.

Keynote3:
Bayesian Adaptive Clinical Trials: From Bandit Problems to Real-World Innovation

Prof. Don Barry, MDACC
Moderator: Bill Wang

Abstract

Decision-analytic Bayesian approaches are ideally suited for designing clinical trials and have been used increasingly over the last 30 years in developing medical devices and drugs. A prototype trial is a bandit problem, in which treating participants is as important as treating patients in clinical practice after the trial.
This keynote provides a comprehensive historical and practical review of Bayesian adaptive trials, with a focus on bandit-inspired designs. The 20th century saw foundational advances in Bayesian methodology enabled by computer simulation. In the 21st century, methods motivated by bandit problems have been applied in designing scores of actual clinical trials. By far the most important Bayesian contributions in clinical trials are the abilities to observe accumulating results and to modify the future course of the trial on the basis of those observations. In the spirit of AI, algorithms are programmed to learn optimal treatment assignments over the remainder of the trial. Bayesian trials are still nascent and represent a small minority of clinical trials, but their existence is changing the way investigators, regulators, and government and industry sponsors view innovation in clinical trial design. The keynote will also include I-SPY2 as a landmark example beyond its Bayesian innovations. It was the first platform trial and its influence and design extend far beyond breast cancer by numerous subsequent trials, including the Phase 3 GBM AGILE trial in glioblastoma. The July 7, 2016 issue of the NEJM reflected the field's early engagement with I-SPY2, publishing four articles related to the trial in a single issue — a notable concentration of attention for any single study in a prominent medical journal. Subsequently, Woodcock and LaVange published a 2017 NEJM review paper introducing the concept of master protocols to a wide medical audience, with I-SPY2 as its primary illustration, demonstrating its regulatory and scientific impact.

Deming Banquet Dinner
Monday 6:00 – 9:00 PM, December 7, 2026

Statistical Talent in the AI Era

Banquet Speakers:

Hongtu Zhu, PhD, Kenan Distinguished Professor, University of North Carolina

Christine Gause, PhD, VP, Late Development Statistics, BARDS, Merck Research Labs

Organizer: ASA BIOP AI-NEXUS Task Force
Facilitator: William Wang, Merck & Co., Inc.

This year's Deming Conference Monday evening gathering will feature a banquet-style dinner organized by the ASA BIOP AI-Nexus Task Force. Dr Hongtu Zhu will open with a brief talk *"Rebuilding Statistics in the Age of AI: Culture, Infrastructure, and Training,"* based on his August 2026 *JASA* article (DOI: 10.1080/01621459.2026.2680161). The article outlines key priorities for the statistics profession to evolve and lead in the AI era, emphasizing system-level thinking and workforce development needed to ensure trustworthy and impactful use of AI. Dr Christine Gause will share an industry perspective on how the role of statisticians is evolving within biopharma R&D. She will discuss how companies can attract, develop, and retain talent in an AI-enabled environment, where statisticians are expected to contribute through scientific judgment, strategic decision-making, evidence synthesis, and cross-functional leadership.

The talks will be followed by an interactive fireside-style dinner discussion and debate on the capabilities, experiences, and training needed for statistical talent to thrive and lead in the AI era.

Hongtu Zhu, PhD, is the Kenan Distinguished Professor of Biostatistics at the University of North Carolina at Chapel Hill. An internationally recognized expert in statistical learning, medical imaging, precision medicine, artificial intelligence, and big-data analytics, he has published more than 345 papers in leading scientific and statistical journals. Dr. Zhu is a Coordinating Editor of the *Journal of the American Statistical Association* and recipient of the 2025 COPSS Snedecor Award and the 2019 INFORMS Daniel H. Wagner Prize. He previously served as Chief Scientist of Statistics at DiDi Chuxing and held the Endowed Bao-Shan Jing Professorship in Diagnostic Imaging at MD Anderson Cancer Center.

Christine Gause is currently Vice President of Biostatistics at Merck, leading a group of ~300 that encompasses Late Development Statistics, Clinical Safety Statistics and Scientific Communications and Information Sciences. In this role, she is responsible for overseeing end-to-end statistical support for the entire late development pipeline across therapeutic areas, partnering with colleagues in clinical, regulatory, and other quantitative groups. Prior to her current role, Christine led the late development oncology statistics group where she supervised a team of more than 70 statisticians focusing on critical project strategy, data analysis and interpretation, fit-for-purpose novel study design, and innovative statistical methodology for multiple high-profile oncology products. Throughout her career, Christine has held positions of increasing responsibility in statistics across several therapeutic areas including vaccines, biosimilars, diabetes, and oncology, and has contributed to multiple regulatory submissions, statistical publications and presentations.