Sheraton Philadelphia Downtown Hotel

Oct 24, 2024 7:30 AM - Oct 25, 2024 4:10 PM

201 North 17th Street, Philadelphia, PA 19103

Real-World Evidence Conference

Translating Insights into Real-World Value

REGISTER →

Early Bird Rates Expire

47	22	29	45
DAYS	HOURS	MINUTES	SECONDS

Print Agenda

Day 1 Oct 24, 2024

7:30 AM — 5:30 PM

Conference Registration

8:30 AM — 8:45 AM

Opening Remarks

Session Chair(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
DIA, United States

Tamei Elliott, MS, serves as the Associate Director of Scientific Programs for the Americas region at DIA. In this pivotal role, she is responsible for identifying and prioritizing content areas and topics crucial to DIA constituents. Tamei assesses the implications of significant regulatory and health policy changes, seamlessly integrating relevant content into the development and advancement of DIA conferences and courses. Her responsibilities extend to overseeing content development and strategy within the Americas region.

David Martin, MD, MPH

Vice President, Global Head RWE
Moderna, United States

David Martin leads Global RWE for Moderna. Previously he completed 20 years of active duty service split between the United States Air Force and Public Health Service. At the FDA he led the Division of Epidemiology in the Center for Biologics. Subsequently, he established the Real World Evidence group in the Office of Medical Policy to drive the agency's scientific, guidance, and submission review responses to the RWE provisions of the 21st Century Cures Act. He initiated key RWE pathfinding efforts with external stakeholders including RCT Duplicate and the open-source FDA MyStudies mobile application. He holds an MD and MPH from Johns Hopkins and is board certified in occupational & environmental medicine as well as clinical informatics.

8:45 AM — 9:45 AM

Session 1: A Year in Review

Session 1: A Year in Review

Track: General Sessions

Eli Lilly & Co., United States

Sarah currently serves as senior director of global regulatory policy for oncology at Eli Lilly. She previously served as senior director of science and regulatory advocacy for the Pharmaceutical Research and Manufacturers of America (PhRMA) where she led their regulatory advocacy efforts on key issues including real-world evidence. Sarah worked for the American Association for Cancer Research (AACR) where she led their efforts to modernize the regulatory process and engage in the development and implementation of programmatic and policy initiatives with the US FDA Oncology Center of Excellence.

9:45 AM — 10:30 AM

Refreshment and Networking Break

10:30 AM — 11:45 AM

Session 2: Early Development Use Cases

Session 2: Early Development Use Cases

Session Chair(s)

Charles Lee, MBA, MS

Executive Regulatory Science Director
AstraZeneca, United States

Charles is currently Executive Regulatory Science Director at Astrazeneca. He oversees Global Regulatory science and strategy for therapeutic products in the renal, cardiovascular, diabetes, and NASH disease areas. Prior to this role, Charles was a Product Development Team Leader over a 10 year period at Astrazeneca and Roche where he led cross-functional project teams for programs in the early development phase (Ph0 to Ph2b). Previous to that, Charles spent 10 years in Global Regulatory affairs where he held leadership roles on programs across several therapeutic areas in different stages of development. Charles holds BS in Biology from The Johns Hopkins University, MS from University of Virginia, MBA from Columbia Business School

Speaker(s)

Why and How: An External Control Used to Contextualize the Results of an Early Phase Single Arm Metastatic Pancreatic Study

Representative Invited

Medidata, a Dassault Systemes Company, United States

Lisa Ensign is a VP of Data Science at Medidata AI. Her current work in the Integrated Evidence team is focused on creating analytical approaches to improve and transform the efficiency and rigor of clinical trials, centered on the use of external controls. Dr. Ensign began her career at MD Anderson Cancer Center and has over 30 years experience in the life sciences sector. She received her MS in biostatistics from Harvard University and her PhD in clinical science from the University of Colorado, where she is also an instructor on ethics and the responsible conduct of research.

Endpoints Optimization for Clinical Trials in Myotonic Dystrophy Type 1 (DM1): A Real World Data-driven Approach

Representative Invited

Sanofi, France

11:45 AM — 12:45 PM

Networking Luncheon

12:45 PM — 2:00 PM

Session 3: Late Phase and Post-Marketing Use Cases #3

Session 3: Late Phase and Post-Marketing Use Cases #3

Session Chair(s)

sciences sector. Earlier in her career, Camille held roles at Clarivate, Sanofi, PhRMA, The World Bank, NIH, The George Washington University, and the American Academy of Child and Adolescent Psychiatry.

Speaker(s)

Utilize Registry-based RCT to Improve Drug Development Efficiency: DAPA-MI as a Case Study

Jingyu (Julia) Luan, PhD

Executive Regulatory Science Director, BioPharmaceuticals R&D
AstraZeneca, United States

Dr. Jingyu (Julia) Luan is a Senior Director of Global Regulatory Affairs in AstraZeneca, leading global drug development and regulatory strategies as well as innovative regulatory initiatives, eg, RWE. Prior to AstraZeneca, she worked at FDA for 13 years and held positions with increasing responsibilities, including Statistical Reviewer, Team Leader, and Acting Deputy Division Director. She had extensive experience in multiple therapeutic areas for both new and generic drugs. In addition, she was a research faculty member at Johns Hopkins University and a statistical consultant at the University of Kentucky. Dr. Luan is President-elect of Chinese Biopharmaceutical Association and Board Member/Committee Co-chair of FDA Alumni Association.

Implementing Clinical Trial Linkage to Real-World Data (RWD)

Representative Invited

Medidata AI, United States

Mehdi NajafZadeh, PhD, is Senior Director at Medidata AI. Before joining Medidata AI, he was an Assistant Professor of Medicine in the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, and the PI of large NIH and FDA funded projects that aimed at linking RCTs to RWD.

Post-Approval Pregnancy Safety Study (PA-PSS) Innovations: New Ways for Studying the Safety of Medications During Pregnancy

Representative Invited

Eli Lilly and Company, United States

2:10 PM — 3:25 PM

Session 4: Real-World Data Standards for Regulatory Submissions: Exploring the Challenges, Solutions, and Potential Alternatives

Real-world data standards have been of great interest since draft guidance was released by the FDA in 2021. This session will discuss developments in this area, case studies of regulatory use cases, and areas of focus for the future.

Learning Objective :

- Share new developments in real-world data (RWD) standards over the past year, including: updates from sponsors, data providers, standards development groups, validation organizations, and themFDA
- Discuss available data standards from FDA's Catalog and assess other common data models that could be considered as additions

Track: General Sessions

Level: Intermediate

Session Chair(s)

Diane Gubernot, DrPH, MPH

Epidemiologist
US FDA, United States

Dr. Diane Gubernot is a Health Scientist in the Office of Biostatistics and Pharmacovigilance at the Center for Biologics Evaluation and Research (CBER) of the USFDA. She conducts regulatory reviews of RWE/RWD submitted in biologic product applications and performs research to help support RWE policy development as well as other public health initiatives. Dr. Gubernot has been with the FDA for more than 30 years and has worked as an Investigator in the Office of Regulatory Affairs, a Team Lead Epidemiologist in the Office of the Commissioner, and a regulatory product reviewer at CBER.

Speaker(s)

Speaker

Representative Invited

assessment of Amgen's medicines. He also has an interest in the new regulatory guidelines for generating RWE and is exploring processes and standards to align with the evolving framework.

3:25 PM — 4:00 PM

Refreshment and Networking Break

4:00 PM — 5:15 PM

Session 5: Social Determinants of Health

Session 5: Social Determinants of Health

Session Chair(s)

Brittany McKelvey, PhD

Director, Regualtory Affairs
Friends of Cancer Research, United States

Speaker(s)

Representative of What? Pragmatic Strategies to Improve Diversity and Inclusion When the Research Questions Demand it

Representative Invited

Mission Health Labs, Inc. (dba PicnicHealth), United States

Discovering Patient Barriers in Real-World Data to

Implementation of Diversity Plans

Representative Invited

Friends of Cancer Research, United States

Mark Stewart is vice president of science policy at Friends of Cancer Research (Friends), an advocacy organization based in Washington, DC that drives collaboration among partners of every healthcare sector and creates and implements policies ensuring patients receive the best treatments in the fastest and safest way possible. Mark leads the development and implementation of the organization's research and policy agenda as well as overseeing the conduct of research projects to inform ongoing policy discussions. He regularly participates in policy discussions and meetings throughout the year to help catalyze meaningful change for oncology healthcare and patients.

5:15 PM — 6:15 PM

Networking Reception

Day 2 Oct 25, 2024

7:30 AM — 4:10 PM

Conference Registration

7:30 AM — 8:00 AM

Networking Breakfast

8:00 AM — 9:15 AM

Emerging Data Sources and New Platforms: Global Perspectives

Opening Remarks and Session 6: Sand in Your Shoes? The Nitty-Gritty in Generating Regulatory-Grade RWE Using Emerging Data Sources and New Platforms: Global Perspectives

Session Chair(s)

Rachele Hendricks-Sturrup, DrSc, MA, MSc

Research Director, Real-World Evidence
Duke-Robert J. Margolis, MD, Center for Health Policy, United States

Rachele Hendricks-Sturrup, DHSc, joins Duke-Margolis as the Research Director leading the Center's Real-World Evidence (RWE) portfolio, including managing its RWE Collaborative. She is a scientist/researcher, health policy and industry professional, journalist, and academician within the fields of health policy, business, and health innovation.

9:20 AM — 10:35 AM

Session 7: Methods

Session 7: Methods

Track: General Sessions

Session Chair(s)

John Concato, MD, MPH, MS

Associate Director for Real-World Evidence Analytics, OMP, CDER
FDA, United States

Dr. John Concato is Associate Director for Real-World Evidence Analytics in the Office of Medical Policy, Center for Drug Evaluation and Research, FDA. As an internist and epidemiologist, his responsibilities related to real-world evidence (RWE) include developing internal Agency processes, interacting with external stakeholders, and coordinating demonstration projects as well as guidance development. Dr. Concato joined FDA from Yale School of Medicine and the U.S. Department of Veterans Affairs, where he was a clinician, educator, independent investigator, research center director, and Professor of Medicine. He has a BE degree from The Cooper

Strengths and Challenges of Test-Negative Designs to Assess Post-Marketing Vaccine Effectiveness

Representative Invited

PPD, part of Thermo Fisher Scientific, France

Executive Director in the RWE group at Evidera, PPD, part of Thermo Fisher Scientific, in Paris, France. Dr. Saragoussi is a physician specialized in Public Health and epidemiologist. In the pharmaceutical industry during 12 years and then as a consultant for the past 5 years, she has developed and implemented various RWE plans to support market access. Her research methods expertise covers the collection of primary data as well as the use of electronic databases. It includes natural history studies, burden of illness evaluations, treatment patterns descriptions, PRO validations, real-world effectiveness studies. Dr. Saragoussi is also well versed in the generation of RWE to meet regulatory needs.

Using Negative Outcome Control Studies to Assess Study Validity in the Real-World

Representative Invited

Target RWE, United States

Traditions and Frontiers in Causal Methods - From the Rise and Fall of Propensity Scores to Causal AI for RWE

Representative Invited

Parexel, United States

I am the Scientific Lead within the Scientific Data Organization at Parexel. My interests are in real-world data applications to scientific questions and the importance of embracing context within the 'data generation process.' Ongoing research is along the intersection of machine learning, causal inference, and reproducibility in research. I have an adjunct appointment at the University of Utah and have affiliations with various other institutions to collaborate as broadly as possible.

10:35 AM — 11:15 AM

Refreshment and Networking Break

Session 8: Innovations in Technology and Operational Excellence

Session 8: Innovations in Technology and Operational Excellence

Session Chair(s)

Jaclyn Bosco, PhD, MPH, FISPE

Vice President and Global Head of Epidemiology
IQVIA, United States

Dr. Jaclyn Bosco Global Head of Epidemiology in Real World Solutions at IQVIA, is responsible for driving real-world evidence (RWE) generation for regulators, clinicians, patients and payers using passive and primary data collection through clinicians and person-generated health to support the safety and effectiveness of drugs, biologics, and medical devices from early clinical development through the post-approval phase. She identifies the best approach for capturing data on a global scale as well applies local approaches to address market-specific needs. As a thought leader in real world research, she is invited to speak at international congresses and sits on scientific advisory boards and committees.

Speaker(s)

AI-Enabled Data Abstraction: Benefits and Risks for Data Curation

Representative Invited

PicnicHealth, United States

Seeing Eye to Eye: Enhancing Inter-Team Communication for Reproducible Real World Evidence

Representative Invited

Target RWE, United States

Supplementing the Identification of Clinical Endpoints through Tokenization of Clinical Trial Participants

medications, particularly for auto-immune disorders. In previous work she was engaged in prostate cancer research, including evaluation of genetic risk factors from inflammatory pathways. Her current interests include linkage of RWD and clinical trial data to enhance the evaluation of drug safety. She is an advocate for communication about pharmacoepidemiology careers in industry and welcomes trainee questions.

12:30 PM — 1:30 PM

Networking Luncheon

1:30 PM — 3:00 PM

Session 9: AI

Session 9: AI

Session Chair(s)

Keri Monda, PhD, MS

Executive Director, Center for Observational Research
Amgen, United States

Keri Monda, PhD, is an Executive Director of Observational Research and Head of the Data & Analytics Center within the Center for Observational Research (CfOR) at Amgen. In her role, she leads a team of epidemiologists and data scientists responsible for generating real-world evidence in support of programs from research and early development through launch and end of patent expiry, and oversees a large, integrated real-world data and analytics ecosystem. Prior to her time at Amgen, Keri was a genetic epidemiologists on faculty in the Department of Epidemiology at the University of North Carolina, Chapel Hill.

Speaker(s)

Unexpected Issues in Pharmacoepidemiology Studies Applying Natural Language Processing to Clinical Notes: MOSAIC NLP Part II

Real-World Data and AI Policy

Representative Invited

Covington & Burling obo RWE Alliance, United States

Unleashing RWD and RWE: Transforming Clinical Study Design with Generative AI

Susant Mallick, MBA

Founder and CEO, Life Sciences Practice Leader
Cloudhub BV, Netherlands

Susant Mallick comes up with 23+yrs of Pharma and IT background on building disruptive solutions/products in Clinical and Regulatory space. He is technology evangelist on cutting edge technology like (Artificial Intelligence, Machine Learning, IoT, Cloud etc) and an industry leading speakers across geographies. He has been working with various customers and partners in pharma and healthcare to drive digital transformation in clinical and regulatory landscape. He was instrumental in implementing/building many Regulatory solutions using advanced technology. Innovation and Digital Transformation in Healthcare and Life Sciences are two key focus areas.

Leveraging RWD to Enable Predictive Treatment Effect Modelling in Personalized Medicine

Representative Invited

Sanofi, United States

3:00 PM — 4:00 PM

Looking Forward

Session Chair(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
DIA, United States

David Martin, MD, MPH

Vice President, Global Head RWE
Moderna, United States

David Martin leads Global RWE for Moderna. Previously he completed 20 years of active duty service split between the United States Air Force and Public Health Service. At the FDA he led the Division of Epidemiology in the Center for Biologics. Subsequently, he established the Real World Evidence group in the Office of Medical Policy to drive the agency's scientific, guidance, and submission review responses to the RWE provisions of the 21st Century Cures Act. He initiated key RWE pathfinding efforts with external stakeholders including RCT Duplicate and the open-source FDA MyStudies mobile application. He holds an MD and MPH from Johns Hopkins and is board certified in occupational & environmental medicine as well as clinical informatics.

4:00 PM — 4:00 PM

Conference Adjourns