The Westin San Diego Bayview Hotel

Oct 16, 2025 7:00 AM - Oct 17, 2025 7:00 PM

400 W Broadway, San Diego, CA 92101, USA

Real-World Evidence Conference

Translating Insights into Real-World Value

REGISTER →

CONTACT US

Send Email

1.888.257.6457

Print Agenda

Day 1 Oct 09, 2025

10:00 AM — 2:00 PM

Short Course: Getting Started with Estimands in Real-World Evidence Studies

Day 2 Oct 16, 2025

7:30 AM — 5:30 PM Ballroom Foyer (Level 2)

Conference Registration

7:30 AM — 8:30 AM Crystal Ballroom

Networking Breakfast

8:30 AM — 8:45 AM Emerald Ballroom

Welcome and Opening Remarks

Welcome and Opening Remarks
Track: General Session

Session Chair(s)

Sorcha McCrohan, MS

Sr. Scientific Project Manager
DIA, United States

Sorcha McCrohan is a Senior Scientific Project Manager for Global Science at DIA. In her current role, she focuses on content development and strategy for DIA's meetings to improve and facilitate innovation in clinical research, drug development, and the fields of devices and diagnostics. Before joining DIA, she conducted COVID-19 research in Chiapas, Mexico, and worked in marketing within Pfizer's Global Vaccines franchise. Sorcha holds a BA in Sociology from Mount Holyoke College and an MSc in Global Health, Disease Prevention & Control from Georgetown University.

8:45 AM — 9:45 AM Emerald Ballroom

Session 1: A Year in Review of Advancing RWE Globally

Over the past year, global regulatory bodies have released pivotal guidance and launched key initiatives shaping the future of Real-World Evidence (RWE). This session will feature updates on EMA's DARWIN EU activities, FDA's latest guidance and submissions involving real-world data (RWD), and progress on ICH M14. Panelists will also highlight the publication of new RWE-related standards and their implications for regulatory and payer decision-making. Insights will focus on how these developments are influencing industry strategies and evidence generation practices.
Learning Objective :

- Discuss key 2024 RWE milestones from global regulators including EMA, FDA, and ICH
- Interpret new standards and guidance shaping the regulatory and payer use of RWE

- Examine how recent regulatory developments are shaping industry approaches to evidence generation and submission

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.

Rachele Hendricks-Sturrup, DrSc, MA, MSc

Research Director, Real-World Evidence
Duke-Margolis Institute For Health Policy, United States

Dr. Rachele Hendricks-Sturrup is the Research Director of Real-World Evidence (RWE) at the Duke-Margolis Institute for Health Policy in Washington, DC, strategically leading and managing the Institute's RWE Collaborative and RWE policy research portfolio and education. As an engagement expert, biomedical researcher, bioethicist, and policy practitioner with over 18 years of experience, her work centers on addressing implementation, regulatory, and ethical, legal, and social implications (ELSI) at the intersection of health policy and innovation. She presently partners with Duke University faculty, scholars, students, and external practicing experts to advance the Institute's biomedical innovation work.

Speaker(s)

Speaker

Robert Reynolds, DrSc, MSc, FISPE

Vice President, Global Epidemiology, CMO, R&D
GSK, United States

Dr. Robert Reynolds is Vice President, Global Epidemiology at GSK, where he leads the group responsible for epidemiology and RWE in support of R&D and regulatory decision-making. He has published extensively on design and methods for RWE and pragmatic trial designs, including numerous studies evaluating medicine safety and effectiveness. He has extensive experience in collaborative international engagements with regulators, industry peers, and other stakeholders. He is a Fellow of ISPE and an Adjunct Associate Professor of Epidemiology at Tulane. Dr. Reynolds holds an AB in Biology from Bard College and a MSc in Epidemiology and ScD in Population/International Health from the Harvard T.H. Chan School of Public Health.

Speaker

Dan Riskin, MD

Founder and Chief Executive Officer
Verantos, United States

Dan Riskin is the founder and CEO of Verantos, the global leader in high-validity real-world evidence at scale. Recognized across the globe as an expert in healthcare AI, Dr. Riskin has developed products that influence the care of millions of patients annually. His advocacy includes testimony before Congress on the 21st

Century Cures initiative and serving on the Health Advisory Committee for two presidents. He is Clinical Professor of Surgery at Stanford University.

Speaker

Hidetaka Kobayashi, MPH

Pharmaceuticals and Medical Devices Agency (PMDA) Office of Drug Safety I, Japan

9:45 AM — 10:30 AM Crystal Ballroom

Networking and Refreshment Break Sponsored by Forian

9:55 AM — 10:25 AM Opal Room

Hosted Session/Non-CE: Case Study hosted by Truveta: Accelerating Evidence Generation: Delivering Insights Ahead of Trials and Registries

Traditional clinical trials and registries take years to generate post-market evidence, leaving critical knowledge gaps that delay patient and provider decision-making. Using Truveta Data – which includes complete EHR data linked with claims and genomic information – researchers have rapidly generated high-quality real-world evidence well ahead of traditional methods. This presentation will highlight two case studies: (1) a GLP-1 comparative effectiveness study that produced results over a year before a major trial, later validated by trial findings, and (2) a device manufacturer that replicated registry outcomes with a significantly larger, more contemporary patient cohort. These examples showcase how real-world data can deliver timely, scalable, and clinically meaningful insights.
Learning Objective :

- How Truveta Data delivers real-world evidence faster than trials and registries, enabling earlier, data-driven decisions
- How linked EHR, claims, and genomic data can be used to power comprehensive, high-quality pre- and post-market research
- How Truveta Data meets and exceeds FDA standards, supporting regulatory submissions of audit-ready real-world evidence

Track: Exhibitor Event

Session Chair(s)

Sponsored Sessions

United States

EXHIBITOR

Speaker(s)

Exhibitor

Conor Wyand

Vice President of Partner Growth
Truveta, United States

Conor Wyand is the Vice President of Partner Growth at Truveta where he leads a team responsible for engaging with potential new life science customers. Prior to joining Truveta in 2021, Conor spent six years in various leadership positions at Optum Life Sciences, working with pharmaceutical and medical device manufacturers across the value chain to generate real-world evidence for therapeutics and devices. Conor graduated from Brown University.

10:30 AM — 11:45 AM

Emerald Ballroom

Session 2: Ensuring Quality and Integrity of Real-World Data: Regulatory Insights

As regulatory use of real-world data (RWD) grows, challenges in data review, inspection, and quality assurance have become increasingly complex. This session will explore the difficulties regulators and industry face in ensuring data integrity, traceability, and compliance with standards like CDISC SDTM. A case study from Nordic registries will illustrate how high-quality RWD supports regulatory-grade pharmacovigilance. Attendees will gain insights into practical solutions and best practices for advancing RWD in regulatory submissions. The panel will also discuss innovations needed to address RWD-specific nuances and enhance global regulatory confidence. Perspectives from both regulators and industry will provide a comprehensive view of current challenges and future opportunities.
Learning Objective :

- Outline key challenges in reviewing and inspecting real-world data (RWD) in regulatory submissions within the session timeframe
- Describe characteristics of high-quality Nordic RWD that support regulatory-grade pharmacovigilance by the end of the session
- Explain practical strategies and emerging solutions to improve data integrity, traceability, and regulatory confidence in RWD during the session

Track: General Session

Session Chair(s)

Motiur Rahman, PhD, MPharm, MS

Senior Epidemiologist and Policy Advisor, Real World Evidence Analytics, OMP, CD
FDA, United States

Dr. Motiur Rahman is a Senior Epidemiologist and Policy Advisor in RWE Analytics within the Office of Medical Policy at CDER, FDA. He leads the consult service for reviewing RWD study submissions, leads international regulatory collaborations including ICH initiatives, and supports internal training and process development. He serves as FDA topic lead for the ICH E23 Working Group, contributes to FDA-funded demonstration projects, and is a core member of the RWE Subcommittee. Dr. Rahman joined FDA in 2022 after more than a decade of academic and industry experience conducting observational studies across diverse therapeutic areas. A pharmacist by training, he holds a PhD in Pharmacoepidemiology and a Master's in Statistics.

Speaker(s)

Review and Inspection of Real-World Data (RWD) in Regulatory Submissions: Challenges and Solutions

Mayur Saxena, PhD

Chief Executive Officer
Droice Labs, United States

As an entrepreneur and scientist, Mayur has concentrated on advancing medicine with high-noise, big data analysis. Before founding Droice, he played key roles in several startups, including co-founding a biotechnology firm in the diabetes space. He earned his BTech at IIT Kanpur and his MS and PhD at Columbia University, focusing on the computational physics of disease.

Making the Grade: How Data Quality Enables Regulatory-Grade Evidence in Pharmacovigilance

Kirk Geale, PhD, MS

CEO
Quantify Research, Sweden

Kirk Geale is the CEO and Board Director of the Quantify Research group. With expertise spanning economics, RWD/E, epidemiology, and strategy, he brings a unique interdisciplinary perspective to the life sciences industry. Dr. Geale holds a PhD from Umeå University (Sweden), an MSc in Economics from Lund University (Sweden), and a B.Comm in Management Economics & Finance from the Gordon S. Lang School of Business and Economics at the University of Guelph (Canada). He is also a graduate of Stanford University's Executive Program for Growing Companies (USA) and the Karolinska Institute's Interdisciplinary Graduate School in Register-Based Research (Sweden).

Assessing Data Reliability in RWD/RWE Studies: Lessons from Regulatory Inspections

Kassa Ayalew, MD, MPH

Director, DCCE, OSI, Office of Compliance, CDER
FDA, United States

Dr. Kassa Ayalew serves as the Division Director for the Division of Clinical Compliance Evaluation within the Office of Scientific Investigation at the FDA's Center for Drug Evaluation and Research. In this role, he oversees the evaluation of the integrity of efficacy and safety data submitted to the FDA and ensures the protection and welfare of human research subjects. He is board certified in Pediatrics and Infectious Diseases and holds an active medical license in the state of Virginia. In addition to his regulatory work, Dr. Ayalew provides clinical care to both pediatric

and adult patients at an urgent care facility. He has delivered numerous didactic lectures and has published research in peer-reviewed journals.

11:45 AM — 12:45 PM Crystal Ballroom

Networking Luncheon

12:45 PM — 2:00 PM Emerald Ballroom

Session 3: RWD and RWE in Support of Clinical Development: Designs, Guidance Gaps, and Practical Strategies

Using real-world data in clinical development offers valuable opportunities but also presents regulatory and methodological complexities. This session will explore hybrid and externally controlled trial designs, integration of RWD with randomized trials, and real-world challenges when applying regulatory guidance. Presenters will share case studies and practical approaches to optimize challenges presented by RWD against and regulatory expectations.
Learning Objective :

- Apply case-based strategies to resolve methodological challenges and support regulatory-grade evidence generation
- Describe the design and application of hybrid and externally controlled trials using RWD
- Differentiate common sources of misalignment between RWD and regulatory guidance

Track: General Session

Session Chair(s)

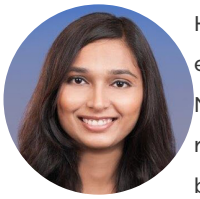
Lina Titievsky, PhD, MPH

Head of Hepatology Epidemiology
GlaxoSmithKline, United States

Lina Titievsky, MPH PhD, is a head of Hepatology Epidemiology in Global Epidemiology at GSK. Prior to joining GSK, Lina's professional journey included working in safety epidemiology across multiple therapeutic at Pfizer, leading a medical research organization at Intercept and RWE team responsible for cell and gene therapies at Vertex. In her current role, she leads a group of epidemiologists responsible for generating RWE in support R&D throughout the products' life cycle, ranging from pre-clinical needs all the way through the regulatory approval. Lina holds a PhD in Epidemiology from Columbia University and is an ISPE Fellow.

Hetal Pansuria, PharmD

Vice President, Regulatory Affairs, Clinical, Nonclinical and Ad-Promo
Pacira Biosciences, United States



Hetal Pansuria, Pharm.D., is an experienced regulatory professional and pharmacist with 20 years of experience in the health care industry. In her role as Vice President of Regulatory Affairs, Clinical, Nonclinical, and Ad-Promo at Pacira BioSciences, Hetal oversees the development and execution of regulatory strategies for clinical, nonclinical, and advertising-promotional reviews of drugs, biologics, and medical devices. Hetal works closely with senior leaders and cross-functional teams to develop effective regulatory strategies that optimize the development pathway for products in all stages of development, including early-stage assets & marketed products. She also oversees ad-promo reviews and labeling activities for all products.

Speaker(s)

Requirement for Prudence – Resolving Regulatory RWD/E Guidance Dilemmas

John Seeger, DrPH, PharmD, FISPE

VIce President
RTI, United States

Innovations in Integrating RWD with RCTs: Case Studies with External Controls and Beyond

Mingyang Shan, PhD

Senior Director
Eli Lilly and Company, United States

Mingyang Shan is a Senior Director of Statistics and the lead of the Real-World Analytic Capabilities team at Eli Lilly and Company. His current focus is on developing methodology and best analytical practices to leverage evidence from real world data in drug development. His research focus includes external control design and analysis methods, data integration, Bayesian analysis, data linkage, and target trial emulation. He has supported trials across immunology, neuroscience, and cardiometabolic health. He is a co-PI on an FDA U01 grant to develop methodology to enhance the robustness of hybrid externally controlled trials using RWD.

Speaker

Xiang Zhang, PhD

Head of Medical Affairs and HTA Statistics/Co-lead FORExcellence
CSL Behring, United States

Xiang Zhang is the Head of Medical Affairs and HTA Statistics and a co-lead of the Forum for Observational Research Excellence at CSL. He leads a team of statisticians, epidemiologists, and RWE scientists to support RWE generation across drug life cycle including clinical development, regulatory submissions, product launches, and commercialization. This team also provide statistical support for HTA submissions and other peri-launch activities to secure market access for CSL products. He has authored or co-authored over 40 peer-reviewed publications and a book in causal inference in RWD analysis. He is a member of both RWE and HTA scientific working groups under the American Statistical Association.

2:10 PM — 3:25 PM

Emerald Ballroom

Session 4: Leveraging RWD and Synthetic Data to Advance Research in Special Populations

The session will share lessons on how to incorporate synthetic data thoughtfully into RWE pipelines, particularly for sensitive, stigmatized, or underrepresented populations. Implications for research design, data validation, and convergence with traditional data sources will be discussed to ensure methodological rigor in synthetic applications.
Learning Objective :

- Examine insights from a preliminary validation study on using synthetic data to test survey instruments with sensitive substance use questions
- Discuss how synthetic cohorts support feasibility assessment, hypothesis refinement, and sample size planning
- Identify methodological applications of synthetic data for accessing hard-to-reach populations, including young adults

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)

Leveraging Synthetic Data for Methodological Insight into Substance Use Research with Hard-to-Reach Young Adults

Red Thaddeus Dela Pena Miguel, MD, MBA, MSc, RAC

Chief Executive Officer
Thera-Business Inc., Canada

Dr. Red Thaddeus Miguel is an executive and sought-after researcher with expertise in regulatory science, evidence-based healthcare, survey methodology, and health economics. He holds an MSc in Evidence-Based Health Care from the University of Oxford, MD–MBA dual degrees, and RAC and RCC certifications. As CEO of Thera-Business, he leads complex regulatory, research, and real-world evidence projects for life sciences clients. He has published widely and received multiple awards, including Ottawa's Forty Under 40 in 2024 for his business leadership, professional expertise, and community impact.

Speaker

Michael Rozycki, PhD

Senior Vice President, Regulatory Affairs
Pacira Pharmaceuticals, Inc., United States

Michael Rozycki started his career in basic research, earning his Ph.D. in Biochemistry from Cornell University and holding post-doctoral research and research appointments at the University of Geneva (Switzerland) and Princeton University. He then moved into management consulting in the pharmaceutical and financial services industries before beginning his Regulatory Affairs career at Merck. Mike then went on to positions of increasing responsibility in Regulatory Affairs at Aventis, Bayer, Allergan, and Pacira, where he currently holds the position of Senior Vice President, Regulatory Affairs.

3:25 PM — 4:00 PM Crystal Ballroom

Networking and Refreshment Break

3:30 PM — 4:00 PM Opal Room

Hosted Session/Non-CE: Case Study hosted by Castor: On the Road to Self-Driving Trials: Faster, Cleaner RWE Data Extraction through AI Agents

Data for observational studies still arrives as unstructured EHR and PDF records—slow, error-prone, and costly to process. Castor Catalyst is an AI agent that pulls regulatory-grade variables from any medical record, then flags exceptions for human review. In a 54-chart validation it cut extraction errors from 6.6 % to none detected, trimmed review time from 30 min to 6 min, and dropped direct cost from ˜ $49 to ˜ $10 per chart. Five live RWE studies now run Catalyst in production; this session shares what worked, what broke, and what's next.

Featured Topics:

- Why AI: Catalyst's extraction beats manual work on error, speed, and cost—numbers from five live RWE studies
- Human supervision stays: Catalyst flags every change for investigator sign-off, meeting ICH E6(R2) expectations
- Guardrails that matter: no autonomous endpoint data, no direct patient contact, every action auditable
- What we've learned so far: error rates, time-to-complete, and user-satisfaction data—where Catalyst shines, where it still needs help
- 2026 roadmap: plug-and-play with other systems, add new "skills," and use predefined metrics before loosening autonomy any further

Track: Exhibitor Event

Session Chair(s)

Sponsored Sessions

United States

EXHIBITOR

Speaker(s)

Speaker

Lisa Charlton

Chief Product Officer
Castor, United States

Lisa Charlton has ten years of experience in eClinical technology with an emphasis on eCOA solutions. Her career within the industry started in supporting consulting work for COA instrument development, linguistic validation, and regulatory interactions and then followed with a focus on eCOA implementation and process improvement. For the past two years, Lisa has led product development for participant solutions including ePRO, eConsent, and a participant portal. Lisa earned her PhD in Biological Chemistry from UNC and her MBA from Point Park University.

4:00 PM — 5:15 PM

Emerald Ballroom

Session 5: Real World Evidence Studies in Peer Reviewed Literature: Moving Towards a Better Approach

Poor-quality RWE studies are increasingly published due to easy access to large datasets and low barriers to analysis, creating challenges for journal editors and peer reviewers. This session will explore how researchers, publishers, and reviewers can improve the reliability and transparency of RWE studies in literature. Panelists will share stakeholder perspectives and discuss opportunities to strengthen practices across the RWE research lifecycle.
Learning Objective :

- Recognize key indicators of high-quality RWE studies and studies and evaluate study methods and reporting with greater confidence
- Outline steps the research community can take to support high-quality peer review of real-world evidence studies

Track: General Session

Session Chair(s)

Sarah Martin, PhD, MS

Senior Director - Global Regulatory Policy (Americas)
Eli Lilly and Company, United States

Sarah currently serves as senior director of global regulatory policy for the Americas region at 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, clinical development, human drug review program, and CGTs. Sarah also

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.

Whitney Steele

Health Scientist
FDA, United States

Speaker(s)

Real World Evidence Studies in Peer Reviewed Literature: Moving Towards a Better Approach

Jeffrey Brown, PhD

Chief Scientific Officer
TriNetX, United States

Jeffrey Brown, PhD, Chief Scientific Officer at TriNetX and Lecturer (parttime) at Harvard Medical School (HMS), is an internationally recognized expert in the use of real-world data to support the evidentiary needs of regulatory agencies and medical product sponsors. He has 25+ years of research experience using real-world data, most recently as an Associate Professor in the Department of Population Medicine (HMS) and a trusted consultant to numerous research groups and pharmaceutical companies. At HMS he served as the Lead Data Scientist for the FDA Sentinel Operations Center and as PI for several multi-site pharmacoepidemiologic studies to support FDA and EMA regulatory requirements.

Speaker

Shirley Wang, PhD, MSc, FISPE

Associate Professor of Medicine
Harvard Medical School, United States

Dr. Wang is an Associate Professor at Brigham and Women's Hospital, Harvard Medical School. She co-led the 1st and 2nd joint task forces between ISPE and ISPOR, co-directs the REPEAT Initiative, a non-profit program with projects aimed at improving the transparency, reproducibility, and robustness of evidence from healthcare databases, and co-directs RCT-DUPLICATE, a series of projects designed to inform FDA guidance on when and how to use real-world data analyses to inform regulatory decision-making.

Speaker

Jaclyn Bosco, PhD, MPH, FISPE

Vice President & General Manager, Global Head of Epidemiology & Database Studies
IQVIA, United States

Dr. Jaclyn Bosco Global Head of Epidemiology & Database Studies 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.

5:15 PM — 6:15 PM Crystal Ballroom

Networking and Poster Reception

Day 3 Oct 17, 2025

7:30 AM — 4:10 PM Ballroom Foyer (Level 2)

Conference Registration

7:30 AM — 8:15 AM Crystal Ballroom

Networking Breakfast

7:45 AM — 8:15 AM Opal Room

Hosted Session/Non-CE: Case Study hosted by Evidation Health: Strengthening Real-World Evidence with Longitudinal, Multimodal Data Collected Directly from Individuals

EHR and claims data are essential to real-world evidence, but they capture only fragments of the patient journey. Evidation enables a longitudinal, multimodal approach to real-world data collection by maintaining a continuous, consented connection with individuals over time.

In this case study, Evidation applied this approach to real-world data collection by maintaining a continuous, consented connection with a cohort of over 150,000 individuals managing their weight including more than 10,000 GLP-1 users. Through this connection, Evidation collected patient-reported outcomes, sensor-based behavioral data, and social

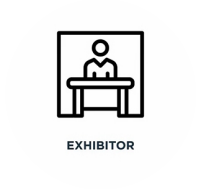
determinants of health, with the ability to enrich these data through linkage to EHRs, claims, and biospecimens. This patient centric model reveals how and why individuals initiate, sustain, or discontinue treatment, enabling earlier signal detection, more targeted study designs, and stronger real-world interpretation.

Featured topics:

- How a continuous, direct-to-individual model supports multimodal real-world data collection
- What traditional RWD sources can miss, and how longitudinal engagement reveals patient behaviors, decisions, and barriers over time
- How to operationalize patient-centered data collection at scale while maintaining trust, consent, and integration with legacy data systems
- Real-world examples of using this approach to surface comorbidity trends, understand patient decision drivers, and segment populations

Track: Exhibitor Event

Session Chair(s)



Sponsored Sessions

United States

Speaker(s)

Speaker

Ernesto Ramirez

Head of Research Science
Evidation Health, United States

8:15 AM — 9:30 AM

Emerald Ballroom

Opening Remarks and Session 6: Scientific Roundtable: ICH Efforts on Convergence and Harmonization of Real-World Data and Evidence

An interactive panel of global regulators and industry experts will share updates on ICH's efforts to align terminology, protocols, and reporting standards for Real-World Evidence (RWE), including progress on guideline M14. The session will cover international collaboration through ICMRA, updates to ICH E6 R3 Annex 2, and new topic proposals. Attendees will participate in roundtable discussions to explore implementation challenges and share perspectives on the evolving global RWD/RWE landscape.

Learning Objective :

- Identify current ICH initiatives focused on harmonizing terminology, protocols, and reporting standards for RWE, including M14, by the end of the session
- Summarize key updates from global regulators on ICMRA collaboration and ICH E6 R3 Annex 2 within the session timeframe
- Discuss regional implementation challenges and stakeholder perspectives on M14 through guided roundtable discussions during the session

Session Chair(s)

Camille Jackson

Director, Regulatory Policy; Legal and Regulatory
Flatiron Health , United States

Camille Jackson is the Director and Head of Regulatory Policy at Flatiron Health, bringing nearly 20 years of experience within policy and program management across various corners of the life 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)

Scientific Roundtable: ICH Efforts on Convergence and Harmonization of Real-World Data and Evidence

Gracy G Crane, PhD, MS

Policy Lead
Roche, United Kingdom

Gracy holds a Ph.D. in Molecular Oncology from King's College Hospital, an M.Sc. in Biomedical Research from King's College. She did her postdoctoral training at Oxford (UK) and at MIT (USA). Gracy brings broad experience in clinical research, medical affairs and health outcomes within the pharmaceutical industry. She currently works as a Regulatory Policy Lead at Roche Pharmaceuticals, focusing on RWD Policy.

Speaker

Kassa Ayalew, MD, MPH

Director, DCCE, OSI, Office of Compliance, CDER
FDA, United States

Dr. Kassa Ayalew serves as the Division Director for the Division of Clinical Compliance Evaluation within the Office of Scientific Investigation at the FDA's Center for Drug Evaluation and Research. In this role, he oversees the evaluation of the integrity of efficacy and safety data submitted to the FDA and ensures the protection and welfare of human research subjects. He is board certified in Pediatrics and Infectious Diseases and holds an active medical license in the state of Virginia. In addition to his regulatory work, Dr. Ayalew provides clinical care to both pediatric and adult patients at an urgent care facility. He has delivered numerous didactic lectures and has published research in peer-reviewed journals.

Speaker

Robert Reynolds, DrSc, MSc, FISPE

Vice President, Global Epidemiology, CMO, R&D
GSK, United States

Dr. Robert Reynolds is Vice President, Global Epidemiology at GSK, where he leads the group responsible for epidemiology and RWE in support of R&D and regulatory decision-making. He has published extensively on design and methods for RWE and pragmatic trial designs, including numerous studies evaluating medicine safety and effectiveness. He has extensive experience in collaborative international engagements with regulators, industry peers, and other stakeholders. He is a Fellow of ISPE and an Adjunct Associate Professor of Epidemiology at Tulane. Dr. Reynolds holds an AB in Biology from Bard College and a MSc in Epidemiology and ScD in Population/International Health from the Harvard T.H. Chan School of Public Health.

Speaker

Julie Schneider, PhD, MSc

Senior Director, RWE and Reliance Policy
Johnson & Johnson Innovative Medicines, United States

Julie Schneider is a Senior Director at Johnson & Johnson Innovative Medicine, where she leads initiatives related to Real-World Evidence (RWE) and Reliance Policy. Previously, she served as Associate Director for Research Strategy and Partnerships at the FDA Oncology Center of Excellence (OCE). At FDA, she founded and led the OCE Scientific Collaborative, the agency's first coordinated oncology regulatory science initiative. This program focused on exploring how emerging data sources—such as RWE, AI/ML, biomarker development, and trial innovation—can be integrated into regulatory decision-making. Julie holds a PhD in molecular biology and genetics from the University of Oxford and a BA in biology from Yale University.

9:35 AM — 10:50 AM

Emerald Ballroom

Session 7: Accelerating Global RWE with OMOP: Scalable, Standardized Collaboration Across Africa, Europe, and Asia

Global real-world evidence efforts increasingly rely on data models that support cross-border collaboration and standardization. OMOP-based networks are enabling scalable, privacy-conscious analytics across Africa, Europe, and Asia by addressing challenges in infrastructure, governance, and interoperability. Speakers will share case studies and practical strategies for implementing OMOP across diverse healthcare systems. Attendees will gain tools to design collaborative, regulatory-grade RWE networks worldwide.
Learning Objective :

- Explain the role of the OMOP Common Data Model in enabling standardized global real-world evidence generation
- Recognize effective strategies used to address governance, privacy, and infrastructure barriers across different regions
- Utilize insights from international case studies to support the development of scalable, collaborative RWE networks

Track: General Session

Session Chair(s)

Alicia Gilsenan, PhD, MS, RPh, FISPE

Vice President, Epidemiology
RTI Health Solutions, United States

Alicia Gilsenan, PhD, is Vice President, Epidemiology within RTI-HS and a licensed pharmacist. Dr. Gilsenan's primary area of expertise is pharmacoepidemiology and therapeutic risk management

and the structured benefit-risk assessment of medications. Since joining RTI in 1997, she has applied state-of-the-art approaches to the design, conduct, and analysis of both retrospective and prospective epidemiologic studies, most recently focusing on consultation, design, and implementation of postauthorization safety studies in the US and in Europe in area of vaccine and drug safety. She is adjunct professor in Epidemiology at the UNC-Chapel Hill and teaches an intro to Pharmacovigilance course to graduate students biannually.

Speaker(s)

Accelerating Global RWE: OMOP Networks Driving Scalable, Standardized Collaboration Across Africa, EU, and Asia

Mui Van Zandt

VP/Global Head, Data Strategy, Access and Enablement
IQVIA, United States

Mrs. Mui Van Zandt is Vice President/Global Head of Data Strategy, Access, and Enablement at IQVIA, leading global real-world data/real world evidence innovation strategies. Her expertise includes extensive knowledge of real-world data globally, understanding of different EMR systems, RWD standardization, ontology harmonization, data collection methodologies, and use of RWD for both prospective and retrospective studies. Her understanding of real-world data, regulatory compliance and technology has enabled her to create the right solutions through innovations data collection methods such as EHR-to-EDC, clinical trial tokenization, patient-mediated and decentralized studies.

Speaker

Alex Asiimwe, PhD

Head of RWE Generation Innovation & Partnerships
Gilead Sciences, United Kingdom

Speaker

Christian G. Reich, DrMed

Chief Science Officer
Nemesis Health , United States

Christian Reich is CSO of Nemesis Health, a Cancer Real-World Evidence company based on the OHDSI approach. He is also Professor of the Practice at the Roux Institute at Northeastern University, where he is responsible for OHDSI Center and the Real-World Master's Program. He is also Principal Investigator at OHDSI, a global Open-Source and Open-Science collaborative generating comprehensive evidence about disease, healthcare delivery and the effects of medical interventions through large-scale analytics. Christian has more than 15 years of experience in life science research and medicine.

10:50 AM — 11:30 AM

Crystal Ballroom

Networking and Refreshment Break Sponsored by Guardian Research Network

11:00 AM — 11:30 AM

Opal Room

Hosted Session/Non-CE: Case Study hosted by Novellia: Unifying Real-World Data with AI: How Biopharma Teams Use Longitudinal Data to Accelerate Adoption and Maximize Impact

Biopharma teams are drowning in data but still missing the insights that matter most. Static snapshots and siloed datasets fail to reflect the full complexity of patient journeys—leading to delayed safety signals, missed adoption barriers, and lost revenue opportunities. This session explores how leading life sciences organizations use Novellia's AI-powered platform to unify 15+ years of longitudinal, patient-permissioned data across care settings. By rapidly transforming fragmented health records into structured, real-world datasets, Novellia helps teams uncover care gaps, validate performance, and act faster—resulting in smarter launches and measurable commercial gains.

Featured Topics:

- How AI transforms fragmented health records into structured, longitudinal data ready for research, regulatory, and real-world use
- A scalable model for building patient-permissioned, therapy-aligned registries using live EMR data and ePRO inputs
- Proven strategies for spotting practice variation, accelerating therapy adoption, and improving field execution using real-time patient insights
- Key regulatory and scientific considerations when deploying dynamic RWD infrastructure that meets HEOR, safety, and commercialization goals

Track: General Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Exhibit

Shashi Shankar

Chief Executive Officer
Novellia, Inc., United States

Shashi Shankar is the co-founder and CEO of Novellia, Inc., an award-winning, AI-enabled data partner trusted by leading biopharma companies to uncover hidden insights in real-world patient data. With a background in healthcare and a passion for leveraging AI and data analytics, Shashi leads Novellia's strategy and business development to transform health data integration for improved patient outcomes. Prior to founding Novellia, Shashi spent nearly a decade at Genentech and Roche, where his personal experience with fragmented health data deeply motivated him to pioneer solutions that give both patients and researchers a more complete, accessible, and actionable view of healthcare data.

11:30 AM — 12:45 PM

Emerald Ballroom

Session 8: AI and Machine Learning Innovations Transforming Real-World Data from Patient Insights to Regulatory-Ready Evidence

Artificial intelligence and machine learning are transforming the use of real-world data (RWD) throughout the evidence generation lifecycle. Innovations include AI-powered enhancement of unstructured clinical data to fill patient journey gaps, advanced applications in pharmacovigilance for faster, more accurate safety insights, and machine learning methods to optimize clinical trial feasibility by refining target patient populations. Speakers will share case studies and practical approaches driving regulatory-ready real-world evidence.
Learning Objective :

- Demonstrate how AI tools can fill gaps in unstructured clinical data and improve patient journey insights within the session timeframe
- Apply knowledge of ML methods to optimize target patient populations and improve clinical trial feasibility during the session
- Explain key AI and ML applications that enhance real-world data for study design and pharmacovigilance by the end of the session

Session Chair(s)

Rachele Hendricks-Sturrup, DrSc, MA, MSc

Research Director, Real-World Evidence
Duke-Margolis Institute For Health Policy, United States

Dr. Rachele Hendricks-Sturrup is the Research Director of Real-World Evidence (RWE) at the Duke-Margolis Institute for Health Policy in Washington, DC, strategically leading and managing the Institute's RWE Collaborative and RWE policy research portfolio and education. As an engagement expert, biomedical researcher, bioethicist, and policy practitioner with over 18 years of experience, her work centers on addressing implementation, regulatory, and ethical, legal, and social implications (ELSI) at the intersection of

health policy and innovation. She presently partners with Duke University faculty, scholars, students, and external practicing experts to advance the Institute's biomedical innovation work.

Speaker(s)

Filling in Gaps in Patient Journeys: Using AI to Enhance RWD

Carl Marci, MD

Chief Clinical Officer and Managing Director, Mental Health and Neuroscience
OM1, United States

Dr. Marci is a physician, scientist, entrepreneur, and author of the book, Rewired: Protecting Your Brain in the Digital Age (Harvard University Press, 2022). He is currently the Chief Clinical Officer and Managing Director of Mental Health and Neuroscience at OM1, a venture backed health technology and data company based in Boston, MA. He is also a board-certified psychiatrist part-time at Massachusetts General Hospital and Assistant Professor of Psychiatry at Harvard Medical School and advises several investment groups and early-stage health companies. He is the 2024 winner of the PharmaVoice100 leaders award, the 2025 Marconi Science Award and is a member of the Aspen Global Leadership Network as a 2014 Henry Crown Fellow.

The Use of Artificial Intelligence for Real-World Evidence in Pharmacovigilance

Juhaeri Juhaeri, PhD

Vice President and Global Head, Epidemiology and Benefit-Risk Evaluation
Sanofi, United States

Juhaeri Juhaeri, Ph.D., is Vice President and Global Head of Epidemiology and Benefit-Risk at Sanofi. An epidemiologist and statistician, he has held global leadership roles in Medical and Pharmacovigilance functions for more than two decades in the pharmaceutical industry. A passionate leader, he has built and developed different new teams at Sanofi and led successful programs leading to products' approval and maintenance. He has led different working groups in various public-private partnerships in benefit-risk evaluation, pharmacovigilance, real-world evidence, and patient preference. He holds adjunct faculty positions at the School of Public Health, University of North Carolina Chapel-Hill.

Novel Applications of Machine Learning Methods in Real-World Data in Clinical Trial Operations: Clinical Trials Feasibility

Sherrine Eid, MPH

Global Head, Epidemiology, RWE and Observational Research
SAS Institute Inc., United States

Sherrine is the Global Head of Epidemiology, RWE and Observational Research and an Ethics Ambassador at SAS with over 25 years of experience. She leads RWE thought leadership efforts and contributes to Trustworthy AI and Responsible Innovation at SAS Institute, Inc. Leveraging her experience in global health, public health, healthcare outcomes research and Teva Pharmaceuticals where she supported Regulatory, Safety, Late Phase and Post-Marketing activities across therapeutic areas using clinical data and RWE, Sherrine has co-authored over 100 peer-

reviewed articles and has been cited over 1000 times, has been a guest on the SAS Health Pulse Podcast, and been invited to be a keynote or plenary speaker over 50 times.

12:45 PM — 1:45 PM Crystal Ballroom

Networking Luncheon

1:45 PM — 3:00 PM Emerald Ballroom

Session 9: Shaping the Future of Real-World Data and Evidence Through Policy and Collaboration

As real-world data and evidence (RWD/E) become increasingly central to regulatory decision-making, evolving policies, technologies, and legal frameworks shape their future use. This session will be a fire-side chat with a panel that brings together perspectives from regulators, and the biopharmaceutical industry, and real-world data and analytics organizations to discuss key issues including data quality, AI integration, transparency, data standards, innovative trial designs, and international harmonization. Attendees will gain insights into collaborative efforts driving the next-generation RWD/E framework amid a dynamic regulatory and policy landscape.
Learning Objective :

- Explain key policy and regulatory considerations affecting the use of RWD/E in regulatory decision-making
- Recognize the importance of data standards, transparency, and international harmonization in advancing RWD/E frameworks
- Assess the role of emerging technologies, including AI, in analyzing and leveraging real-world data

Track: General Session

Session Chair(s)

Jaclyn Bosco, PhD, MPH, FISPE

Vice President & General Manager, Global Head of Epidemiology & Database Studies
IQVIA, United States

Dr. Jaclyn Bosco Global Head of Epidemiology & Database Studies 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)

Speakers

Motiur Rahman, PhD, MPharm, MS

Senior Epidemiologist and Policy Advisor, Real World Evidence Analytics, OMP, CD
FDA, United States

Dr. Motiur Rahman is a Senior Epidemiologist and Policy Advisor in RWE Analytics within the Office of Medical Policy at CDER, FDA. He leads the consult service for reviewing RWD study submissions, leads international regulatory collaborations including ICH initiatives, and supports internal training and process development. He serves as FDA topic lead for the ICH E23 Working Group, contributes to FDA-funded demonstration projects, and is a core member of the RWE Subcommittee. Dr. Rahman joined FDA in 2022 after more than a decade of academic and industry experience conducting observational studies across diverse therapeutic areas. A pharmacist by training, he holds a PhD in Pharmacoepidemiology and a Master's in Statistics.

Speaker

Ulka B Campbell, PhD

Head of Scientific Strategy
Aetion Inc, United States

Ulka Campbell is an epidemiologist and the Head of Scientific Strategy at Aetion, a Datavant company, providing methods and regulatory support across therapeutic areas and leading research to inform regulatory RWE best practices. Previously, she was at Pfizer for 14 years leading regulatory studies and serving as the Head of Safety Surveillance Research, overseeing a team responsible for post-approval safety studies obligated to FDA and EMA. She has co-authored several publications and taught courses on pharmacoepidemiology, standards for decision-grade real world studies, causal inference, and epidemiologic methods, and is an Adjunct Assistant Professor of Epidemiology at Columbia University.

Speaker

Trevan Locke, PhD

Director, Global Regulatory Policy and Intelligence
Amgen, United States

Trevan Locke is a Director of Global Regulatory Policy and Intelligence at Amgen with a focus on real-world evidence, trial innovation, and oncology. Prior to Amgen, he held a role at Duke-Margolis overseeing policy workstreams on evidence generation including work under the Duke-Margolis Real-World Evidence Collaborative. Previously, he worked at the American Association for Cancer Research on regulatory issues impacting cancer care and the development of cancer therapies, including considerations for equitable clinical trial enrollment. Dr. Locke completed a Bachelor of Engineering in Chemical and Biomolecular Engineering at Vanderbilt University and a PhD in Chemical and Biochemical Engineering at Rutgers University.

3:00 PM — 3:15 PM Emerald Ballroom

Looking Forward and Closing Remarks

Looking Forward and Closing Remarks

Session Chair(s)

Rachele Hendricks-Sturrup, DrSc, MA, MSc

Research Director, Real-World Evidence
Duke-Margolis Institute For Health Policy, United States

Dr. Rachele Hendricks-Sturrup is the Research Director of Real-World Evidence (RWE) at the Duke-Margolis Institute for Health Policy in Washington, DC, strategically leading and managing the Institute's RWE Collaborative and RWE policy research portfolio and education. As an engagement expert, biomedical researcher, bioethicist, and policy practitioner with over 18 years of experience, her work centers on addressing implementation, regulatory, and ethical, legal, and social implications (ELSI) at the intersection of health policy and innovation. She presently partners with Duke University faculty, scholars, students, and external practicing experts to advance the Institute's biomedical innovation work.

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)

Speaker

Sorcha McCrohan, MS

Sr. Scientific Project Manager
DIA, United States

Sorcha McCrohan is a Senior Scientific Project Manager for Global Science at DIA. In her current role, she focuses on content development and strategy for DIA's meetings to improve and facilitate innovation in clinical research, drug development, and the fields of devices and diagnostics. Before joining DIA, she conducted COVID-19 research in Chiapas, Mexico, and worked in marketing within Pfizer's Global Vaccines franchise. Sorcha holds a BA in Sociology from Mount Holyoke College and an MSc in Global Health, Disease Prevention & Control from Georgetown University.

3:15 PM — 3:15 PM

Conference Adjourns