Bethesda North Marriott Hotel and Conference Center

Oct 19, 2026 7:00 AM - Oct 20, 2026 5:00 PM

5701 Marinelli Road, North Bethesda, MD 20852

Real-World Evidence Conference

Translating Insights into Real-World Value

REGISTER →

Print Agenda

Day 1 Oct 19, 2026

7:30 AM — 5:00 PM

Conference Registration

7:30 AM — 8:30 AM

Networking Breakfast

8:30 AM — 8:45 AM

Welcome and Opening Remarks

8:45 AM — 10:00 AM

Session 1: RWE Regulatory Update: Perspectives from Around the Globe

The use of real-world data and evidence (RWD/RWE) to support regulatory decisions for drug and biological products including premarket effectiveness determinations and postmarket study requirements is expanding, bringing with it evolving standards, frameworks, and expectations for data quality and study rigor. In this session, representatives from regulatory agencies provide updates on the foundational issues shaping the next generation of RWD/RWE-based regulatory science. The participants will discuss issues such as fit-for-purpose data assessment, study design standards, bias identification and mitigation, outcome ascertainment, data standards compliance, and the evidentiary role of RWE within the totality-of-evidence framework for demonstrating substantial evidence of effectiveness.

Session Chair(s)

Motiur Rahman, PhD, MPharm, MS

Senior Epidemiologist & Policy Advisor, Real World Evidence Analytics, OMP, CDER
FDA, United States

Dr. Motiur Rahman is a Senior Epidemiologist and Policy Advisor in Real-World Evidence (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.

Namangolwa Jane Mutanga, MD, PhD, MPH

RWE Reviewer, Division of Analytics and Benefit Risks Assessment
FDA, United States

Speaker(s)

Speaker

Masanao Sasaki, PhD

Pharmaceuticals and Medical Devices Agency, Japan

Dr. Masanao Sasaki is a biostatistics reviewer at the Pharmaceuticals and Medical Devices Agency (PMDA). He has research experience in academia and has worked in biostatistics, data science, and regulatory science. Dr. Sasaki holds a PhD in Mathematical Medical Science from the Institute of Science Tokyo.

Speaker

Patrice Verpillat, DrMed, MD, MPH

Head of Real World Evidence
European Medicines Agency, Netherlands

Dr. Verpillat is the Head of the Real-World Evidence (RWE) Workstream at the European Medicines Agency (EMA). He has worked before during 20 years in the pharmaceutical industry where he had global positions in several international companies, always dealing with RWD and non-interventional studies (NIS) in order to bring RWE into research, access and life-cycle product management. He has published over 90 articles in Medline referenced journals. He is/has been involved in many organisations such as ENCePP, ICH (M14 topic leader & E23 rapporteur), European pharma association (efpia) and ISPE (Chair of "Government, Regulators and Public Health Organisations" Council.

Speaker

Representative Invited

Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

Dr Alison Cave is Chief Safety Officer at the Medicines and Healthcare products Regulatory Agency (MHRA), with responsibility for the safety of medicines and medical devices in the UK. She holds a BSc (Hons) and PhD from the University of London and has extensive academic and regulatory experience, including roles at both the European Medicines Agency and at the MHRA. Her previous positions include Head of Cellular, Developmental and Physiological Sciences at the Wellcome Trust and an Industrial Strategy Challenge Fund Director at UK Research and Innovation.

10:00 AM — 10:45 AM

Refreshment and Networking Break

10:45 AM — 12:00 PM

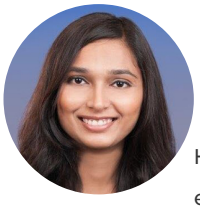
Session 2: Navigate Building Credible, Regulator-Ready RWE: Path from Protocol to Submission

Real-world Evidence (RWE) is increasingly used to support regulatory decision making, and yet a persistent gap remains between methodological intent and regulator-ready deliverables. This session will address three interconnected pillars of rigorous RWE practice that can bring success: 1. Pre-specification and execution transparency, 2. bias identification and

control, and 3. the operational demands of modern RWE-enabled trial designs. We will cover a statistical analysis plan (SAP) that codes the framework to eliminate analytical drifts, negative control methodology for detecting and adjusting unmeasured confounding, and the full operational lifecycle of a regulatory RWE submission from study design through submission. An FDA representative will then walk us through a regulator's lens, addressing where proposed approaches align with the agency's expectations, what adjustments sponsors should consider and when to approach the agency in this process. Together, these perspectives will give you a concrete and actionable framework for designing, executing, and delivering RWE that meets the evidentiary standards regulators increasingly expect.
Learning Objective : At the conclusion of this session, participants should be able to:

- Use modern, simulation-enabled SAPs for transparent, audit-ready RWE analyses.
- Apply negative controls to detect and mitigate unmeasured confounding.
- Design and deliver FDA-ready, regulatory-grade RWE.
- Understand FDA expectations for sponsor-proposed RWE approaches.

Session Chair(s)



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)

Negative Control for Generating Robust Real-World Evidence in Drug Development and Regulatory Decision-Making

Representative Invited

Astrazeneca, United States

Dr. Binbing Yu is an Director of Statistical Science in the Oncology Statistical Innovation group in AstraZeneca. He serves as the statistical expert across the whole spectrum of drug R&D process, including early-clinical and clinical research, design, operation and manufacturing, clinical pharmacology, oncology medical affairs and post-marketing surveillance. He obtained his PhD in Statistics from the George Washington University. His primary research interests are clinical trial design and analysis, cancer epidemiology, cause inference in observation studies, PK/PD modeling and Bayesian analysis. He has over 80 publications in scientific and statistical journals and published three books on cure modeling, immunogenicity and RWD/RWE.

Simulating Your Way to Success: From SAP to Study, Just Add Data

Nicole Turner, PhD

Data Scientist
Plinth Analytics, United States

Nicole Mirea Turner, PhD, is a Data Scientist at Plinth Analytics, where she designs and develops software that helps epidemiologists and HEOR scientists work with real-world data, from feasibility dashboards to data-quality monitoring and automated reporting. Trained as a linguist and cognitive scientist, she knows a dataset means little until you understand how and why it was produced. That background also helps her guard against human error and misreadings that erode good science. She does this by building reproducibility and provenance into every tool, so researchers do the right thing by default and their evidence stands up to scrutiny. She's happiest spotting the problem everyone else works around, then solving it.

Where Design Meets Delivery: Operationalizing Modern Trial Designs Using RWD/E for Regulatory Submissions

Mayur Saxena, PhD, MS

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.

12:00 PM — 1:00 PM

Networking Luncheon

1:00 PM — 2:15 PM

Session 3: Design Scalable RWD Infrastructure: Integrate Multimodal Data and Standards for Efficient RWE Generation

This session addresses key challenges in generating real-world evidence (RWE) across fragmented data ecosystems and evolving regulatory expectations. Presentations highlight innovative approaches, including federated multimodal data networks, analysis-driven abstraction for CDISC transformation, and transportability frameworks for applying evidence across populations. Together, these approaches provide practical solutions to improve scalability, efficiency, and traceability of RWE generation. Attendees will gain actionable strategies to design interoperable data infrastructures and align with regulatory and global evidence needs.
Learning Objective : At the conclusion of this session, participants should be able to:

- Explain how federated multi-modality networks integrate heterogeneous RWD sources across regions to support RWE generation

- Evaluate analysis-driven abstraction approaches to improve efficiency, scalability, and traceability in CDISC transformation
- Apply transportability frameworks to assess the use of nonlocal data in regulatory and HTA decision-making contexts

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)

A Federated Multi-Modality, Multi-Regional Network for Cardiometabolic RWE

Eva Oakkar, PhD, MS

Head of Secondary Database Studies
IQVIA, United States

Dr. Eva Oakkar is an epidemiologist with more than 10 years of real world research experience, both in academia and industry. She is responsible for developing novel study methodologies to build comprehensive patient records for research, linking primary and secondary real world data (RWD). In prior roles, Dr. Oakkar focused on designing innovative studies leveraging real world evidence (RWE) in clinical development, developing regulatory strategies for use of RWD and methods and providing scientific leadership for observational research on the natural history of disease, comparative safety/effectiveness and cost of medical treatment.

Analysis Driven Abstraction of RWD for CDISC: Improving Efficiency, Scalability, and Traceability

Zachariah William Peterson, MPH

Senior Manager, Biostatistical Programming
Amgen, United States

Zachariah W Peterson, MPH, BS is a Manager of Biostatistical Programming in the Center for Observational Research at Amgen, Inc. Zach leads a regulatory RWE programming team focused on incorporating regulatory data standards to RWD to support the utilization of RWE in regulatory setting including new drug applications and label expansions. He received his MPH in Epidemiology from the University of Arizona College of Public Health and his BS in Molecular and Cellular Biology from the University of Arizona College of Science.

Transportability for Real-World Evidence Generation: Synthesizing the Recent Flood of Frameworks

Patrick Arena, PhD, MPH

Senior Director, Science
Datavant, United States

Patrick (Pat) Arena, PhD, MPH, is Senior Director at Datavant, where he leads initiatives advancing the generation and use of RWE for regulatory, HTA, and payer decision-making. His focus includes real-world study design, RWD transportability and transferability, and improving the applicability of RWE across decision contexts. Pat has contributed to global collaborations and thought-leadership efforts focused on RWE methodology, regulatory and HTA alignment, and methodological innovation in pharmacoepidemiology. Across these efforts, his work centers on strengthening the rigor, transparency, and relevance of evidence used by regulators, HTA bodies, payers, and other healthcare stakeholders.

2:20 PM — 3:35 PM

Session 4: Innovative Approaches and Considerations for Use of External Controls in Drug Development

This session will explore the current state of external controls for use in drug development. Specifically, the session opens with an overview of the history and evolving use of external controls, a case study, considerations around selection of appropriate data sources and concludes with an exploration of AI derived digital twin for use as external controls. The session will provide current state information selected from this exciting and evolving area of drug development science.

Session Chair(s)

Gillis Carrigan, PhD, MS

Director, Center for Observational Research
Amgen, United States

Dr. Carrigan has over 20 years of experience in observational studies with a focus on study design and methodology. He is experienced with the use of electronic medical records (EMR), administrative claims data, and registry data. He has worked with observational data in a number of settings and therapeutic areas including oncology, neuroscience, respiratory disease, and vaccine safety. In recent years, he has focused on applying epidemiological methods to real-world oncology data to augment evidence from clinical trials.

Speaker(s)

Externally Controlled Trials Using Real-World Data: Adapting SPIFD2 to Ensure Principled Design and Data Selection (SPIFD-ECT)

Representative Invited

Datavant, United States

Advancing External Control Arms for Regulatory Use: Lessons from a Multi-Stakeholder Pilot

Bernat Navarro, PhD

Senior Science Policy Analyst
Friends of Cancer Research, United States

Bernat Navarro, PhD, is a Senior Science Policy Analyst at Friends of Cancer Research, where he works at the intersection of science, policy, and regulation to advance more efficient and patient-centered approaches to cancer drug development. In this role, he supports multi-stakeholder initiatives that bring together FDA, industry, academia, and patient advocates to address practical challenges in oncology regulatory science, clinical trial design, and evidence generation. He oversees Friends' External Control Arms Pilot Project as part of the organization's real-world evidence portfolio, with a focus on how external data sources can be used to support more reliable and fit-for-purpose evidence generation in oncology.

Digital Twins

Daniele Bertolini, PhD, MS

Principal Machine Learning Scientist
Unlearn.AI, United States

Daniele Bertolini is a Principal Machine Learning Scientist at Unlearn.AI, where he develops machine learning methods to improve clinical trials. His work focuses on disease progression modeling and statistical approaches for integrating machine learning into clinical trial design, conduct, and analysis. Before joining Unlearn.AI, he worked on natural language processing and machine learning applications in computational physics. He holds a PhD in Theoretical Physics from the Massachusetts Institute of Technology.

3:35 PM — 4:10 PM

Refreshment and Networking Break

4:10 PM — 5:25 PM

Session 5: The Economics of RWD and RWE: How to Estimate and Maximize Return on Investment

Interest in real-world data (RWD) and real-world evidence (RWE) has grown significantly over the past decade, driving increased investment across the biopharmaceutical industry. As organizations expand their use of RWD and RWE to support clinical development, regulatory decision-making, market access, and business strategy, understanding the return on these investments has become increasingly important. This interactive session will explore the economics of RWD and RWE, including the costs associated with acquiring and analyzing existing RWD, conducting noninterventional studies, and generating evidence to support a variety of use cases. Speakers will introduce key concepts and frameworks for evaluating return on investment (ROI), including approaches to estimating value across different decision-making

scenarios. The session will feature brief presentations, guided small-group discussions, and a roundtable exchange of lessons learned and practical considerations for assessing the value of RWD and RWE investments.
Learning Objective : At the conclusion of this session, participants should be able to:

- Identify key cost drivers associated with generating and analyzing RWD and RWE
- Compare approaches for evaluating the value of RWD and RWE across different use cases
- Apply basic concepts and frameworks for assessing ROI in RWD and RWE initiatives
- Discuss challenges and opportunities in maximizing the value of RWD and RWE investments

Session Chair(s)

Simon Dagenais, PhD, MSc

Asset lead, Medical evidence development
Pfizer Inc, United States

Simon is an epidemiologist and health economist with expertise in designing, conducting, and communicating scientific studies related to the clinical and economic value of therapies for neurologic conditions. He is currently the global RWE lead for Internal Medicine at Pfizer. Prior to Pfizer, Simon was the global lead for Neurology in the RWE COE at Vertex Pharmaceuticals and supported programs for acute pain, Duchenne muscular dystrophy, and other neurologic conditions. Prior to Vertex, Simon worked in RWE, health economics and outcomes research, and pharmacovigilance at Pacira Pharmaceuticals.

Speaker(s)

Economics of RWD/RWE from a Biopharma Consulting Perspective

Shelby Corman

Vice President
Precision AQ, United States

5:25 PM — 6:30 PM

Networking Reception

Day 2 Oct 20, 2026

7:45 AM — 5:00 PM

Conference Registration

7:45 AM — 8:30 AM

Networking Breakfast

8:30 AM — 9:15 AM

Opening Remarks and Session 6: A 10 year Retrospective on RWE since the 21st Century Cures Act

Since the enactment of the 21st Century Cures Act in 2016, Real-World Evidence (RWE) has continued to evolve as an important component of healthcare decision-making, regulatory review, and biopharmaceutical development. This session will examine key milestones, policy developments, and methodological advances that have shaped the RWE landscape over the past decade. Using a timeline-based approach, speakers will explore how major events from 2016 to 2026 influenced the generation, evaluation, and use of RWE. The discussion will highlight contributions from biopharmaceutical companies, regulatory agencies, academic researchers, and industry partners involved in the development and application of real-world data (RWD) and RWE. This session is intended to provide attendees with an overview of key events related to RWE that have occurred in the past 10 years (2016-2026) since the 21st Century Cures Act was enacted
Learning Objective : At the conclusion of this session, participants should be able to:

- Identify key milestones that have shaped the evolution of RWE from 2016 to 2026
- Describe how regulatory, scientific, and industry developments have influenced the use of RWE
- Discuss the roles of key stakeholders in advancing the generation and application of RWE

Session Chair(s)

Simon Dagenais, PhD, MSc

Asset lead, Medical evidence development
Pfizer Inc, United States

Simon is an epidemiologist and health economist with expertise in designing, conducting, and communicating scientific studies related to the clinical and economic value of therapies for neurologic conditions. He is currently the global RWE lead for Internal Medicine at Pfizer. Prior to Pfizer, Simon was the global lead for Neurology in the RWE COE at Vertex Pharmaceuticals and supported programs for acute pain, Duchenne muscular dystrophy, and other neurologic conditions. Prior to Vertex, Simon worked in RWE, health economics and outcomes research, and pharmacovigilance at Pacira Pharmaceuticals.

Speaker(s)

9:15 AM — 10:30 AM

Session 7: Open Regulatory Intelligence: A Deep Dive Into Strategies, Data, Tools, Insights, and Best Practices

Regulators, sponsors, and their collaborators continue to explore, share, and publish best practices and guidance documents to support RWE implementation in regulatory settings. They also seek practical alignment between regulatory guidance provisions and regulatory decisions involving RWE, particularly when RWE serves as primary evidence in regulatory submissions. High-quality open-source analytical tools and resources have quickly become available online for end-users seeking to (1) quickly gain actionable and meaningful regulatory intelligence using publicly available information, and (2) potentially determine the most effective RWE implementation strategies in regulatory submissions. Therefore, this session will present:

- Publicly available tools and resources intended to support trust and transparency around regulatory decision-making regarding RWE;
- Best practices and strategies around how to navigate publicly available tools and resources to extract meaningful and actionable regulatory insights focused on RWE; and
- Methods to assess practical alignment between regulatory guidance provisions and regulatory decisions involving RWE using publicly available information.

Learning Objective : At the conclusion of this session, participants should be able to:

- Describe publicly available tools, data, and resources that can be useful to assess RWE regulatory guidance in a nuanced way that builds actionable intelligence and guides practical decision-making.
- Describe analytical approaches and best practices proven useful to assess and compare, using open data and resources, both regulatory guidance documents and use cases involving RWE.

Session Chair(s)

Rachele Hendricks-Sturrup, MA

Research Director, Real-World Evidence
Duke-Margolis Institute For Health Policy (DMI), 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, 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

Representative Invited

Canal Row Advisors, United States

Donna Rivera, PharmD., MSc., FISPE is Executive Vice President, Clinical Evidence Modernization at Canal Row Advisors, sharing strategic guidance on the use of real-world data (RWD), real-world evidence (RWE), artificial intelligence (AI), and innovative trial designs for drugs, biologics, and devices to support regulatory objectives. She was the Former Associate Director for Pharmacoepidemiology and Founding Director of the Oncology RWE Program in the FDA Oncology Center of Excellence, leading national and international initiatives

to transform RWD into RWE to accelerate innovation in oncology drug development. She also formed the FDA Oncology AI Program to guide the use of artificial intelligence applications in regulatory review, researc

Speaker

Representative Invited

Black Swan Causal Labs, United States

John D. Diaz-Decaro, PhD, MS is a pharmacoepidemiologist and real-world evidence strategist with expertise in real-world evidence, observational study design, and AI-enabled evidence generation. He served as Senior Director and Lead Epidemiologist at ModernaTX, directing a global RWE portfolio across infectious disease and autoimmune programs. He is the founder of Black Swan Causal Labs and chairs the ISPE Digital Technology & AI Special Interest Group. He holds prior adjunct faculty appointments at UCLA and California State University, Dominguez Hills.

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.

10:30 AM — 11:15 AM

Refreshment and Networking Break

11:15 AM — 12:30 PM

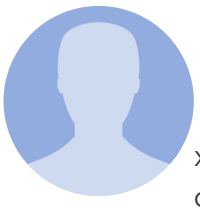
Session 8: Translate RWD into Decision-Ready for HTA and Market Access

RWD/RWE is increasingly used to support HTA, reimbursement, and market access decisions, but its impact depends on whether the evidence is credible, relevant to local decision questions, and actionable across the access lifecycle. This session will examine practical strategies for translating RWD into decision-ready RWE, including fit-for-purpose data selection, transparent causal and statistical methods, use in comparative effectiveness and economic evaluation under uncertainty, and alignment with payer and HTA evidence needs. Through examples from HTA submissions and market access contexts, speakers will discuss where RWE can reduce uncertainty, where it may be discounted, and how sponsors

can plan lifecycle evidence to improve decision usefulness. Attendees will leave with a cross-functional framework for designing RWE that connects methodology, HTA decision-making, and access strategy.
Learning Objective : At the conclusion of this session, participants should be able to:

- Identify criteria that make RWE fit for purpose for HTA and access decisions
- Compare common uses of RWE across appraisal, re-appraisal, and lifecycle planning
- Apply a credibility–relevance–actionability framework to plan payer-relevant RWE

Session Chair(s)



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.

Speaker(s)

Speaker

Representative Invited

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

Representative Invited

UMC Utrecht, Netherlands

12:30 PM — 1:45 PM

Networking Luncheon

1:45 PM — 3:00 PM

Session 9: Trust, but Verify: Governing AI-Enabled Real-World Evidence from Regulation to Rapid Deployment

As AI and generative tools rapidly reshape how real-world evidence (RWE) is generated and analyzed, regulators, HTA bodies, and specialty organizations are grappling with how to govern these technologies without stifling their potential. This session tackles that challenge from three angles: comparing how regulatory, HTA, and specialty bodies are operationalizing AI governance frameworks for RWE; outlining practical strategies to establish credibility for AI-enabled RWE in regulatory decision-making; and examining real-world results from deploying off-the-shelf generative AI tools—what works, what doesn't, and why human oversight remains essential. Together, these presentations offer a pragmatic roadmap for balancing speed and innovation with the rigor and trust required for high-stakes evidence generation. Attendees will leave with concrete frameworks and lessons learned for governing AI responsibly while still capturing its efficiency gains.
Learning Objective : At the conclusion of this session, participants should be able to:

- Describe varied AI governance frameworks for Real-World Evidence (RWE) across regulatory, Health Technology Assessment (HTA), and specialty bodies
- Apply criteria to assess AI-generated RWE credibility for regulatory decisions
- Explain why human oversight is critical for compliant AI deployment in RWE workflows

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.

Matthew Curtis

Director of Regulatory Affairs
AstraZeneca, United States

Speaker(s)

Operationalizing AI Governance for RWE: A Comparative Analysis of Regulatory, HTA, and

Specialty Bodies

John Diaz-Decaro, PhD, MS

Founder
Black Swan Causal Labs, United States

John D. Diaz-Decaro, PhD, MS is a pharmacoepidemiologist and real-world evidence strategist with expertise in real-world evidence, observational study design, and AI-enabled evidence generation. He served as Senior Director and Lead Epidemiologist at ModernaTX, directing a global RWE portfolio across infectious disease and autoimmune programs. He is the founder of Black Swan Causal Labs and chairs the ISPE Digital Technology & AI Special Interest Group. He holds prior adjunct faculty appointments at UCLA and California State University, Dominguez Hills.

Establish Credibility for AI Enabled Real World Evidence in Regulatory Decision Making: From Promise to Practice

Representative Invited

Johnson and Johnson Innovative Medicine, United States

Minutes, Not Days: Off-the-Shelf Generative AI in RWE — Works, What Doesn't, and Why Humans Stay in the Loop

Representative Invited

IQVIA, United States

Sneha Kishnani is Head of RWE Innovation & Implementation at IQVIA, where she leads the evaluation and deployment of innovative methodologies, AI-enabled solutions, and emerging technologies to advance real-world evidence generation. With more than 19 years of experience across the drug development lifecycle, including over 12 years in RWE, she specializes in translating innovation into scalable solutions that enhance the speed, quality, and impact of evidence generation.

3:00 PM — 4:15 PM

Session 10: Unlock the Future of RWE: Shaping the Next Era of Regulatory-Grade RWE

This panel brings together leading voices from academia, industry, and regulatory science—Nancy A. Dreyer, Sebastian Schneeweiss, Khaled Sarsour, and Marie Bradley—to explore how real-world evidence is reshaping the future of drug development, regulatory decision-making, and patient access. Drawing on diverse perspectives, the discussion will examine evolving methodological standards, data reliability, and the increasing expectations for RWE in global regulatory frameworks. Panelists will highlight emerging use cases across the product lifecycle, from early development to post-

market evaluation, and address barriers to broader adoption. Attendees will gain forward-looking insights into how to operationalize RWE strategies that align with scientific rigor and regulatory requirements in a rapidly evolving landscape.
Learning Objective : At the conclusion of this session, participants should be able to:

- Discover RWE trends shaping regulatory decisions over the next 3–5 years
- Hear future regulatory perspectives and pinpoint gaps for submissions
- Take away actions to build a future-ready RWE strategy in 6–12 months

Session Chair(s)

Jaclyn Bosco, MPH, FISPE

Vice President & General Manager, Global Head of Epidemiology & Scientific Strat
IQVIA, United States

Dr. Jaclyn Bosco Global Head of Epidemiology & Scientific Strategy in Real World Evidence 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.

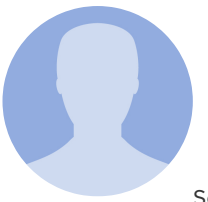
Speaker(s)

Speaker

Nancy A Dreyer, PhD, MPH, FISPE

Founder
Dreyer Strategies LLC, United States

Nancy Dreyer brings her experience as Chief Scientific Officer at IQVIA Real World Solutions and SVP roles at IQVIA, Quintiles, Outcome Sciences Inc and UnitedHealth Group to independent consultancy. Her work focuses on advancing the use of real-world evidence for safety, effectiveness and natural history research, using diverse forms of data including patient-generated health data, electronic medical records, medical and pharmacy claims, data linkage and data integration. She is a Fellow of International Society of Pharmacoepidemiology (ISPE) and of DIA, and is a Science and Policy Advisor to DIA, Adjunct Professor of Epidemiology at the Univ of North Carolina at Chapel Hill and a member of ISPOR's RWE Leadership Team.



Speaker

Representative Invited

Harvard Medical School and Brigham and Women's Hospital, United States

Sebastian Schneeweiss, M.D., Sc.D., is a Professor of Medicine at Harvard Medical School and Chief of the Division of Pharmacoepidemiology, Department of Medicine, Mass General Brigham in Boston. His research focuses on understanding the effectiveness and safety of biopharmaceuticals in clinical practice. He has developed and applied analytic methods to improve the accuracy of estimating causal treatment effects of medical products using complex digital healthcare databases published in >600 articles. He is working closely with the US FDA and EMA to promote robust evidence generation with non-randomized data that supports regulatory decision-making. He is a Fellow of the American College of Epidemiology, of Clinical Pharmacology, and ISPE

Speaker

Khaled Sarsour, PhD, MPH

Global Head, RWD Hematology-Oncology
Genentech, A Member of the Roche Group, United States

Khaled Sarsour joined Genentech in 2012 where he currently is the global head of RWE hematology leading a team of multidisciplinary scientists delivering RWE and insights across the phases of drug development. Before joining Genentech, Khaled spent 5 years at Eli Lilly and company in the global RWE group. Khaled has coauthored more than 39 peer-reviewed publications and many more conference abstracts in a range of therapeutic areas investigating the safety and real world effectiveness of treatments and informing R&D decisions. He holds a doctorate in epidemiology from the school of public health at the University of California, Berkeley.

Speaker

Marie Bradley, MPH

Senior Advisor, Real-World Evidence , Office of Medical Policy, CDER
FDA, United States

Dr. Marie Bradley is a Senior Advisor for RWE in the Office of Medical Policy, Center for Drug Evaluation and Research (CDER). Her responsibilities related to real-world evidence (RWE) include serving as lead for the Advancing Real-World Evidence Program, the Real-World Evidence Subcommittee, and a portfolio of RWE demonstration projects. She also evaluates complex real-world evidence related study protocols submitted to FDA. Recently, she has been helping to drive Agency level RWE initiatives and is co-chair of FDA-RWE-ACCELERATE. Dr Bradley is an established advocate, speaker, and panelist across national and international platforms on RWE related topics and participates extensively in external engagement

4:10 PM — 4:30 PM

Closing Remarks

4:30 PM — 4:30 PM

Conference Adjourns