Real-World Evidence Conference

North Bethesda, MD | October 19-20

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Overview

In today's dynamic healthcare environment, Real-World Evidence (RWE) is no longer confined to post-market safety. It is reshaping the entire product lifecycle, from early development through regulatory decision-making and reimbursement.

DIA's 2026 Real-World Evidence Conference will convene global regulators, industry leaders, data scientists, and policy experts to examine the latest developments shaping the field. The program will feature regulatory perspectives from agencies including the FDA, EMA, and other global authorities, alongside discussions on data quality, governance, and evolving standards for the use of real-world data in regulatory and clinical decision-making.

Sessions will highlight emerging approaches to generating and applying real-world evidence, including advances in data science, study design, and collaborative research models. Discussions will also consider the opportunities and challenges associated with using diverse data sources and analytical tools to support evidence generation across healthcare and regulatory environments.

Through case studies, expert panels, and collaborative discussions, participants will gain practical insights into generating credible, regulatory-relevant evidence that supports better decisions, fosters innovation, and ultimately improves patient outcomes.

Who Should Attend

Conference Designed for: Professionals involved in the following areas of

- Academia
- Advocacy and Service Provider Professionals
- Biopharma/Medical Device Industry
- Clinical Research
- Data analytics
- Epidemiology
- Health Authority
- Health Economics and Outcomes Research
- Payer
- Pharmacovigilance
- Policy
- Real-World Evidence
- Real-World Data
- Regulatory Science
- Technology Development

DAY ONE | MONDAY, OCTOBER 19		ROOM
7:30-5:00PM	Registration	Grand Ballroom E Foyer
7:30-8:30AM	Networking Breakfast	Grand Ballroom E
8:30-8:45AM	Welcome and Opening Remarks	Grand Ballroom FGH
8:45-10:00AM	Session 1: **RWE Regulatory Update: Perspectives from Around the Globe** **Session Co-Chairs: Motiur Rahman**, CDER, FDA and **Jane Mutanga**, CBER, FDA Session Description: 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. **Motiur Rahman,** CDER, FDA **Jane Mutanga,** CBER, FDA **Patrice Verpillat,** EMA **Allison Cave,** MHRA **Masanao Sasaki,** PMDA	Grand Ballroom FGH
10:00-10:45AM	Refreshment and Networking Break	Grand Ballroom E
10:10-10:40AM	Case Study (Non-CE) Hosted by Truveta: **From Two Trials to One: Maximizing the Opportunity with Real-World Data in the Evolving Regulatory Landscape** The FDA's acceptance of single pivotal trial pathways is creating new opportunities to accelerate drug development while managing cost and risk. Success in this one-trial paradigm requires a new approach to trial design and evidence generation. Real-world data are helping organizations optimize study design, support external comparators, improve enrollment, and extend evidence generation beyond traditional trial endpoints. In this session, we'll explore how real-world data can be applied across the clinical development lifecycle, from feasibility and enrollment through post-market evidence generation, including key regulatory use cases. Attendees will gain practical insights into how leading organizations are modernizing development programs to make faster, more confident decisions and bring therapies to patients sooner. **Sapna Prasad,** Truveta	Strathmore A&B
10:45-12:00PM	Session 2: **Navigate Building Credible, Regulator-Ready RWE: Path from Protocol to Submission** **Session Chair: Hetal Pansuria, Pharma.D** 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	Grand Ballroom FGH

	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. **Nicole Turner,** Plinth Analytics **Yun Lu,** CBER, FDA **Mayur Saxena,** Droice Labs **Motiur Rahman,** CDER, FDA	
12:00–1:00PM	Networking Luncheon	Grand Ballroom E
1:00–2:15PM	Session 3: **Design Scalable RWD Infrastructure: Integrate Multimodal Data and Standards for Efficient RWE Generation** **Session Chair: Alicia Gilsenan,** RTI Health Solutions 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. **Eva Oakkar,** IQVIA **Zachariah Peterson,** Amgen **Patrick Arena,** Aetion, Datavant Company	Grand Ballroom FGH
2:20–3:35PM	Session 4: **Innovative Approaches and Considerations for Use of External Controls in Drug Development** **Session Chair: Gil Carrigan,** Amgen Interest is growing in innovative uses of external control arms (ECAs) in drug development, as reflected in recent global regulatory guidance on the role of real-world evidence (RWE) in regulatory decision-making. This session will highlight current research in this dynamic and rapidly evolving area of drug development and RWE. The session begins with an oncology case study, followed by considerations for selecting fit-for-purpose data, and concludes with a discussion on AI-derived digital twins as synthetic controls. Key takeaways will inform a roundtable discussion and give attendees an opportunity to participate in the discussion. **Bernat Navarro,** Friends of Cancer Research **Ulka Campbell,** Datavant **Daniele Bertolini,** UnlearnAI	Grand Ballroom FGH
3:35–4:10PM	Refreshment and Networking Break	Grand Ballroom E

3:40-4:10PM	Case Study (Non-CE) Hosted by Verily Health: **Accelerate Real-World Evidence Generation: Powering Patient Registries for Disease Impact** Patient registries often struggle with data fragmentation and scaling challenges, limiting their ability to impact disease research and support treatment advances. Verily Health will present a real-world case study on working with patient advocacy groups to collect, curate, and disseminate data and insights for advancing patient care. Attendees will explore the strategic value proposition of this tech-enabled model—showing how registries can scale their infrastructure to increase actionable RWE value across healthcare stakeholders. **Sharon Hensley Alford,** Verily Health	Strathmore A&B
4:10-5:25PM	Session 5: **The Economics of RWD and RWE: How to Estimate and Maximize Return on Investment** **Session Chair: Simon Dagenais,** Pfizer 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. **Shelby Corman,** Precision AQ **Simon Dagenais,** Pfizer	Grand Ballroom FGH
5:25-6:30PM	Networking Reception	Grand Ballroom E
DAY TWO | TUESDAY OCTOBER 20		**ROOM**
7:45-5:00PM	Registration	Grand Ballroom E Foyer
7:45-8:30AM	Networking Breakfast	Grand Ballroom E
8:30-9:15AM	Opening Remarks and Session 6: **A 10-year Retrospective on RWE Since the 21st Century Cures Act** **Session Chair: Simon Dagenais,** Pfizer 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. **Simon Dagenais,** Pfizer	Grand Ballroom FGH

9:15-10:30AM	Session 7: **Open Regulatory Intelligence: A Deep Dive Into Strategies, Data, Tools, Insights, and Best Practices** **Session Chair: Rachele Hendricks-Sturrup,** Duke-Robert Margolis, Center for Health Policy 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. **Rachele Hendricks-Sturrup,** Duke-Robert Margolis, Center for Health Policy **Donna Rivera,** Canal Row Advisors **John Diaz-Decaro,** Black Swan Casual Labs **Shirley Wang,** Harvard Medical School	Grand Ballroom FGH
10:30-11:15AM	Refreshment and Networking Break	Grand Ballroom E
10:45-11:15AM	Case Study (Non-CE) Hosted by Curavit: **Build Regulatory-Grade by Deploying Prospective Linkage and Virtual Sites to Satisfy FDA Standards** Retrospective real-world evidence often fails regulatory scrutiny due to data gaps, selection bias, and unresolvable data provenance. To overcome these structural limitations, life sciences organizations must shift to prospective, execution-driven evidence generation. This session presents an integrated blueprint combining virtual clinical sites, instant eligibility screening, and patient-authorized record linkage to capture audit-ready data continuously across multi-year horizons. Attendees will explore real-world case examples demonstrating how to generate defensible, regulatory-grade RWE that satisfies FDA mandates while accelerating trial timelines. **Dave Hanaman,** Curavit	Strathmore A&B
11:15AM-12:30PM	Session 8: **Translate RWD into Decision-Ready for HTA and Market Access** **Session Chair: Xiang Zhang,** CSL Behring RWD/RWE is increasingly used to support HTA, reimbursement, and market access decisions, but its impact depends on whether the evidence is methodologically credible, relevant to the decision context, and usable by decision-makers. This session will examine how RWE can become decision-ready through rigorous study design (e.g., target trial emulation) and analysis, lifecycle applications spanning regulatory and reimbursement decisions, and approaches to assessing RWE acceptance and uncertainty in HTA. Through case studies from payer, national policy, and European HTA settings, speakers will discuss where RWE can strengthen decision-making, where it may be discounted, and what methodological, contextual, and implementation barriers remain. Attendees will gain practical insights for planning RWE that better connects evidence generation with HTA, reimbursement, and market access decisions.	Grand Ballroom FGH

	Renske Ten Ham, UMC Utrecht **Mingyang Shan,** Eli Lilly and Company **Wenxue Zhao,** Hainan Lecheng Institute of Real-World Study **Wei Hong Yuan,** Hainan Boao Lecheng Real-World Data Research Institute	
12:30-1:45PM	Networking Luncheon	Grand Ballroom E
1:10-1:40PM	Case Study (Non- CE) Hosted by Briya Health: **Fixing Cohort Blindness: How Methodologically Aware AI Cuts Data Gaps and Amendment Costs** Cohort blindness is the gap between the patient population a protocol describes and the one structured data can actually see: eligibility criteria written against clinical reality, then tested against coded fields that never captured it. The cost is measurable. Seventy-six percent of clinical trial protocols now require an amendment, most often to eligibility criteria, at $141K to $535K and an average of 260 days each (Tufts CSDD), and most of these trace back to cohort assumptions that could not be validated before protocol lock. Dr. Or Shaked will show how cohort blindness arises from coding practice, missingness, and data model constraints, why it stays invisible until enrollment fails, and what changes when eligibility logic can be tested, kept visible, and recalculated before lock. Attendees will leave with a framework for diagnosing cohort blindness in their own studies and criteria for judging whether an AI approach is methodologically aware or simply fast. **Or Shaked,** Briya Health	Strathmore A&B
1:45-3:00PM	Session 9: **Trust, but Verify: Governing AI-Enabled Real-World Evidence from Regulation to Rapid Deployment** **Session Chairs: Lina Titievsky,** GlaxoSmithKline and Matt Curtis, Amgen 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. **John Diaz-Decaro,** Black Swan Casual Labs **Wei Liu,** Johnson and Johnson Innovative Medicine **Sneha Kishnani,** Director, Business Strategy, IQVIA	Grand Ballroom FGH
3:00-4:15PM	Session 10: **Navigating RWE: Practical Data, Evidence, and Innovative Considerations for the Future** **Session Chair: Jaclyn Bosco,** IQVIA This fire-side chat brings together leading voices from academia, industry, and FDA—Nancy Dreyer, Sebastian Schneeweiss, Khaled Sarsour, and Marie Bradley—to examine how real-world evidence is evolving for regulatory decision-making including as substantial evidence of effectiveness, and confirmatory evidence in drug approvals, and in safety. The discussion will focus on practical challenges that often determine whether RWE can be used credibly, including data provenance, documentation, transparency, data access, submission constraints, and inspection-readiness. Panelists will also discuss how AI may help scale RWE generation and causal inference while	Grand Ballroom FGH

	requiring human-in-the-loop checkpoints, clear documentation, and appropriate boundaries. Attendees will leave with practical considerations for designing regulatory-grade RWE strategies that are scientifically rigorous, operationally feasible, and aligned with evolving expectations. **Jaclyn Bosco,** IQVIA **Nancy Dreyer,** Dreyer Strategies **Sebastian Schneeweiss,** Harvard Medical School **Marie Bradley,** FDA **Khaled Sarsour,** Head, Astellas Pharma	
4:10–4:30PM	Closing Remarks	Grand Ballroom FGH
4:30PM	Conference Adjourns	

Learning Objectives

At the conclusion of this activity, participants should be able to:

- Interpret evolving global regulatory expectations for RWD and RWE
- Apply practical approaches for generating credible, decision-ready RWE
- Evaluate emerging methodologies, technologies, and AI-enabled approaches for evidence generation
- Assess the use and value of RWE across the product lifecycle, from clinical development to regulatory, HTA, and
- market access decisions
- Identify strategies to improve the scalability, efficiency, and impact of RWE generation

Why You Can't Miss It

- Hear directly from global regulators and RWE leaders about evolving expectations and the future of
- regulatory-grade evidence.
- Move from theory to practice with real-world case studies, practical frameworks, and strategies you can apply
- within your organization.
- Explore what's next in RWE, including AI-enabled evidence generation, external controls, digital twins, multimodal
- data, and innovative study designs.
- Connect RWE across the evidence lifecycle, from clinical development and regulatory submissions to HTA, reimbursement, and market access.
- Understand the business value of RWE, including how organizations can evaluate ROI and maximize investments in
- data and evidence generation.
- Engage with the RWE community through interactive discussions, roundtables, case studies, and networking across regulators, industry, academia, and other stakeholders.

Want to view the detailed agenda? Download DIA's Mobile App!

- Agenda at your fingertips
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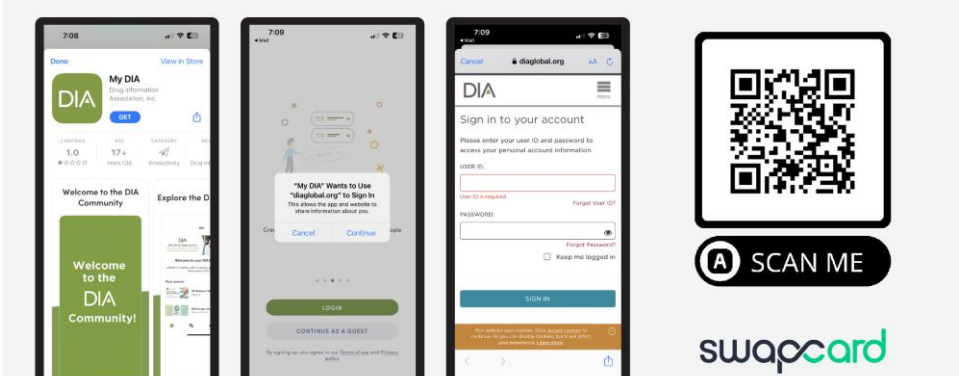
- Ask questions live during sessions through the session chat function



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Real World Evidence Conference:

- October 19 Day 1: Real World Evidence Conference: 6.5 contact hours or .65 CEUs Type of Activity: Knowledge, 0286-0000-26-063-L04-P
- October 20 Day 2: Real World Evidence Conference: 6 contact hours or .6 CEUs Type of Activity: Knowledge, 0286-0000-26-064-L04-P

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