Real-World Evidence Conference

Virtual Short Course: Getting Started with Estimands in Real-World Evidence Studies | October 9
Conference | October 16-17 | San Diego, CA

PROGRAM COMMITTEE CHAIR

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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 Real-World Evidence Conference will bring together global regulators, industry leaders, data scientists, and policy experts to explore regulatory updates from EMA, FDA, and ICH, advances in data quality and integrity, and innovative trial designs that integrate real-world data with randomized studies. Sessions will also address synthetic data for hard-to-reach populations, evolving publication standards, global OMOP collaborations, and the role of AI and machine learning in advancing patient insights, pharmacovigilance, and trial feasibility—alongside policy and collaboration efforts shaping the next generation of RWE frameworks.

Through case studies, interactive panels, and networking, attendees will gain practical strategies to generate high-quality, regulatory-ready RWE that informs decisions, drives innovation, and improves patient outcomes.

Event Goals and Offerings

- Gain a comprehensive understanding of the latest advancements and regulatory updates in RWE from leading experts in the field
- Engage with industry leaders, regulatory authorities, and peers to discuss innovative strategies and practical applications in RWE
- Explore diverse use cases and methodological insights across early development, late-phase, and post-marketing scenarios to enhance your knowledge and practice
- Discover cutting-edge technologies and operational strategies that are shaping the future of RWE generation
- Examine the intersection of AI and RWE, and discuss the implications for policy and regulatory frameworks

Who Should Attend

- 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

VIRTUAL SHORT COURSE | THURSDAY, OCTOBER 9	
10:00AM-2:00PM EST	Short Course: Getting Started with Estimands in Real-World Evidence Studies **This Short Course requires an additional registration fee. You do not need to be registered for the conference to attend**

DAY ONE | THURSDAY, OCTOBER 16		ROOM
(ALL TIMES LISTED ARE PACIFIC TIME)		
7:30AM-5:30PM	Conference Registration	Ballroom Foyer (Level 2)
7:30-8:30AM	Networking Breakfast	Crystal Ballroom
8:30-8:45AM	Welcome and Opening Remarks	Emerald Ballroom
8:45-9:45AM	Session 1: A Year in Review of Advancing RWE Globally	Emerald Ballroom
9:45-10:30AM	Refreshment and Networking Break Sponsored by Forian	Crystal Ballroom
9:55–10:25AM	Hosted Event/Non-CE: Case Study hosted by Truveta: Accelerating Evidence Generation: Delivering Insights Ahead of Trials and Registries	Opal Room
10:30-11:45AM	Session 2: Ensuring Quality and Integrity of Real-World Data: Regulatory Insights	Emerald Ballroom
11:45AM-12:45PM	Networking Luncheon	Crystal Ballroom
12:45-2:00PM	Session 3: RWD and RWE in Support of Clinical Development: Designs, Guidance Gaps, and Practical Strategies	Emerald Ballroom
2:10-3:25PM	Session 4: Leveraging RWD and Synthetic Data to Advance Research in Special Populations	Emerald Ballroom
3:25-4:00PM	Refreshment and Networking Break	Crystal Ballroom
3:30-4:00PM	Hosted Event/Non-CE: Case Study hosted by Castor: On the Road to Self-Driving Trials: Faster, Cleaner RWE Data Extraction through AI Agents	Opal Room
4:00-5:15PM	Session 5: Real World Evidence Studies in Peer Reviewed Literature: Moving Towards a Better Approach	Emerald Ballroom
5:15-6:15PM	Networking and Poster Reception	Crystal Ballroom

DAY TWO | FRIDAY, OCTOBER 17		ROOM
7:30AM-3:15PM	Conference Registration	Ballroom Foyer (Level 2)
7:30-8:15AM	Networking Breakfast	Crystal Ballroom
7:45-8:15AM	Hosted Event/Non-CE: Case Study hosted by Evidation Health: Strengthening Real-World Evidence with Longitudinal, Multimodal Data Collected Directly from Individuals	Opal Room
8:15-9:30AM	Opening Remarks and Session 6: Scientific Roundtable: ICH Efforts on Convergence and Harmonization of Real-World Data and Evidence	Emerald Ballroom
9:35-10:50AM	Session 7: Accelerating Global RWE with OMOP: Scalable, Standardized Collaboration Across Africa, Europe, and Asia	Emerald Ballroom
10:50-11:30AM	Networking and Refreshment Break Sponsored by Guardian Research Network	Crystal Ballroom
11:00-11:30AM	Hosted Event/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	Opal Room

11:30AM-12:45PM	Session 8: AI and Machine Learning Innovations Transforming Real-World Data from Patient Insights to Regulatory-Ready Evidence	Emerald Ballroom
12:45-1:45PM	Networking Luncheon	Crystal Ballroom
1:45-3:00PM	Session 9: Shaping the Future of Real-World Data and Evidence Through Policy and Collaboration	Emerald Ballroom
3:00-3:15PM	Looking Forward and Closing Remarks	Emerald Ballroom
3:15PM	Conference Adjourns	

Learning Objectives

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

- List recent global regulatory updates on RWE from EMA, FDA, and ICH, including new guidances, DARWIN EU progress, and the evolving M14 standard
- Discuss lessons from regulatory inspections and international registry case studies on data quality, transparency, and integrity
- Describe innovative trial designs that integrate real-world data with randomized studies to address evidence gaps
- Examine the use of synthetic data for research in hard-to-reach populations and sensitive therapeutic areas
- Outline evolving standards for peer-reviewed publications and how global OMOP collaborations are advancing regulatory-grade evidence generation
- Discuss evolving standards for peer-reviewed publications and how global OMOP collaborations are advancing regulatory-grade evidence generation
- Explain how artificial intelligence and machine learning are transforming RWE applications in patient journey insights, pharmacovigilance, and trial feasibility
- Summarize emerging policy priorities and cross-stakeholder collaborations shaping the next generation of RWE frameworks

Continuing Education Credits

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, NOVEMBER 28, 2025.

Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education with Commendation. This program is designated for up to 15.25 contact hours or 1.525 continuing education units (CEU's). Type of Activity: Knowledge.

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by Friday, November 28, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.

Drug Information Association (DIA) is accredited by the International Accreditors for Continuing Education and Training (IACET) and offers IACET CEUs for its learning events that comply with the ANSI/IACET Continuing Education and Training Standard. IACET is recognized internationally as a standard development organization and accrediting body that promotes quality of continuing education and training. As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to .4* CEUs for this program. Participants must attend the entire virtual short course to be able to receive an IACET statement of credit. No partial credit will be awarded. ***IACET CEUs are only available for the virtual Short Course.**

Continuing Education Credit Allocation

October 9 Short Course: Getting Started with Estimands in Real-World Evidence Studies: 3.75 contact hours or .375 CEUs, 0286-0000-25-064-L04-P Type of Activity: Knowledge; IACET 0.4 CEUs

October 16, 2025 Real World Evidence Conference – Day 1: 6.25 contact hours or .625 CEUs, UAN: 0286-0000-25-062-L04-P Type of Activity: Knowledge

October 17, 2025 Real World Evidence Conference – Day 2: 5.25 contact hours or .525 CEUs, UAN: 0286-0000-25-063-L04-P Type of Activity: Knowledge

Statement of Credit

If you would like to receive a statement of credit for the days you attend the conference, you must attend one or both days of the conference, in their entirety, sign in at the DIA registration desk upon arrival, and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Friday, October 31, 2025.**

If you are claiming CE credit for the conference you must:

1. Attend one or both days of the conference, (in their entirety)
2. Sign in at the DIA registration desk each day, upon arrival
3. Access your DIA account and select My Transcript to claim your CE credit, available on **Friday, October 31, 2025**
4. ACPE credit must be submitted by **Friday, November 28, 2025**

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.
Disclosure statements are included with each speaker's biographical sketch.

The faculty who reported relevant financial relationships with ineligible entities related to the educational content of this CE activity have been mitigated.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

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

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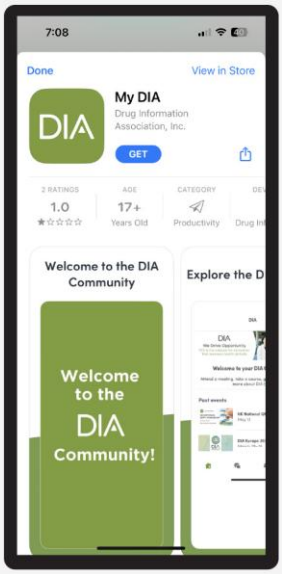

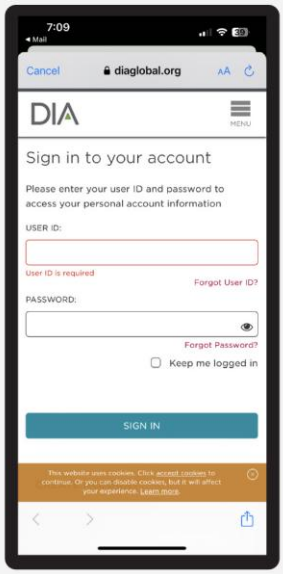

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Follow the instructions on screen, or please see the registration desk/contact NAEvents@DIAglobal.org if you need additional assistance.

DIA 2026 is the premier gathering for industry leaders, regulatory authorities, governmental representatives, academia, innovators, and patients. Set against the vibrant backdrop of Philadelphia, PA, DIA 2026 will beckon stakeholders from around the world to converge, collaborate, and catalyze transformative change within the life sciences realm.

At DIA 2026, we will transcend boundaries, inviting diverse voices to the table to address both local and global challenges. From regulatory hurdles to technological innovations, from healthcare disparities to patient-centric solutions, our agenda is comprehensive and forward-thinking.