

Real-World Evidence Conference

Short Course: October 12 Virtual | Short Course: October 13 Virtual
Conference: October 16-17, Baltimore MD



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Overview

In a market that is constantly adapting and adjusting to the needs of the healthcare field, real-world evidence (RWE) is becoming increasingly important for regulatory and reimbursement decision-making. Historically used for post-market safety monitoring, RWE is now integrated throughout the product development lifecycle, and has led to the real-time analysis of data to better understand and gain insights on disease, approaches to treatment, and how to substantiate coverage decisions.

DIA's *Real-World Evidence Conference* will explore new, innovative applications of RWE, and deliver cutting-edge insights to leverage this knowledge to advance healthcare decision-making.

Event Goals and Offerings

- Identify key events related to RWE in the past 1 year period
- Compare various data standards used for the analysis and submission of real-world data
- Evaluate how external control arm data can be used to inform early decisions in drug development programs.
- Explain the methodological approaches underlying tokenization
- Describe key consideration for the use of RWD and RWE to support regulatory decision-making and apply lessons learned from recent use cases (recent approvals of RWD/RWE submissions)
- Identify how to utilize clinical notes to create a representative natural language processing (NLP) training sample
- Explain the need for collaborative studies to address a lack of harmonization on RWD/E methodologies and quality
- Recognize trends in clinical post-marketing commitments (PMC) and requirements (PMR) issued by US FDA in oncology and how RWE can be applied

Why You Can't Miss It

- Network with like-minded professionals focused on real-world data and real-world evidence to discuss best practices and lessons learned from multiple disciplines
- Intimate setting with interaction with regulators from FDA: CDER, CBER, and OCE as well as the EMA
- Learn how to apply successful use cases, real-world examples, and practical outcomes into your own company or organization from regulators and industry representatives
- Gain insights and discuss how stakeholders are impacted by real-world data and real-world evidence
- Evaluate future applications of real-world evidence in drug development, clinical trials, and evidence generation
- Networking Reception sponsored by 

Who Should Attend

Join professionals from every corner of the vast realm of real-world data and real-world evidence:

- Academia
- Clinical Research
- Data analytics
- Epidemiology
- Health Economics and Outcomes Research
- Pharmacovigilance
- Policy
- Real-World Evidence
- Real-World Data
- Regulatory Science
- Technology development

Thank you to our media partner:



SHORT COURSE | THURSDAY, OCTOBER 12

10:00AM-2:00PM

Virtual Short Course: How Good is Good Enough? Fit-for-Purpose Considerations for RWD/RWE for Regulatory Purposes**This course requires a separate registration fee. You do not need to be registered for the full conference to attend this Short Course.*

SHORT COURSE | FRIDAY, OCTOBER 13

10:00AM-2:00PM

Virtual Short Course: Measuring the Quality of Real-World Data (RWD)**This course requires a separate registration fee. You do not need to be registered for the full conference to attend this Short Course.*

DAY ONE | MONDAY, OCTOBER 16

ROOM

7:30AM-5:30PM

Conference Registration

Maryland Ballroom Foyer

7:30-8:30AM

Networking Breakfast

Baltimore Ballroom

8:30-8:45AM

Opening Remarks

Maryland Ballroom

**Tamei Elliott, MS**, Associate Director, Scientific Programs, DIA**David Martin, MD, MPH**, Vice President, Pharmacovigilance Global Head RWE, Moderna; DIA RWE Conference Program Committee Chair

8:45-10:00AM

Session 1: A Year in Review

Maryland Ballroom

10:00-10:45AM

Refreshment and Networking Break

Baltimore Ballroom

10:10-10:40AM

Hosted Session/Non-CE: Case Study Spotlight hosted by OM1:
A New Era of Integrated Evidence Generation

Homeland

10:45AM-12:00PM

Session 2: Standardization of Real-World Data for Regulatory Submissions

Maryland Ballroom

12:00-1:00PM

Networking Luncheon

Baltimore Ballroom

1:00-2:15PM

Session 3: Methodological Insights on External Controls and Sensitivity Analyses

Maryland Ballroom

2:25-3:40PM

Session 4: "Tokenization": Privacy-Preserving Data Integration to Enhance Clinical Trials and Real-World Evidence Studies

Maryland Ballroom

3:40-4:10PM

Hosted Session/Non-CE: Case Study Spotlight hosted by Truveta: Using the EHR to Identify Long COVID Patients in Near-real-time: A Feasibility Assessment of Truveta Data

Homeland

3:40-4:15PM

Refreshment and Networking Break

Baltimore Ballroom

4:15-5:30PM

Session 5: Case Studies from Recent Approvals of RWD/RWE Submissions

Maryland Ballroom

5:30-6:30PM

Networking Reception hosted by Merative

Baltimore Ballroom

7:15AM-4:10PM	Conference Registration	Maryland Ballroom Foyer
7:15-8:00AM	Networking Breakfast	Baltimore Ballroom
7:30-8:00AM	Hosted Session/Non-CE: Case Study Spotlight hosted by Clinetic: Accelerating Research Through Electronic Health Record (EHR) Surveillance	Homeland
8:00-9:15AM	Opening Remarks and Session 6: Objectivity and Transparency: Roundtable Discussions on Real-World Studies to Support Regulatory Decision-making	Maryland Ballroom
9:20-10:35AM	Session 7: Unexpected Issues in Pharmacoepidemiology Studies Applying Natural Language Processing to Clinical Notes	Maryland Ballroom
10:35-11:15AM	Refreshment and Networking Break	Baltimore Ballroom
10:40-11:10AM	Hosted Session/Non-CE Case Study Spotlight hosted by Purpose Life Sciences: RWE Integration by Design: An Essential Component of Early RCT Design	Homeland
11:15AM-12:30PM	Session 8: Cross-Industry Consortia Initiatives Addressing RWD Heterogeneity	Maryland Ballroom
12:30-1:30PM	Networking Luncheon	Baltimore Ballroom
1:30-2:45PM	Session 9: Special Populations' Perspectives on RWD and RWE	Maryland Ballroom
2:55-4:10PM	Session 10: The Future of RWD and RWE	Maryland Ballroom
4:10-4:25PM	Closing Remarks	Maryland Ballroom
4:25PM	Conference Adjourns	

Learning Objectives

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

- Identify key events related to RWE in the past 1-year period
- Compare various data standards used for the analysis and submission of real-world data
- Evaluate how external control arm data can be used to inform early decisions in drug development programs
- Explain the methodological approaches underlying tokenization
- Describe key consideration for the use of RWD and RWE to support regulatory decision-making and apply lessons learned from recent use cases (recent approvals of RWD/RWE submissions)
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Continuing Education Credits



DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 20.25 contact hours or 2.025 continuing education units (CEU's). Type of Activity: Knowledge



ACPE CREDIT REQUESTS MUST BE SUBMITTED BY MONDAY, NOVEMBER 27, 2023

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 Monday, November 27, 2023, 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 .8 CEUs for this program.

*IACET CEUs are only available for the Short Course. Participants must attend the entire short course in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

October 12 Short Course 1: 3.75 contact hours or .375 CEUs Type of Activity: Knowledge, 0286-0000-23-072-L04-P

October 13 Short Course 2: 3.75 contact hours or .375 CEUs Type of Activity: Knowledge, 0286-0000-23-073-L04-P

October 16 Day 1: Real World Evidence Conference: 6.25 contact hours or .625 CEUs Type of Activity: Knowledge, 0286-0000-23-074-L04-P

October 17 Day 2: Real World Evidence Conference: 6.5 contact hours or .65 CEUs Type of Activity: Knowledge, 0286-0000-23-075-L04-P

Continuing Education Credit and My Transcript

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 each day, 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 **Tuesday, October 31, 2023**.

If you are claiming ACPE credit for this event 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 ACPE credit, available on **Tuesday, October 31, 2023**

To Access My Transcript

- Visit DIAglobal.org, select "Sign in" and you will be prompted for your user ID and password
- Under EVENTS select "Continuing Education"
- Select the blue "My Transcript" button followed by "Credit Request" to process your credit request for the course

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.

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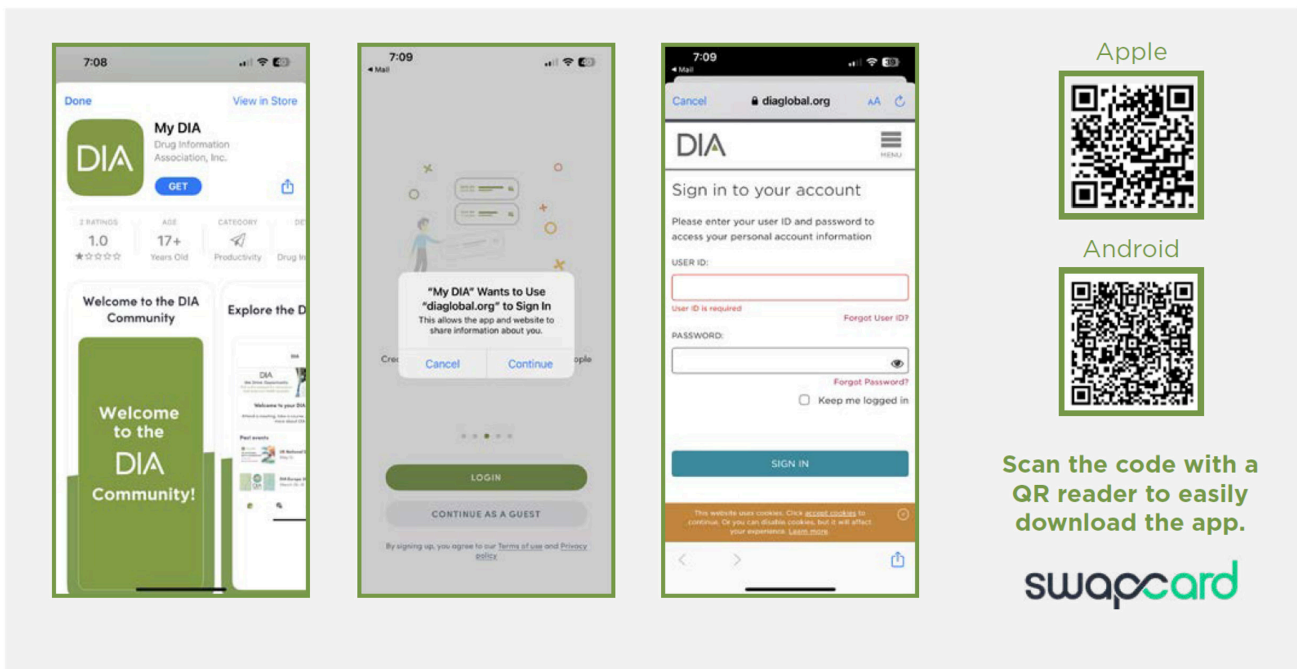
Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

Want to view the detailed agenda?

Download DIA's Mobile App!

DIA Global App

- DIA Global App is run through Swapcard
- App is available in Apple and Android app stores (search for My DIA)
- Access for all attendees, speakers, and exhibitors registered for RWE 2023. There is single sign-on for SwapCard – individuals will be redirected to login with their DIA Username and Password.
 - You are unable to login in with multiple devices on the same account so individuals cannot share username/password



Highlights of the My DIA App

- Create "My Agenda" with your personal sessions
- Browse and bookmark speakers, sessions, and exhibitors so they can access with one touch
- Access helpful information from the conference
- Find exhibitors on the floor plan, view their information, etc.
- Send and receive meeting invites from conference participants
- Share DIA 2023 experiences through photos, posts, and more

Become a DIA Member

DIA Membership Opportunities

- Connect with global influencers and uncover ways to deliver impactful change.
- Access new knowledge that keeps you on the cutting-edge of healthcare conversations.
- Open doors to new pathways towards leadership growth.
- Expand your network to include global peers who support one another in real-time
- Access to discounted rates for all DIA's global events and learning products.

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