Overview

Translating Insights into Real-World Value

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

- Define key recent events related to RWE in the past year (2021-2022)
- Recognize the role of Prescription Drug User Fee Act (PDUFA) in evolving RWE regulatory landscape
- Interpret and apply newly published guidance documents from US FDA and EMA RWE to regulated product development
- Recognize how regulatory agencies and health technology organizations support research and related initiatives.

- Recognize how real-world data can be used to assist in study design and as a data source to facilitate clinical research
- Recognize the regulatory and clinical development context that made an RWE-enabled development strategy attractive in each case
- Identify key aspects of real-world data that can have an impact on data quality and approaches to addressing these factors
- Recognize future opportunities to leverage RWD and RWE in generating RWE for regulatory decision-making

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
- Learn how to apply successful use cases, real-world examples, and practical outcomes into your own company or organization

- 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

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

PROGRAM COMMITTEE CHAIR

Brian Bradbury, DrSc, MA
Vice President, Center for Observational Research
Amgen

PROGRAM COMMITTEE

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Moderna

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Evidera, France

Mark Stewart, PhD
Vice President, Science Policy
Friends of Cancer Research
# Schedule At-A-Glance

## SHORT COURSE | MONDAY, NOVEMBER 7

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:00AM-2:30PM ET</td>
<td>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.</td>
<td>Presidential Ballroom</td>
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## DAY ONE | THURSDAY, NOVEMBER 10

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>7:00AM-5:30PM</td>
<td>Conference Registration</td>
<td>Presidential Ballroom Foyer</td>
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<tr>
<td>7:00-8:00AM</td>
<td>Networking Breakfast</td>
<td>Presidential Ballroom Foyer</td>
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<tr>
<td>8:00-8:10AM</td>
<td>Opening Remarks</td>
<td>Presidential Ballroom</td>
</tr>
<tr>
<td>8:10-9:25AM</td>
<td>Session 1: A Year in Review</td>
<td>Presidential Ballroom</td>
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<tr>
<td>9:30-10:45AM</td>
<td>Session 2: Regulatory Updates</td>
<td>Presidential Ballroom</td>
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<tr>
<td>10:45-11:15AM</td>
<td>Refreshment and Networking Break</td>
<td>Presidential Ballroom Foyer</td>
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<tr>
<td>10:45-11:15AM</td>
<td>SPONSORED SESSION: Case Study Spotlight hosted by OM1: Getting the Most out of Structured and Unstructured Real-World Data for Evidence Generation Separate RSVP is required for this session. By registering for this sponsored session, you are agreeing to share full contact information with the Solution Provider. You also understand that the Solution Provider, and DIA, may contact you with messages regarding products and/or services. Click here to RSVP or sign up in Mobile App. Please Note that this is an exhibitor sponsored event and is not eligible for CE credit.</td>
<td>Executive Room</td>
</tr>
<tr>
<td>11:15AM-12:15PM</td>
<td>Session 3: Research and Related Initiatives to Evaluate and Improve Real-World Evidence and Real-World Data</td>
<td>Presidential Ballroom</td>
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<tr>
<td>12:15-1:15PM</td>
<td>Networking Luncheon</td>
<td>Palm Court (Lower Level)</td>
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<tr>
<td>1:15-2:15PM</td>
<td>Session 3 (continued): Evaluate and Improve Real-World Evidence and Real-World Data</td>
<td>Presidential Ballroom</td>
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<tr>
<td>2:20-3:35PM</td>
<td>Session 4: Evolving the Clinical Trial Landscape Using Real-World Data</td>
<td>Presidential Ballroom</td>
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<tr>
<td>3:35-4:20PM</td>
<td>Refreshment and Networking Break</td>
<td>Presidential Ballroom Foyer</td>
</tr>
<tr>
<td>3:50-4:20PM</td>
<td>SPONSORED SESSION: Case Study Spotlight hosted by HealthVerity: Applying Public Health Lessons to Life Sciences: Linking primary and real-world data to drive integrated evidence generation Separate RSVP is required for this session. By registering for this sponsored session, you are agreeing to share full contact information with the Solution Provider. You also understand that the Solution Provider, and DIA, may contact you with messages regarding products and/or services. Click here to RSVP or sign up in Mobile App. Please Note that this is an exhibitor sponsored event and is not eligible for CE credit.</td>
<td>Executive Room</td>
</tr>
<tr>
<td>4:20-5:35PM</td>
<td>Session 5: Positive Regulatory Decisions Enabled by Real-World Evidence</td>
<td>Presidential Ballroom</td>
</tr>
<tr>
<td>5:35-6:35PM</td>
<td>Networking Reception Sponsored by PointClickCare</td>
<td>Palm Court (Lower Level)</td>
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DAY TWO | FRIDAY, NOVEMBER 11

7:00AM-12:30PM  Conference Registration  Presidential Ballroom Foyer

7:00-8:00AM  Networking Breakfast  Presidential Ballroom Foyer

8:00-9:15AM  Opening Remarks and Session 6: Round Table Discussions  Presidential Ballroom

9:15-10:00AM  Refreshment and Networking Break  Presidential Ballroom Foyer

9:30-10:00AM  SPONSORED SESSION: Case Study Spotlight hosted by Executive Room
Target RWE: Engaging Academia, Community Investigators, and Other Important Stakeholders to Generate Influential Real-World Evidence that Improves Patient Care
Separate RSVP is required for this session. By registering for this sponsored session, you are agreeing to share full contact information with the Solution Provider. You also understand that the Solution Provider, and DIA, may contact you with messages regarding products and/or services. Click here to RSVP or sign up in Mobile App. Please Note that this is an exhibitor sponsored event and is not eligible for CE credit.

10:00-11:00AM  Session 7: Relevance and Reliability: The Role of Data Quality in Advancing the use of RWE for Regulatory Decision-Making  Presidential Ballroom

11:05AM-12:20PM  Session 8: Leaping Forward: The Future of Real-World Evidence  Presidential Ballroom

12:20-12:30PM  Closing Remarks  Presidential Ballroom

12:30-12:30PM  Conference Adjourns

Learning Objectives

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

• Identify key events related to RWE in the past year and how these events are interrelated and contribute to its advancement
• Recognize the role of Prescription Drug User Fee Act (PDUFA) in evolving RWE regulatory landscape
• Interpret and apply newly published guidance documents from US FDA and EMA RWE to regulated product development
• Recognize how regulatory agencies and health technology organizations support research and related initiatives
• Recognize how real-world data can be used to assist in study design and as a data source to facilitate clinical research
• Recognize the regulatory and clinical development context that made an RWE-enabled development strategy attractive
• Identify key aspects of real-world data that can have an impact on data quality and approaches to addressing these factors
• Recognize future opportunities to leverage RWD and RWE in generating RWE for regulatory decision-making

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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 Wednesday, December 28, 2022, 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

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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.

*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.

**November 7 Short Course:** How Good is Good Enough? Fit-for-Purpose Considerations for RWD/RWE for Regulatory Purposes: 4 contact hours or .4 CEUs Type of Activity: Knowledge, 0286-0000-22-099-L04-P

**November 10 Day 1:** Real-World Evidence Conference: 7 contact hours or .7 CEUs Type of Activity: Knowledge, 0286-0000-22-100-L04-P

**November 11 Day 2:** Real-World Evidence Conference: 3.75 contact hours or .375 CEUs Type of Activity: Knowledge, 0286-0000-22-101-L04-P

**Continuing Education Credit and My Transcript**

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**DIA Disclosure Policy**

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Disclosure statements are included with each speaker’s biographical sketch.

**Planning Committee**

DIA staff members have no relevant financial relationships to disclose.

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Click the menu in the upper left, then “Switch Event”. Selection Real-World Evidence Conference.

Email Address: Please use the email address that was used to register for the Real-World Evidence Conference
Event Password: rwe2022

Step 2: Verify Your Account
You’ll receive an email from support@crowdcompassmail.com with a verification code to access the app on your device. Please check your SPAM filter should you have any difficulties.
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Use code **DIA23Thanks** at checkout!
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Cardinal Health™ Real-World Evidence and Insights

Uncover actionable insights through deep data and unique research

- Access our network of GPO- and EMR-agnostic community and academic providers across established and growing therapeutic areas
- Identify hard-to-find patients
- Generate real-world data for regulatory submissions
- Prove your product’s clinical effectiveness with real-world evidence

Connect with our RWE experts at cardinalhealth.com/rwe

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The Real-World Evidence and Insights experts at Cardinal Health Specialty Solutions work with key stakeholders to critically analyze data and provide clinically and scientifically meaningful results to demonstrate value. Our specialty focus, real-world data and real-world evidence (RWE) solutions and outcomes research strategies help to give you a precise picture of your product’s comparative value in the real world.

Cisiv’s technology platform, Baseline Plus, is a bespoke solution for real world, late phase research that spans every aspect of data collection and analysis. This intuitive, modular web-based platform is highly configurable, providing unrivalled flexibility, no matter the scope or scale. Baseline Plus is an industry leading EDC, eConsent, ePRO, eCOA, eDiary, Surveys, S/AE, with functionality suitable for site-based, decentralized, and hybrid research which engages both physicians and patients.

FDB (First Databank) is the leading provider of drug and medical device knowledge that helps healthcare professionals make precise decisions. We empower our information system developer partners to deliver valuable solutions used by millions of clinicians, business associates, and patients every day. For more than four decades, our drug knowledge has helped improve patient safety, operational efficiency, and healthcare outcomes.
OM1

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Specializing in chronic conditions, OM1 is re-imagining real-world data and evidence by developing large electronically connected networks of clinicians and health data in rheumatology, dermatology, gastroenterology, cardiometabolic, respiratory, mental health, central nervous system, and other specialty areas. Leveraging its extensive clinical networks and AI platform, OM1 offers enriched healthcare datasets, research analytics, data modeling, and retrospective and prospective clinical studies.

OncoHealth

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OncoHealth is a leading digital health company dedicated to helping navigate the physical, mental, and financial complexities of cancer through technology-enabled services and real-world data analytics. OncoHealth’s clinically rich, de-identified, deep data sets and market and therapy dashboards are used by pharmaceutical and biotech researchers to study comparative effectiveness and market performance and for conducting health economics and outcomes research. www.oncohealth.us/life-sciences

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Facebook: https://facebook.com/picnichealth
LinkedIn: https://www.linkedin.com/company/picnichealth/
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PicnicHealth builds deep real-world datasets to spur innovation while giving patients control of their own medical records. These complete, clinically-rich datasets produce unique insights to get the right treatments to patients faster. We do this by working directly with patients and leveraging human-assisted machine learning to transform messy medical records into structured research-ready datasets. We’ve helped tens of thousands of patients contribute to research that impacts their lives.

Target RWE

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Website: https://www.targetrwe.com/
LinkedIn: https://www.linkedin.com/company/targetrwe/?lang=en

As the industry’s best-in-class, complete real world evidence (RWE) solution, Target RWE is a distinctly collaborative enterprise that unifies real world data (RWD) sets and advanced RWE analytics in an integrated community, shifting the paradigm in healthcare for how decisions are made to improve lives.

Verantos

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Verantos is the market leader in high-validity real-world evidence for life sciences. By incorporating robust clinical narrative data, artificial intelligence technology, and measured validity, Verantos is the first company to generate research-grade evidence at scale across all therapeutic areas. The Verantos Evidence Platform integrates heterogeneous real-world data sources and generates evidence with the accuracy necessary for market access, HEOR, medical affairs, and regulatory use.

Vivalink

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Website: www.vivalink.com
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Vivalink is a provider of digital healthcare solutions including biometrics technology for virtual patient care and decentralized clinical trials. We leverage unique physiology-optimized medical wearable sensors and data services to enable a deeper and more clinical understanding between provider and patient.