DIA

Real-World Evidence Conference

Short Course November 7 Virtual | Conference November 10-11 San Diego, CA

PROGRAM COMMITTEE CHAIR

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Vice President, Center for Observational Research
Amgen

PROGRAM COMMITTEE

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Associate Director for Real-World Evidence Analytics, OMP, CDER
FDA

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Executive Director, Real-World Evidence
Evidera, France

Mark Stewart, PhD
Vice President, Science Policy
Friends of Cancer Research

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

Schedule At-A-Glance

SHORT COURSE | MONDAY, NOVEMBER 7

10:00AM-2:30PM ET	**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.*	

DAY ONE | THURSDAY, NOVEMBER 10

7:00AM-5:30PM	**Conference Registration**	Presidential Ballroom Foyer
7:00-8:00AM	**Networking Breakfast**	Presidential Ballroom Foyer
8:00-8:10AM	**Opening Remarks**	Presidential Ballroom
8:10-9:25AM	**Session 1:** A Year in Review	Presidential Ballroom
9:30-10:45AM	**Session 2:** Regulatory Updates	Presidential Ballroom
10:45-11:15AM	**Refreshment and Networking Break**	Presidential Ballroom Foyer
10:45-11:15AM	**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.*	Executive Room
11:15AM-12:15PM	**Session 3:** Research and Related Initiatives to Evaluate and Improve Real-World Evidence and Real-World Data	Presidential Ballroom
12:15-1:15PM	**Networking Luncheon**	Palm Court (Lower Level)
1:15-2:15PM	**Session 3 (*continued*):** Research and Related Initiatives to Evaluate and Improve Real-World Evidence and Real-World Data	Presidential Ballroom
2:20-3:35PM	**Session 4:** Evolving the Clinical Trial Landscape Using Real-World Data	Presidential Ballroom
3:35-4:20PM	**Refreshment and Networking Break**	Presidential Ballroom Foyer
3:50-4:20PM	**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.*	Executive Room
4:20-5:35PM	**Session 5:** Positive Regulatory Decisions Enabled by Real-World Evidence	Presidential Ballroom
5:35-6:35PM	**Networking Reception** Sponsored by PointClickCare	Palm Court (Lower Level)

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 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.*	Executive Room
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

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 14.75 contact hours or 1.475 continuing education units (CEU's). Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY WEDNESDAY, DECEMBER 28, 2022

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

Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

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.

*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.

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

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 Friday, November 25, 2022.

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 Friday, November 25, 2022

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.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

To view DIA's Disclosure and Grievance Policies, visit DIAglobal.org/CE

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

https://crowd.cc/s/4vceM

- Agenda at your fingertips
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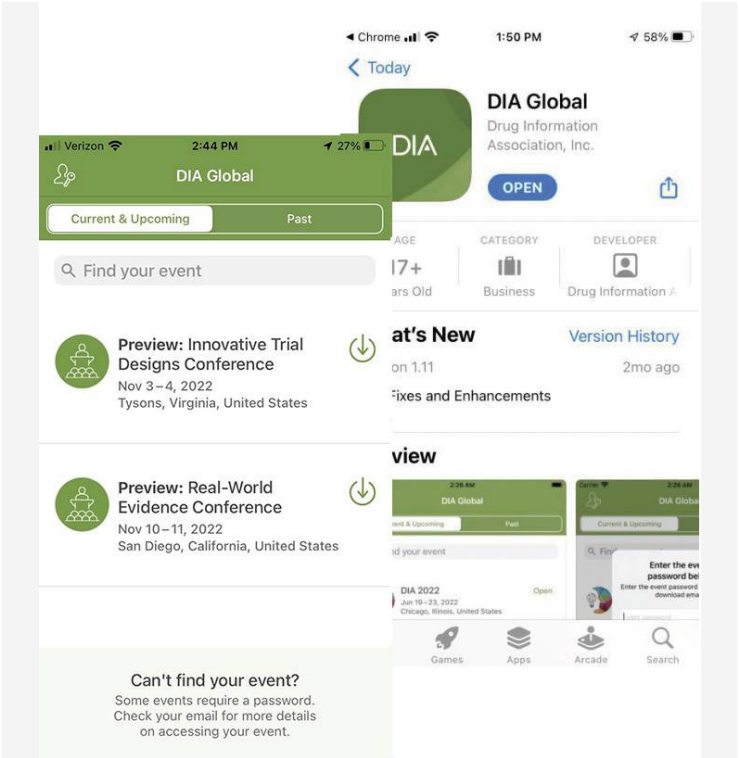
- Frequently Asked Questions answered all in one place!



Scan this code with a QR reader to easily download the app.

CrowdCompass by Cvent

Already have the DIA App from a previous 2022 event?
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.

DIA 2023
GLOBAL ANNUAL MEETING
BOSTON, MA | JUNE 25-29

ILLUMINATE

DIAglobal.org/DIA2023

Thank you for joining us at this DIA Conference!

We want to thank you with a **10% off** discount code for DIA's Global Annual Meeting!
Use code **DIA23Thanks** at checkout!

Exhibitor Directory

Real-World Evidence Conference

November 10-11, 2022

THE US GRANT, a Luxury Collection Hotel | San Diego, CA

DIA

Cardinal Health
7000 Cardinal Pl
Dublin, OH 43017

Contact: Tammy Schuler
Phone: 614.757-5000
Email: tammy.schuler@cardinalhealth.com
Website: https://www.cardinahealth.com/rwe
Facebook: https://www.facebook.com/CardinalHealthInc
LinkedIn: *https://www.linkedin.com/company/cardinal-health/*
Twitter: *https://twitter.com/cardinalhealth*

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.

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

DIA Real-World Evidence Conference Exhibitor Directory

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THE US GRANT, a Luxury Collection Hotel | San Diego, CA

Cardinal Health — Table 4

Contact: Tammy Schuler
Phone: 614.757.5000
Email: tammy.schuler@cardinalhealth.com
Website: *https://www.cardinahealth.com/rwe*
*Facebook: https://www.facebook.com/CardinalHealthInc_*
LinkedIn: https://www.linkedin.com/company/cardinal-health/
Twitter: https://twitter.com/cardinalhealth

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 — Table 10

Contact: Cassandra Adams
Phone: 617.448.6170
Email: cassandra.adams@cisiv.com
Website: *https://www.cisiv.com*
LinkedIn: https://www.linkedin.com/company/cisiv-ltd

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, Inc.) — Table 7

Contact: Christine Navarrete
Phone: 800.633.3453
Email: cnavarrete@fdbhealth.com
Website: *https://www.fdbhealth.com/*
Twitter: https://twitter.com/fdb_Us
LinkedIn: https://www.linkedin.com/company/firstdatabank

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.

HealthVerity — Table 5

Contact: Jen Kaczmarczyk
Phone: 267.262.6776
Email: info@healthverity.com
Website: *https://www.healthverity.com*
LinkedIn: https://www.linkedin.com/company/healthverity
Twitter: https://twitter.com/@healthverity.com

Top pharma, payers, and government agencies partner with HealthVerity to solve their most complicated use cases through transformative technologies and real-world data (RWD) infrastructure. The HealthVerity IPGE platform, based on the foundational elements of Identity, Privacy, Governance, and Exchange, enables the discovery of RWD across the broadest healthcare data ecosystem, the building of more complete patient journeys and the ability to power next-gen analytics and applications.

IQVIA — Table 9

Contact: Linda Maxson
Phone: 267.398.4973
Email: linda.maxson@iqvia.com
Website: *https://www.iqvia.com/solutions/real-world-evidence/regulatory-and-safety*
LinkedIn: https://www.linkedin.com/showcase/iqvia-united-states/

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry dedicated to creating intelligent connections that deliver unique and actionable insights. With approximately 82,000 employees, IQVIA conducts operations in more than 100 countries. Learn more at www.iqvia.com.

OM1 Table 3

Contact: Renee Hurley
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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 Table 8

Contact: John Vernon
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Email: inquiries@oncohealth.us
Website: *https:/www.oncohealth.us*
LinkedIn: https://www.linkedin.com/company/oncohealth/

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

PicnicHealth Table 11

Contact: parternships@picnichealth.com
Phone: +609.468.4136
Email: partnerships@picnichealth.com
Website: https://picnichealth.com/
Facebook: https://facebook.com/picnichealth
LinkedIn: https://www.linkedin.com/company/picnichealth/
Twitter: https://twitter.com/PicnicHealth

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 Table 2

Contact: Lutz Schlicht
Phone: 984.234.0268
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Website: https://www.targetrwe.com/
LinkedIn: https://www.linkedin.com/company
Twitter: https://twitter.com/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 Table 6

Contact: Chet Kumar
Phone: 510.999.9999
Email: marketing@verantos.com
Website: https://verantos.com
LinkedIn: https://www.linkedin.com/company/verantos/

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 Table 1

Contact: info@vivalink.com
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Email: info@vivalink.com
Website: www.vivalink.com
LinkedIn: https://www.linkedin.com/company/3878950/admin/

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.

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