Real-World Evidence Conference

Conference | October 24-25

PROGRAM COMMITTEE CHAIR

David Martin, MD, MPH
Vice President, Head, PCO Center of Excellence
Novartis

PROGRAM COMMITTEE

Jaclyn Bosco, PhD, MPH, FISPE
Vice President and Global Head of Epidemiology
IQVIA

John Concato, MD, MPH, MS
Associate Director for Real-World Evidence Analytics, OMP, CDER
FDA

Diane Gubernot, DrPH, MPH
Epidemiologist, CBER
FDA

Rachele Hendricks-Sturrup, DrSc, MA, MSc
Research Director, Real-World Evidence, Duke-Robert J. Margolis, MD, Center for Health Policy

Charles Lee, MBA, MS
Executive Regulatory Science Director
AstraZeneca

Sarah Martin, PhD, MS
Senior Director - Global Regulatory Policy (Oncology)
Eli Lilly & Co.

Brittany Avin McKelvey, PhD
Director, Regulatory Affairs
Friends of Cancer Research

Keri Monda, PhD, MS
Executive Director, Center for Observational Research
Amgen

Overview

In an ever-evolving healthcare landscape, real-world evidence (RWE) has emerged as a pivotal tool for shaping regulatory and reimbursement decisions. Traditionally associated with post-market safety monitoring, RWE now plays a critical role throughout the entire product development lifecycle. It enables real-time data analysis to enhance our understanding of diseases, refine treatment approaches, and substantiate coverage decisions.

DIA's *Real-World Evidence Conference* is designed to delve into the latest advancements and innovative applications of RWE. This conference will provide participants with cutting-edge insights into how RWE is transforming drug development and regulatory practices. By exploring new methodologies, technological advancements, and practical case studies, the event will equip attendees with the knowledge and tools necessary to leverage RWE effectively and drive forward healthcare decision-making. Don't miss this opportunity to stay ahead in the field and harness RWE's full potential to impact patient outcomes and policy.

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

Why You Can't Miss It

- Stay at the forefront of real-world evidence (RWE) with the latest advancements, regulatory updates, and practical applications from leading experts and key industry players
- Deep dive into various stages of drug development, from early-phase studies to post-marketing safety, and understand how RWE is applied across different use cases
- Learn about the latest methodological approaches and innovations in RWE, including causal methods, negative control outcomes, and sensitivity analyses
- Discover new technologies and operational strategies that enhance RWE generation, such as AI-enabled data abstraction and data linkage techniques
- Explore strategies to address health equity and improve diversity in drug development, leveraging RWE to build more representative and inclusive study populations
- Gain insights into international regulatory perspectives and practical challenges in using RWE, and learn how to balance data innovation with scientific rigor
- Understand how artificial intelligence is transforming clinical study designs and policy frameworks, and explore the future intersection of AI and RWE in pharmacoepidemiology

Schedule-At-A-Glance (All times listed are Eastern Time)

DAY ONE | THURSDAY, OCTOBER 24		ROOM
7:30AM-5:15PM	Conference Registration	Liberty Ballroom Foyer (Ballroom Level)
7:30-8:30 AM	Networking Breakfast	Liberty Ballroom A
8:30-8:45AM	Opening Remarks	Liberty Ballroom B
8:45-9:45AM	Session 1: A Year in Review	Liberty Ballroom B
9:45-10:30AM	Refreshment and Networking Break	Liberty Ballroom A
9:55–10:25AM	Hosted Session/Non-CE: Case Study Spotlight hosted by OM1: Elevate Your Real-World Evidence Without Stretching Your Resources	Salon 5/6 (Mezzanine Level)
10:30-11:45AM	Session 2: Early Development Use Cases	Liberty Ballroom B
11:45AM-12:45PM	Networking Luncheon	Liberty Ballroom A
12:45–2:00PM	Session 3: RWD Innovations in Late Phase and Postmarket Settings: A Review of Use Cases	Liberty Ballroom B
2:10–3:25PM	Session 4: Real-World Data Standards for Regulatory Submissions: Exploring the Challenges, Solutions, and Potential Alternatives	Liberty Ballroom B
3:25–4:00PM	Refreshment and Networking Break	Liberty Ballroom A
3:30–4:00PM	Hosted Session/Non-CE: Case Study Spotlight hosted by by Verantos: Asthma and IBD on the Impact of Curation and Enrichment for Rich and	Salon 5/6 (Mezzanine Level)
4:00–5:15PM	Session 5: Health Equity in Drug Development: Leveraging RWD to Inform and Improve Diversity	Liberty Ballroom B
5:15-6:15PM	Networking Reception	Liberty Ballroom A
DAY TWO | FRIDAY, OCTOBER 25		**ROOM**
7:30AM-4:10PM	Conference Registration	Liberty Ballroom Foyer (Ballroom Level)
7:30-8:00AM	Networking Breakfast	Liberty Ballroom A
8:00-9:15AM	Opening Remarks and Session 6: Sand in Your Shoes? The Nitty-Gritty in Generating Regulatory-Grade RWE Using Emerging Data Sources and New Platforms: Global Perspectives	Liberty Ballroom B
9:20-10:35AM	Session 7: Methodological Insights on Aspects of Non-Interventional Studies	Liberty Ballroom B
10:35-11:15AM	Refreshment and Networking Break	Liberty Ballroom A
10:40-11:10AM	Hosted Session/Non-CE: Case Study Spotlight hosted by Parexel: Transforming Evidence Generation: Scalable Solutions for Complex Requirements	Salon 5/6 (Mezzanine Level)
11:15AM-12:30PM	Session 8: Innovations in Technology and Operational Excellence	Liberty Ballroom B
12:30-1:30PM	Networking Luncheon	Liberty Ballroom A
1:30-3:00PM	Session 9: Is the Future Here, Near, or Neither? Exploring the Intersection of AI and RWD in Pharmacoepidemiology	Liberty Ballroom B
3:00-4:00PM	Looking Forward and Closing Remarks	Liberty Ballroom B
4:00PM	Conference Adjourns	

Learning Objectives

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

- Identify the new key milestones and significant advancements in real-world evidence (RWE) since last year
- Determine how RWE is used across different stages of drug development
- Identify advanced methodological approaches for generating RWE, including causal methods, negative control outcome studies, and sensitivity analyses, to improve the design and validity of non-interventional studies
- Evaluate the latest technological innovations and operational strategies, such as AI-enabled data abstraction and data linkage methods, to enhance the quality and efficiency of RWE generation
- Discuss how to leverage RWE to address health equity and improve diversity in drug development
- Examine international regulatory perspectives and practical challenges in applying RWE
- Assess the role of artificial intelligence in transforming clinical study designs, optimizing patient selection, and shaping policy frameworks to integrate AI with RWE effectively

Continuing Education Credits

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 12.5 contact hours or 1.25 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 29, 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

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, NOVEMBER 29, 2024.

Continuing Education Credit Allocation

October 24 Day 1: Real World Evidence Conference: 6.25 contact hours or .625 CEUs Type of Activity: Knowledge, 0286-0000-24-071-L04-P

October 25 Day 2: Real World Evidence Conference: 6.25 contact hours or .625 CEUs Type of Activity: Knowledge, 0286-0000-24-072-L04-P

Continuing Legal Education

For attorneys who would like to receive continuing legal education credits for attending The 2024 A Real-World Evidence Conference, please complete your state's application for credit and submit accordingly. If you require additional information, please contact CE@DIAglobal.org.

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, November 8, 2024.**

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, November 8, 2024**
4. **ACPE credit must be submitted by Friday, November 29, 2024**

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.

DIA staff members have no relevant financial relationships to disclose. To view DIA's Disclosure and Grievance Policies, visit **DIAglobal.org/CE**

TO ACCESS MY TRANSCRIPT:

- Visit **DIAglobal.org**
- **Sign In** with your DIA User ID and Password
- Select the **Welcome Menu** in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Select **My Transcripts** then **Manage My Transcripts**

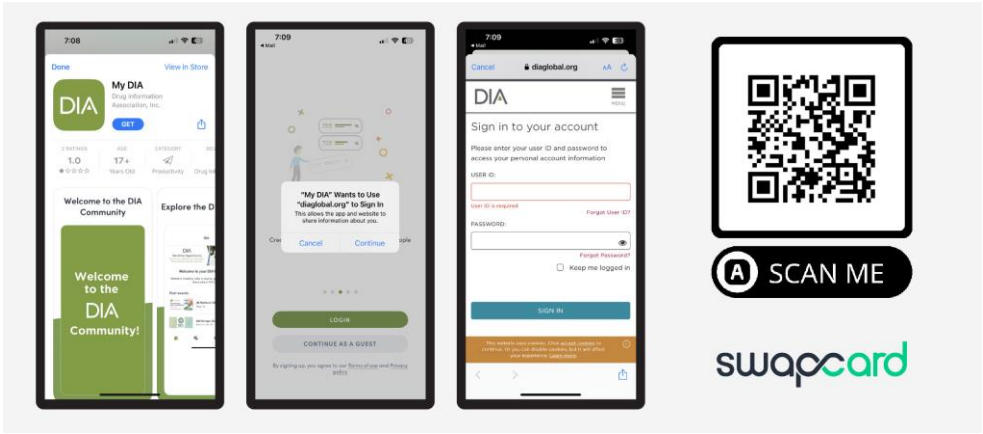
ACCESS PRESENTATIONS:

- Visit **DIAglobal.org**
- **Sign In** with your DIA User ID and Password
- Select the **Welcome Menu** in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Choose **My Presentation**

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!

- Agenda at your fingertips
- Network with Attendees, Speakers, Exhibitors
- Ask questions live during sessions through the session chat function



You will be directed to login to our My DIA Account in order to access the mobile app.

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

EXHIBITOR DIRECTORY

Real-World Evidence Conference

OCTOBER 24-25, 2024

201 NORTH 17TH STREET, PHILADELPHIA, PA 19103

REAL-WORLD EVIDENCE CONFERENCE

October 24-25, 2024
Sheraton Philadelphia Downtown Hotel | Philadelphia, PA

AETION

Website: https://aetion.com/
LinkedIn: https://www.linkedin.com/company/aetion-inc-/

Our mission is to power critical decisions in healthcare with data science-driven technology.

Building on decades of experience in epidemiology and health outcomes research, our founders joined forces with out-of-industry technologists to develop the Aetion Evidence Platform®—an extensible engine to tap into the vast potential of real-world data.

BRIYA

Website: *https://briya.com/*
LinkedIn: *https://www.linkedin.com/company/briyahealth*

Briya's goal is to provide access to high quality medical data quickly, securely, compliantly through an infrastructure that connects data systems and users without friction.

We remove the boundaries holding back research and shorten time to medicine, accelerate innovation 10 fold, and drive better health outcomes, while ensuring our partners remain fully compliant and 100% in control.

CURAVIT

Website: *https://www.curavit.io/*
LinkedIn:
https://www.linkedin.com/company/https://www.linkedin.com/company/curavit/

Curavit is a "Virtual CRO" that designs and executes decentralized clinical trials (DCTs) by combining a virtual site with a full range of CRO services in a digital-first approach to research and a Virtual Site. Curavit's Virtual Site, STRATUS, is where patients, investigators, and our clinical study team meet to conduct research.

STRATUS lives in the cloud and augments or replaces the brick-and-mortar sites used in traditional clinical trials. Each trial is configured on this validated, HIPAA compliant virtual site, where we engage patients, collaborate with sponsors, and work with innovative researchers using remote data capture, telehealth, and real world data. Founded by industry experts with decades of experience in technology and clinical research, Curavit leverages emerging technologies in digital health, cloud computing, machine learning, and data science to recruit and engage diverse patient populations, eliminating the need for physical infrastructure and increasing data quality.

INNOVA SOLUTIONS

Website: *https://www.innovasolutions.com/*
LinkedIn: *https://www.linkedin.com/company/innova-solutions/*

Innova combines domain-specific talent and advanced technology, backed by over 25 years of industry experience, to deliver exceptional RWE services to our clients.

We would love to show you how Innova Solutions' RWE capabilities take a proven and structured approach to mine real-world data, revealing crucial insights across business functions.

Our integrated approach, emphasizing people, processes, and technology, spans the entire value chain—from Research & Development to Post-Commercialization. At Innova, we're more than technologists—we're pioneers at the intersection of technology and healthcare, dedicated to advancing your mission.

MEDICAL DATA VISION CO.,LTD

Website: *https://en.mdv.co.jp/*
LinkedIn: *https://www.linkedin.com/company/medical-data-vision-co-ltd/*

Our company, "Medical Data Vision(MDV)" was named to fulfill the purpose of achieving a vision to create a better medical and healthcare in Japan through utilization of abundant real world data.

In recent years, the expectation towards EBM (Evidence Based Medicine) has been in high demand.
In order to be able to utilize medical and healthcare data effectively, technologies on information and communications was required; however, the medical field in Japan has greatly taken delays from these technologies.

MDV was established in 2003 aiming to effectively utilize the abundant medical and healthcare data by improving the quality of medical and healthcare and creating merits for people's daily lives.

Our ultimate mission is "Creating a society where one individual can track and understand their whole medical and healthcare data (lifetime data)" and "Creating a society where one individual can select the necessary medical and healthcare services based on one's lifetime data".

MDV will continue to operate to fulfill its mission.
We look forward to your continuous support.

OM1

Website: *https://www.om1.com/*
LinkedIn:
https://www.linkedin.com/company/@OM1,%20Inc.

OM1 is pioneering cutting-edge healthcare innovation through its insights-driven technology and data. It specializes in personalized medicine, evidence generation, and real-world evidence (RWE) research powered by next-generation AI platforms, regulatory-grade deep longitudinal data, and globally recognized thought leadership. OM1 is led by a diverse group of scientists, engineers, researchers, and clinicians with over 30 years of experience in RWD/RWE. They have written the handbook on building clinical registries and developing the outcomes measure framework. OM1's unprecedented innovation takes RWE from bench to practice, delivering unparalleled personalized impact on the outcomes of patients and the advancement of research.

OMNY HEALTH

Website: *https://www.omnyhealth.com/*
LinkedIn: *https://www.linkedin.com/company/omnyhealth*

OMNY Health™ is a national data ecosystem connecting the world of healthcare to fuel partnerships that improve clinical outcomes and drive patient care. OMNY's dynamic partnerships with specialty health networks, healthcare systems, academic medical centers, and integrated delivery networks span all fifty states and cover over 75 million patient lives. The company's comprehensive data layer and analytics power health tech companies to drive the next generation of innovation.

ONTADA

Website: *http://www.ontada.com/*
LinkedIn: *https://www.linkedin.com/company/ontada/*

While Ontada is a new business, the assets and the people that make up this organization have a long history of creating value for stakeholders across the field of oncology and driving better patient outcomes for those at the center of the fight against cancer.

Ontada is an oncology data science and technology business dedicated to improving the lives of cancer patients. We specialize in generating insights:

- Real-world data and evidence generation that accelerates life science research
- Clinical and operational technology that supports community providers with precise care
- Provider engagement channels that drive insights and support treatment educational programs

PAREXEL

Website: *https://www.parexel.com/*
LinkedIn: *https://www.linkedin.com/company/parexel*

Parexel is one of the largest CROs, providing full range of Phase I to IV clinical development services to help life-saving treatments reach patients faster. Leveraging the breadth of our clinical, regulatory and therapeutic expertise, our team of global professionals works in partnership with biopharma leaders, emerging innovators & sites to design and deliver clinical trials with patients in mind, increasing access and participation to make clinical research a care option for anyone, anywhere.

PROTOKINETICS GAIT ANALYSIS WALKWAYS

Website: *https://protokinetics.com/*

We are a team of engineers and biomechanists dedicated to simplifying actionable data collection, advancing technology, and building products which help patients regain their independence by analyzing gait and balance to improve mobility. Since our start in April 2012, the ProtoKinetics Zeno™ Walkway Gait Analysis System and PKMAS (ProtoKinetics Movement Analysis Software) have provided meaningful data for clinicians and researchers to better understand gait function during clinical intervention at major hospitals and research at key institutions.
Our core products provide a platform for researchers and clinicians to build custom protocols to evaluate real world gait analysis. Zeno™ Walkway and PKMAS produce optimal footfall identification and biomechanical data across a wide array of nontraditional gait, turning, and standing studies. PKMAS can also be used with alternative walkways, such as the GAITRite™ mat.

TARGET RWE

Website: *https://www.targetrwe.com/*
LinkedIn:
https://www.linkedin.com/company/targetrwe/

Target RWE is redefining and revolutionizing the generation and delivery of real-world evidence. With high-quality and comprehensive fit-for-use datasets captured across a broad range of chronic illnesses, Target RWE is well-positioned to support pharmaceutical, industry, life sciences, and healthcare partners with their RWE initiatives and programs.
We design custom datasets, analyses, and evidence to address the complexities of healthcare evidence questions and quality initiatives. Our regulatory-grade data has been leveraged to support new drug development and label expansion opportunities, address regulatory demands, assess decision-making processes for research and development strategies such as sales, marketing, and pricing, as well as fulfill post-marketing drug safety requirements/commitments in the United States and Europe.

VERANTOS

Website: *https://verantos.com/*
LinkedIn: *https://www.linkedin.com/company/verantos/v*

Verantos enables high-validity real-world evidence generation at scale. High-validity evidence requires high-quality data. With data curation, linkage, and enrichment for every patient record resulting in the highest accuracy, completeness, and traceability in the industry, you can have confidence in our data and evidence.

VERADIGM

Website: *https://veradigm.com/*
LinkedIn:
https://www.linkedin.com/company/veradigm/mycompany/

Veradigm is a healthcare technology company that drives value through its unique combination of platforms, data, expertise, connectivity, and scale. The Veradigm Network features a dynamic community of solutions and partners providing advanced insights, technology, and data-driven solutions for the healthcare provider, payer, and biopharma markets. For more information about how Veradigm is fulfilling its mission of Transforming Health, Insightfully, visit www.veradigm.com, or find Veradigm on LinkedIn, Facebook, Twitter, and YouTube.

CONNECT WITH ALL OUR EXHIBITORS!

SCAN ME

swapcard

SCAN THE QR CODE TO ACCESS THE APP AND STAY CONNECTED WITH OUR EXHIBITORS. EXPLORE SESSIONS, SPEAKERS, AND MORE—ALL IN ONE PLACE!