DIA

Real-World Evidence Conference

Short Course: October 22 | Conference: October 25-26 | Virtual

PROGRAM CHAIR

Brian Bradbury, PhD, MA
Vice President, Center for Observational Research
Amgen, Inc.

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Head of Global Real-World Evidence and Digital Science
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Executive Director, Real-World Evidence
Evidera, France

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

Sulabha Ramchandran, PhD, MS
Vice President, and Head, US and Regions, Value Evidence and Outcomes
GlaxoSmithKline

Overview

In a market that is constantly adapting and adjusting to the needs of the healthcare field, real-world evidence (RWE) is increasingly becoming important for regulatory and reimbursement decision-making. RWE, in relation to the real-world data that is collected in combination with the advancement of artificial intelligence-based analytics platforms, 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. Historically used for post-market safety monitoring, RWE is now becoming integrated throughout the product development lifecycle. DIA's *Real-World Evidence Conference* will explore new and innovative applications of RWE and deliver cutting-edge insights through successful use cases, case examples, and practical applications on how stakeholders are leveraging RWE to advance healthcare knowledge and decision-making.

Highlights

Short Course on October 22: The Evolving Landscape of Real-World Data (RWD) and the Use of Pharmacoepidemiologic Methods and Machine Learning to Generate Credible Real-World Evidence (RWE)

Who Should Attend

Professionals involved in:

- Real-World Evidence
- Real-World Data
- Epidemiology
- Policy
- Regulatory Science
- Technology development
- Data analytics
- Clinical Research

SHORT COURSE | FRIDAY OCTOBER 22

10:00AM-1:30PM	**Short Course:** The Evolving Landscape of Real-World Data (RWD) and the Use of Pharmacoepidemiologic Methods and Machine Learning to Generate Credible Real-World Evidence (RWE) **This course requires an additional registration fee.*

DAY ONE | MONDAY OCTOBER 25

10:00-11:25AM	**Opening Remarks and Session 1:** Year in Review
11:25AM-12:00PM	BREAK/Visit the Virtual Exhibit Hall
11:30AM-12:00PM	Exhibitor Event/Non-CE: Sponsored Coffee Corner
12:00-1:15PM	**Session 2:** What's New in RWE Generation? A Global Regulatory Update
1:15-2:00PM	BREAK/Visit the Virtual Exhibit Hall
1:15-2:00PM	Exhibitor Event/Non-CE: Innovation Theater
2:00-3:15PM	**Session 3:** How Does the Growing Use of RWE to Support Regulatory Decision-Making Impact Generation of Post-Marketing RWE?
3:15-3:45PM	BREAK/Visit the Virtual Exhibit Hall
3:45-5:00PM	**Session 4:** Cross Industry Consortia Addressing RWE: Impact and Future Directions
5:00-5:45PM	Exhibitor Event/Non-CE: Happy Hour

DAY TWO | TUESDAY OCTOBER 26

10:00-11:15AM	**Session 5:** RWE Studies to Support Effectiveness in Regulatory Decision-making
11:15-11:45AM	BREAK/Visit the Virtual Exhibit Hall
11:15-11:45AM	Exhibitor Event/Non-CE: Coffee Corner
11:45AM-1:00PM	**Session 6:** RWE in Payer and HTA Decision Making and Considerations for R&D Organizations
1:00-2:00PM	BREAK/Visit the Virtual Exhibit Hall
1:00-1:30PM	Exhibitor Event/Non-CE: Case Study Spotlight
2:00-3:15PM	**Session 7:** Leveraging COVID-19 Learnings to Transform Clinical Trials using RWE
3:15-3:45PM	BREAK/Visit the Virtual Exhibit Hall
3:45-5:15PM	**Session 8:** The Future of RWE – Emerging Trends and Opportunities to Benefit Patients and Closing Remarks
5:15PM	Conference Adjourns

Learning Objectives

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

- Explain how RWE is being used today to inform biopharmaceutical development across the product lifecycle
- Discuss "lessons learned" from current uses of RWE by regulators, and how they can be applied for other future applications of RWE
- Recognize general considerations and key features of successful RWE studies acceptable to the regulators for effective decision-making
- Identify guidance and best practices for generating fit-for-purpose RWE for payers and HTA bodies
- Define the expanding applications of RWE to support clinical trials and evidence generation
- Evaluate the future applications of RWE in drug development
- Appraise how mobile technologies, artificial intelligence, machine learning, and other technologies are being used to generate RWE
- Evaluate how patient reported outcomes, electronic health records, and other patient data is expanding the resources for RWE

Continuing Education

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY MONDAY, DECEMBER 6, 2021

Drug Information Association (DIA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This conference is designated for up to 13.5 contact hours or 1.35 continuing education units (CEU's).

*ACPE credit is available if you attend the live virtual Real-World Evidence Conference October 25-26, 2021. Credit will not be awarded for watching the sessions On Demand post-conference.

CE Allocation:

October 22 Short Course 1: The Evolving Landscape of Real-World Data (RWD) and the Use of Pharmacoepidemiologic Methods and Machine Learning to Generate Credible Real-World Evidence (RWE) – 3.25 contact hours or .325 CEUs Type of Activity: Knowledge, 0286-0000-21-086-L04-P
October 25 Day 1: Real-World Evidence Conference – Day 1: 5 contact hours or .5 CEUs Type of Activity: Knowledge, 0286-0000-21-073-L04-P

October 26 Day 2: Real-World Evidence Conference – Day 2: 5.25 contact hours or .525 CEUs Type of Activity: Knowledge, 0286-0000-21-074-L04-P

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, December 6, 2021**, 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 .3 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.

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the live virtual conference, you must virtually attend (in their entirety) the short course and/or one or both days of the conference, complete and return a CE Verification of Attendance Form (see instructions below), complete the post program evaluation 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, November 9, 2021**.

If you are claiming ACPE credit for this event you must:

- Attend one or both days of the live virtual conference
- Complete a Verification of Attendance Form
- Send back to **CE@DIAglobal.org** by November 2, 2021
- Access your DIA account and select My Transcript to claim your ACPE credit, available on Tuesday, November 9, 2021

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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.

DIA staff members have no relevant financial relationships to disclose.

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

SHORT COURSE | FRIDAY OCTOBER 22

10:00AM-1:30PM

Short Course: The Evolving Landscape of Real-World Data (RWD) and the Use of Pharmacoepidemiologic Methods and Machine Learning to Generate Credible Real-World Evidence (RWE) **This course requires an additional registration fee*

Real-world data availability (RWD) and utilization continue to evolve, bringing challenges and opportunities for evidence generation and assessment. This session includes primers on types of RWD, causal inference methods for estimating treatment effects, and the opportunities for incorporating machine learning methods. Speakers will discuss the future of RWD and effective communication of real-world evidence to stakeholders.

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

- Describe the evolution of the RWD landscape
- Define types of RWD and RWE use cases and appraise their importance
- Recognize potential future RWD challenges and opportunities, including privacy, linkage and completeness
- Explain the counterfactual and exchangeability principles as foundations of causal inference
- Recognize key sources of confounding and time-related biases and their impact on treatment effect estimates
- Describe best practices in retrospective cohort study design and data analysis
- Introduce the concept of artificial intelligence/machine learning (AI/ML) methods and how they relate to pharmacoepidemiology, drug development and RWE
- Explain the main differences in terminology and expertise required in AI/ML studies compared to established epidemiology and biostatistics
- Provide examples of where AI/ML methods can benefit RWD use and research

The Evolving Landscape of Real-World Data
Gillis Carrigan, MSc, PhD, Director, Center for Observational Research, Amgen

Applying Pharmacoepidemiologic Methods to Estimate Treatment Effects
Carrie Nielson, MPH, PhD, Observational Research Senior Manager, Amgen

Machine Learning Using Real-World Data: from Hype to Reality
Dorothee Bartels, MSc, PhD, Head of Global Real-World Evidence and Digital Science, UCB, Germany

Harriett Dickinson, MPhil, PhD, RWE Innovation and Women's Health Lead, UCB Biociences GmbH, United Kingdom

10:00-11:25AM

Opening Remarks and Session 1: Year in Review

Session Chair
Simon Dagenais, PhD, MSc, Senior Director, Real-World Evidence, Pfizer, Inc.

This session is intended to provide an overview of recent events related to RWE in the past year, including regulatory decisions, guidance, and projects, as well as publications, guidelines, and industry activities. The session will choose a few key examples for discussion, provide a brief description of each event, place the event in a historical context to highlight what is new, and attempt op highlight key themes that may emerge in the future related to these events. This session may provide some background for other sessions that will delve into these events and themes in more depth.

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

- Describe recent events related to RWE in the past year
- Discuss why these recent events are important to RWE
- Identify new events in context of existing information on the topic

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

Recent Examples of RWE Submissions
Nirosha Lederer, PhD, MS, Director, Real-World Evidence Strategy, Aetion

Update on RWE Reporting Quality
Shirley Wang, PhD, MSc, FISPE, Assistant Professor of Medicine, Harvard Medical School; Associate Epidemiologist, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital

Update on RCT DUPLICATE Project
Jessica Franklin, PhD, Principal Consultant, Epidemiology and Real-World Evidence, Optum

Financial Trends in the RWE Industry
Dan Gebremedhin, MD, MBA, Partner, Flare Capital Partners

11:25AM-12:00PM

BREAK/Visit the Virtual Exhibit Hall

11:30AM-12:00PM

Exhibitor Event/Non-CE: Sponsored Coffee Corner
See Page 10 for more information and instructions on how to RSVP!

12:00-1:15PM

Session 2: What's New in RWE Generation? A Global Regulatory Update

Session Co-Chairs
Marni Hall, PhD, MPH, Vice President, Clinical Evidence, IQVIA

Delphine Saragoussi, MD, Executive Director, Real-World Evidence, Evidera, France

This session will bring together regulatory leaders from the United States, Europe, and Japan to discuss the evolving regulatory landscape for RWE, and related emerging topics. Speakers will address forward -looking priorities, opportunities, and trends, by region, including their current thinking, latest trends, regulations, and guidance. Lessons learned from expanded use of RWE during the COVID-19 pandemic will also be discussed.

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

- Identify lessons learned from the use of RWE by regulators to inform the pandemic response
- Describe at least three trends in the use of RWE for regulatory decision making
- Compare RWE regulatory frameworks in three major geographies

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

Xavier Kurz, MD, MSc, PhD, Head of Data Analytics Workstream, European Medicines Agency, The Netherlands

Yoshiaki Uyama, PhD, RPh, Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

1:15-2:00PM **BREAK/Visit the Virtual Exhibit Hall**

1:15-2:00PM **Exhibitor Event/Non-CE:** Innovation Theatre Session
See Page 10 for more information and instructions on how to RSVP!

2:00-3:15PM **Session 3:** How Does the Growing Use of RWE to Support Regulatory Decision-Making Impact Generation of Post-Marketing RWE?

Session Co-Chairs
Marni Hall, PhD, MPH, Vice President, Clinical Evidence, IQVIA

Delphine Saragoussi, MD, Executive Director, Real-World Evidence, Evidera, France

The focus of RWE generation in the regulatory space has recently expanded from the post-marketing phase to the pre-marketing phase with increasing focus on generating RWE to support regulatory decision-making. This has been driven first by the need to optimize data generation in rare diseases and precision medicine, has been boosted by the COVID-19 pandemic and an unprecedented wave of emergency use authorizations; it is also used as a way to ensure more diversity in clinical research.

By putting RWE under the spotlight and by creating a continuum of RWE between the pre- and post-marketing space, this recent development is expected to impact the way post-marketing RWE is generated, e.g. in terms of scope, methods and data quality.

Experts from the pharmaceutical industry will share their experience and perspective on these changes globally and how they impact the way they generate post-marketing RWE on a daily basis and will have the opportunity to exchange with a regulator. In particular, they will focus on the early planning of post-marketing RWE, the choice of data sources, and data quality requirements. They will also share practical learnings on engaging with regulators on RWE.**At the conclusion of this session, participants should be able to:**

- Discuss the most current trends for the use of real-world evidence and data
- Describe some scenarios where post-marketing RWE generation is influenced by current trends in the pre-marketing space
- Identify opportunities and challenges of RWE generation in the regulatory context

Richard Forshee, PhD, Associate Director for Analytics and Benefit-Risk Assessment, CBER, FDA

Alison Cave, PhD, Chief Safety Officer, MHRA, United Kingdom

Patrice Verpillat, DrMed, PhD, MPH, MD, Head of Global Epidemiology and ISPE RWE Task Force, Merck Healthcare KGaA, Germany

Rohini Hernandez, PhD, MPH, Director of Observational Research, Amgen, Inc.

3:15-3:45PM **BREAK / Visit the Virtual Exhibit Hall**

3:45-5:00PM **Session 4:** Cross Industry Consortia Addressing RWE: Impact and Future Directions

Session Co-Chairs
David Martin, MD, MPH, Vice President, Pharmacovigilance, Moderna

Sulabha Ramchandran, PhD, Vice President, US and Regions, Value Evidence and Outcomes, GlaxoSmithKline

This session will bring together leaders from cross-industry consortia to discuss key strategic objectives for RWE. Speakers will address existing RWE initiative priorities, deliverables to date, key learnings, and the manner in which they are shaping future priorities. Participants will be exposed to resources for best practices, assess opportunities to engage, consider applications within biopharmaceutical development.

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

- Gain awareness of the strategic goals and foci of cross-industry RWE initiatives
- Identify key learnings and deliverables generated to date
- Apply key resources for best practices and assess opportunities to engage

PhRMA and Bio RWE Initiatives
Rebecca Lipsitz, PhD, Senior Director, Late R&I, AstraZeneca

Transcelerate RWE Workstreams
Cathy Critchlow, PhD, MSc, Vice President, R&D Data Strategy, Amgen

Learnings from OPERAND
William Crown, PhD, MA, Distinguished Research Scientist, The Heller School for Social Policy and Management, Brandeis University

Overview of Duke Margolis RWE Initiatives
Morgan Romine, MPA, Chief of Staff, Duke University

FOCR Oncology RWE Validation and Endpoints
Jeff Allen, PhD, President and Chief Executive Officer, Friends of Cancer Research

5:00-5:45PM **Exhibitor Event/Non-CE: Sponsored Happy Hour**
See Page 11 for more information and instructions on how to RSVP!

DAY TWO | TUESDAY OCTOBER 26

10:00-11:15AM **Session 5:** RWE Studies to Support Effectiveness in Regulatory Decision-making

Session Chair
Jingyu (Julia) Luan, PhD, Global Regulatory Affairs Director, BioPharmaceuticals R&D, CVRM, AstraZeneca

The industry has been utilizing RWE studies to support pre- and post-market safety evaluation for many years. Regulators around the world have accepted RWE studies for safety decision-making and published various guidelines to guide the industry through this process. There are many successful experiences and examples that we can learn from. However, using RWE studies to support effectiveness decision-making is still an area under development. Even though all stake holders have been actively exploring this topic for some years, methodological, operational, technical, and regulatory challenges are still to be conquered. In this session, speakers and panelists from regulatory agencies, industry, and academia will discuss the general considerations in RWE studies to support effectiveness in regulatory decision-making. Both successful and unsuccessful cases studies will be shared.

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

- Evaluate the general considerations in RWE studies to support effectiveness in regulatory decision-making
- Recognize the key features of successful RWE studies acceptable to the regulators for effectiveness decision-making
- Identify the common issues that prevent RWE studies from supporting effectiveness

Considerations in RWE Studies to Support Effectiveness in Regulatory Decision-making
Charles Lee, MS, MBA, Executive Regulatory Science Director, AstraZeneca

Successful and Unsuccessful Real-life Examples in RWE Studies to Support Effectiveness in Regulatory Decision-making
LaRee Tracy, PhD, MA, Director, Statistics Lead, Medical and RWD Analytics, Otsuka Pharmaceuticals Development and Commercialization

Panel Discussion
Norman Stockbridge, MD, PhD, Director, Division of Cardiology and Nephrology, OND, CDER, FDA

Shein-Chung Chow, PhD, Professor, Department of Biostatistics and Bioinformatics, School of Medicine, Duke University

Yoshiaki Uyama, PhD, RPh, Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

11:15-11:45AM — **BREAK / Visit the Virtual Exhibit Hall**

11:15-11:45AM — **Exhibitor Event/Non-CE: Sponsored Coffee Corner**
See Page 11 for more information and instructions on how to RSVP!

11:45AM-1:00PM — **Session 6:** RWE in Payer and HTA Decision Making and Considerations for R&D Organizations

Session Chair
James Hartnett, PharmD, MS, Executive Director, Health Economics & Outcomes Research, Regeneron Pharmaceuticals, Inc.

RWE is playing an increasing role in informing decisions across stakeholders with significant attention focused on regulator acceptance. Payers and HTA bodies can also leverage RWE to address gaps in evidence around subpopulations, longer-term outcomes and comparative effectiveness. Further, there is an increasing intersection of evidence requirements between regulators and payers. This session will focus on case studies, best practices and how to prepare R&D organizations for addressing future regulatory and reimbursement evidence requirements.

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

- Assess the expanding role of RWE for informing decisions by payers and HTA bodies
- Identify guidance and best practices for generating fit-for-purpose RWE for payers and HTA bodies
- Evaluate implications of growing intersection of regulatory and payer/HTA requirements for biopharmaceutical R&D organizations

Speakers
Oriol Solà-Morales, Chief Executive Officer, HITT, Spain

Jon Campbell, PhD, Senior Vice President for Health Economics, Institute for Clinical and Economic Review (ICER)

Páll Jónsson, PhD, MS, Programme Director-Data,, National Institute for Health and Care Excellence (NICE), United Kingdom

Daniel Ollendorf, PhD, MPH, Director, Value Measurement & Global Health Initiatives, Center for the Evaluation of Value and Risk in Health

1:00-2:00PM — **BREAK / Visit the Virtual Exhibit Hall**

1:00-1:30PM — **Exhibitor Event/Non-CE:** Case Study Spotlight
See Page 12 for more information and instructions on how to RSVP!

2:00-3:15PM — **Session 7:** Leveraging COVID-19 Learnings to Transform Clinical Trials using RWE

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

The COVID-19 pandemic presented unique issues managing clinical trials and exacerbated routinely encountered challenges with patient enrollment, patient access, and complex trial designs. This led to the necessity to modify clinical trials and increased uptake of real-world evidence (RWE) to address these challenges. This session will highlight applications of RWE to optimize clinical trial processes, outline regulatory actions to support these uses, and characterize opportunities to translate learnings from the COVID-19 pandemic into sustainable methods for future clinical trials.

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

- Define the expanding applications of RWE to support clinical trials and evidence generation
- Discuss efforts to support high quality research using RWD/E
- Translate lessons from COVID-19 into actionable opportunities for future clinical trials

Shifting Use and Rapid Uptake of RWE Before and During the Pandemic
Jeff Elton, PhD, MBA, Chief Executive Officer, ConcertAI

Seeing Opportunity through Challenge: Pragmatic Approaches to Evidence Generation
Donna Rivera, PharmD, MSc, Associate Director of Pharmacoepidemiology, RWD and RWE, FDA Oncology Center of Excellence

Using Real World Data and Technology to Transform Clinical Trials
Matthew Roe, MD, Chief Medical Officer, Verana Health

3:15-3:45PM — **BREAK** / Visit the Virtual Exhibit Hall

3:45-5:15PM — **Session 8:** The Future of RWE – Emerging Trends and Opportunities to Benefit Patients and Closing Remarks

Session Co-Chairs
Dorthee Bartels, MSc, PhD, Head of Global Real-World Evidence and Digital Science, UCB, Germany

Paul Coplan, DrSc, MBA, MSc, FISPE, Vice President, Medical Device Epidemiology & Real-World Data Analytics, Johnson & Johnson

This session will explore emerging trends for the future of Real-World Evidence (RWE) and the complementary value of advanced analytics. The speakers will focus on the growing role of RWE for decision making, using the approach of emulating Randomized Controlled Trials (RCTs). We will address how new sources of data can be combined with more traditional research databases to provide much richer and more informative data for conducting studies, such as Patient Generated Health Data (PGHD), omics, and imaging. The session will also address challenges in combining advanced analytics with more established designs and methods. Advances in using AI-based image analysis of tumors that will facilitate the inclusion of AI-analyzed tumor images into classical RWE databases with be reviewed. Finally, the topic of how the UK researchers have been able to include genomic data into EHR databases for the purposes of RWE studies will be discussed.

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

- Identify the complementary value of RWE to clinical trials
- Envision new RWD sources for RWE generation and understand their challenges and opportunities
- Evaluate some of the opportunities and risks when including ML/AI in their RWE research

Speakers
Sebastian Schneeweiss, DrSr, MD, Professor, Medicine and Epidemiology; Chief of the Division of Pharmacoepidemiology, Harvard Medical School and Brigham and Women's Hospital

William Marks, MD, MS, Head of Clinical Science & Head of Neurology, Verily

Pallavi Tiwari, PhD, Assistant Professor of Biomedical Engineering, School of Medicine, Case Western Reserve University

5:15PM — **Conference Adjourns**

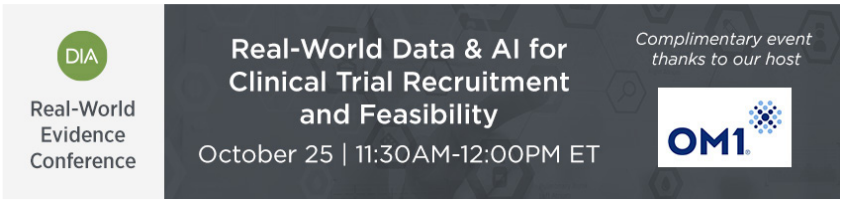
Real World Evidence Exhibitor Sponsored Events

Separate RSVP is required for each event. These sponsored sessions are open to all, including those not registered for the full conference. These sponsored sessions are separate to the conference content included in registration. Upon completion of your RSVP a login link will be sent to you for the 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.

MONDAY, OCTOBER 25

11:30AM-12:00PM

Exhibitor Event/Non-CE: Coffee Corner hosted by OM1



Real-World Data & AI for Clinical Trial Recruitment and Feasibility

Real-world data (RWD) and Artificial Intelligence (AI) technology and models are increasingly being used for accelerating and optimizing clinical development. Join Dr. Richard Gliklich as he explores how RWD and AI can be used for patient finding, clinical trial recruitment, feasibility and more. Come ready to share your experiences and ask questions on areas such as RWD methods, sourcing, quality, AI validity, and real-world case examples.

Featured Topics

- RWE & AI for patient identification, clinical trial recruitment, and feasibility
- Case examples and interactive discussion

Richard Gliklich, MD, CEO, OM1

Separate RSVP is required. **Click here to RSVP.**

MONDAY, OCTOBER 25

1:15-2:00PM

Exhibitor Event/Non-CE: Innovation Theatre hosted by Intersystems

Harnessing EHR Data for Clinical Development and Market Access

EHR data is disparate, complicated, and nearly impossible for researchers to access outside of a hospital's four walls. Yet it has the potential to improve both research and market access. But how can we utilize it if we can't get to it? In this session InterSystems demystifies EHR data and presents several use cases leveraging our technology and data sharing framework to blend together real-world data sources and paint the complete picture of the patient.

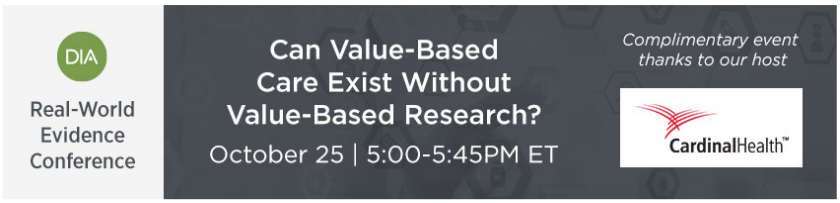
Matthew Stannard, Life Sciences Advisor, Intersystems
Kathleen Aller, Director of Market Strategy, Healthcare, Intersystems
Alex MacLeod, Director of HealthShare Commercial Initiatives, Intersystems
Qi Li, Physician Executive, Intersystems

Separate RSVP is required. **Click here to RSVP!**

MONDAY, OCTOBER 25

5:00-5:45PM

Exhibitor Event/Non-CE: Happy Hour hosted by Cardinal Health



Can Value-Based Care Exist Without Value-Based Research?

The concept of value-based care continues to play a significant role in healthcare policy discussions. But can value-based care every be fully realized without value-based research? All too often clinical trial outcomes are statistically significant but clinically meaningless. Even when clinical trials are clinically relevant, the populations studied are not representative or the control arms at time of study design no longer represent the standard of care. Experts from Cardinal Health weigh in on the critical importance of research in driving improved quality and outcomes for patients.

Featured Topics:

- What defines value?
- Are traditional RCTs valuable?
- Statistically significant but clinically meaningless
- Value-based research – How do we get there
- Solution = pragmatic and adaptive trials, RWE components, reliable accrual-PRN, CIRN

Bruce Feinberg, Vice President of Clinical Affairs and Chief Medical Officer, Cardinal Health Specialty Solutions

Scott Swain, Director of Real-World Evidence and Regulatory Sciences, Cardinal Health Specialty Solutions

Separate RSVP is required. **Click here to RSVP!**

TUESDAY, OCTOBER 26

11:15-11:45AM

Exhibitor Event/Non-CE: Coffee Corner hosted by Lumiio Inc.

Applying Disruptive Social Science Technology for Robust Data Outcomes

Research programs regularly fail or miss their metrics due to disorganized, siloed or fragmented patient communities; competing priorities across stakeholders; and waning enthusiasm and sustainability. When stakeholder incentives and priorities are aligned and fully understood, programs can be designed that motivate participation and drive successful outcomes. In this Coffee Chat, Lumiio's Victoria Hodgkinson will speak about Lumiio's experience in launching global data programs that use an innovative approach to using fully integrated data, ultimately putting social science before data science.

Victoria has extensive and varied experience in data analysis and publishing findings utilizing real-world data. She is a recognized global expert in patient registries following her work on large-scale international projects such as the Global SMA Registry and the Global Acromegaly Registry.

Featured Topics:

- Should social science lead the data science?
- Using disruptive technology to drive patient outcomes
- Building community engagement and sustainability
- Designing successful digital health programs

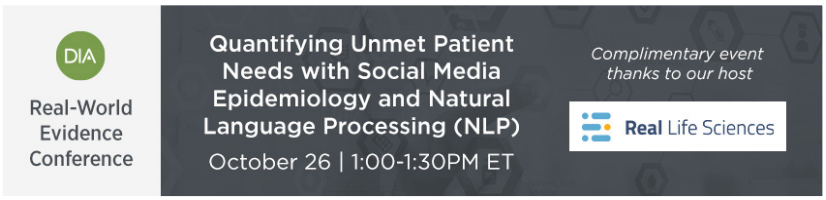
Victoria Hodgkinson, PhD, BA, Director, Real-World Evidence, Lumiio

Separate RSVP is required. **Click here to RSVP!**

TUESDAY, OCTOBER 26

1:00-1:30PM

Exhibitor Event/Non-CE: Case Study Spotlight hosted by Real Life Sciences



Quantifying Unmet Patient Needs with Social Media Epidemiology and Natural Language Processing (NLP)

By leveraging deep NLP frameworks and Social Media Data we can generate novel insights along the patient journey. With the SPEC-F impairment framework, we apply structure to unstructured social media narratives and remove noise to generate novel insights from previously uncaptured real-world data. In this webinar, we discuss how multiple functions within Pharma use the same platform, approaches, and insights to power their respective functional activities. We will examine a case study on amplifying the patient voice in a variety of diseases and functional areas across the drug lifecycle.

Featured Topics:

- Industry Challenges with RWD
- Defining "Social Media Epidemiology"
- How effective NLP supports amplification of the patient voice
- Explaining the SPEC-F Framework
- Case Study: Novel Insights From Social Media Epidemiology - Alzheimer's Disease

Stephen Doogan, Outcomes Research Strategy, Real Life Sciences

Dr. Nardin Farid, Strategy Lead, Real World Patient Analytics, Real Life Sciences

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