



Real World Evidence Conference

Short Course November 13 | Conference November 14-15
Hyatt Regency Cambridge



PROGRAM COMMITTEE

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GlaxoSmithKline

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Mark Stewart, PhD

Vice President, Science Policy
Friends of Cancer Research

Robert Suruki

RWE Strategy Lead, Immunology
UCB Pharma, Inc.

Overview

Real world evidence (RWE) is increasingly becoming important for regulatory decision-making and beginning to touch all areas of the healthcare value chain. Historically used for post-market safety monitoring, sponsors are now beginning to use RWE to support clinical trial design and observational studies in order to generate better treatment approaches, while healthcare systems are collecting and using RWE to substantiate coverage decisions. DIA's *Real World Evidence Conference* will explore new and innovative applications of RWE and deliver cutting-edge insights in how stakeholders are leveraging RWE to advance healthcare knowledge and decision-making.

Highlights

- Short Course on November 13: Introduction to Real World Data for Data Geeks
- “Speed Networking” luncheon where you can engage with fellow attendees in short increments to make the maximum amount of contacts
- DIA 2020 Exclusive: RWE is Changing Regulatory Decision-Making: Where do We go from Here?
- A jam-packed agenda with seven sessions covering all aspects of RWE, where it's been and, most importantly, where it's going

Who Should Attend

Professionals involved in:

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



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#RWE19 | DIAGlobal.org

As of November 7, 2019

Schedule At-A-Glance

SHORT COURSE | NOVEMBER 13

ROOM

12:30-5:00PM Short Course Registration Cambridge Foyer (2nd Floor)

1:00-5:00PM **Short Course:** Introduction to Real World Data for Data Geeks Cambridge (2nd Floor)

DAY ONE | NOVEMBER 14

ROOM

7:30AM-4:30PM Registration Ballroom Foyer (Lobby Level)

7:30-8:30AM Networking Breakfast and Exhibits Ballroom D

8:30-8:45AM **Welcome and Opening Remarks** Ballroom ABC

8:45-10:15AM **Session 1:** Regulatory Frameworks for Real World Evidence Ballroom ABC

10:15-10:45AM Refreshment, Networking, and Exhibits Break Ballroom D

10:45AM-12:00PM **Session 2:** Sizing Up Data Bases and Their Sufficient Fit for Purpose Ballroom ABC

12:00-1:15PM Networking Luncheon and Exhibits Ballroom D

1:15-2:30PM **Session 3:** Patient Relevant Outcomes from Drug Development to Clinical Practice Ballroom ABC

2:30-3:00PM Refreshment, Networking, and Exhibits Break Ballroom D

3:00-4:15PM **Session 4:** Incorporating Mobile Technologies into Real World Evidence Studies Ballroom ABC

4:15-6:30PM **Networking Reception and DIA 2020 Exclusive:** RWE is Changing Regulatory Decision-Making: Where do We go from Here? Ballroom D

DAY TWO | NOVEMBER 15

ROOM

7:00AM-12:30PM Registration Ballroom Foyer (Lobby Level)

7:00-8:00AM Networking Breakfast and Exhibits Ballroom D

8:00-8:05AM Opening Remarks Ballroom ABC

8:05-9:25AM **Session 5:** Use of Real World Evidence to Support Regulatory Decision-Making for Medical Devices Ballroom ABC

9:25-10:40AM **Session 6:** New Platforms for Clinical Research Purposes Ballroom ABC

10:40-11:00AM Refreshment, Networking, and Exhibits Break Ballroom D

11:00AM-12:15PM **Session 7:** What's Next: Real World Evidence in the Development and Access of Novel Therapeutics Ballroom ABC

12:15-12:30PM Closing Remarks Ballroom ABC

12:30PM Conference Adjourns

Learning Objectives

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

- Discuss how RWE is being used today to inform biopharmaceutical development across product lifecycle
- Describe the recent FDA strategic framework for RWD in regulatory decisions
- Evaluate the future applications of RWE in drug development
- Appraise how mobile technologies, AI, machine learning, and other technologies are being used to generate RWE
- Evaluate how patient reported outcomes, EHR, and other patient data is expanding the resources for RWE
- Discuss “lessons learned” from current uses of RWE, and how these can be applied for other future applications of RWE

Continuing Education



DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 12.75 contact hours or 1.275 continuing education units (CEU's). Type of Activity: Knowledge



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DECEMBER 30, 2019**

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DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer 1.3 CEUs for this conference. Participants must complete the entire conference in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit for the day(s) that you attended the conference, you must sign in each day at the DIA registration desk upon arrival and complete the online credit request process through My Transcript. 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 **Wednesday, November 27, 2019**.

Continuing Education Credit Allocation

Short Course: Introduction to Real World Data for Data Geeks: 3.5 Contact Hours .35 CEUs, UAN: 0286-0000-19-084-L04-P

Day One: 5.25 Contact Hours .525 CEUs, UAN: 0286-0000-19-076-L04-P

Day Two: 4 Contact Hours 4 CEUs, UAN: 0286-0000-19-077-L04-P

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SHORT COURSE | NOVEMBER 13

12:30-5:00PM **Short Course Registration**

1:00-5:00PM **Short Course:** Introduction to Real World Data for Data Geeks

Simon Dagenais, PhD, MSc, Director, Global Center of Excellence, Real World Evidence, Vertex Pharmaceuticals

Cort Hayflinger, MS, President, Hayflinger Analytic Services, LLC

This short course will provide an overview of analyzing common sources of real world data (RWD) from the United States (US) for those who are interested in real world evidence (RWE). The intended audience for this short course includes data science professionals from biopharmaceuticals, consulting companies, academia, government, or policy groups, who may be involved with RWE, health economics and outcomes research, pharmacoepidemiology, clinical development, medical affairs, and related functions. This course will discuss the regulatory framework for RWE in the US, common sources of RWD that are available to biopharmaceutical companies through licensing agreements (eg, deidentified medical claims), common use cases for RWD within biopharmaceutical companies, case studies involving analyses of RWD, as well as challenges and opportunities for data science to facilitate the analysis of RWD.

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

- Understand regulatory framework for RWE and RWD in the US
- Identify common types of RWD available through licensing agreements in the US
- Describe common use cases for RWD in biopharmaceutical companies in the US
- Synthesize case studies involving analyses of RWD
- Evaluate challenges and opportunities for data science to facilitate the analysis of RWD

DAY ONE | NOVEMBER 14

7:30AM-4:30PM **Registration**

7:30-8:30AM **Networking Breakfast and Exhibits**

8:30-8:45AM **Welcome and Opening Remarks**

Sudip Parikh, PhD, Senior Vice President and Managing Director, DIA Americas

8:45-10:15AM **Session 1:** Regulatory Frameworks for Real World Evidence

Session Chair

Jacqueline Corrigan-Curay, JD, MD, Director, Office of Medical Policy, CDER, FDA

This session will be an update on FDA's RWE program including review of top priorities, program initiatives, and demonstration programs and updates from EMA on their RWE initiatives.

Optimizing the Use of Real World Evidence to Inform Regulatory Decision-Making

Andrew Raven, MSc, Manager for Biostatistics and Epidemiology Unit, HPFB, Health Canada

Use of Real World Evidence for Regulatory Decision Making: Perspectives from the European Medicines Agency

Xavier Kurz, MD, MSc, PhD, Head of Surveillance and Epidemiology Service, European Medicines Agency, European Union, United Kingdom (Participating remotely)

10:15-10:45AM **Refreshment, Networking, and Exhibits Break**

10:45AM-12:00PM Session 2: Sizing Up Data Bases and Their Sufficient Fit for Purpose**Session Co-Chairs**

Nancy Dreyer, PhD, MPH, FISPE, DIA Fellow, Chief Scientific Officer, IQVIA

Brian Bradbury, PhD, MA, Executive Director and Head, Data and Analytics, Center for Observational Research, Amgen, Inc.

The spectrum of data sources for RWE runs the spectrum from pure reliance on existing data to prospective non-interventional studies, randomized trials, and various combinations of linked data. Evaluating quality for a given purpose starts with understanding how the data is collected, where it comes from, and how must-have exposures and outcomes are recorded. Real-world examples showing how diverse types of real-world data outcomes are being validated and used will be presented.

Michael Fried, MD, Scientific Advisor, TARGET PharmaSolutions

Making Fit-for-Purpose EHR Data Scalable Via a Digital Research Network

Todd Johnson, MD, MBA, Senior Vice President, Clinical Research and Head, Digital Research Network, Optum

Primary Data Collection Through the FDA MyStudies Mobile App

David Martin, MD, MPH, Associate Director for Real World Evidence Analytics, OMP, CDER, FDA

12:00-1:15PM Networking Luncheon and Exhibits**Speed Networking, Hosted by the DIA Diversity in Life Sciences Community****Session Chair**

Sheila Mahoney-Jewels, MBA, Independent Workforce Advocate, LifeSciHub

Meet interesting peers during this highly interactive lunch “speed networking” session. Attendees will pair up for five-minute meet and greets, then switch seats to start all over again. This session is hosted by the DIA Diversity in Life Sciences Community, which is dedicated to fostering industry-level dialog in both corporate diversity, as well as diversity in clinical trials. Reminder to all attendees: Bring business cards! Please visit the Registration Desk to sign up!

1:15-2:30PM Session 3: Patient Relevant Outcomes from Drug Development to Clinical Practice**Session Co-Chairs**

Bart Barefoot, Director, Real World Evidence Policy and Advocacy, GlaxoSmithKline

Robert Suruki, RWE Strategy Lead, Immunology, UCB Pharma, Inc.

Most outcomes (endpoints) used in clinical trials are not designed for sustainable use in clinical practice and do not reflect treatment impact in a larger population over the long term. Focusing on outcomes that matter most to patients and can be measured in both trials and clinical practice, would support better decision making for individual patients and population-level health. During this session, we will discuss current initiatives that are driving a new approach to more aligned outcome measurement and broader stakeholder input in measure development. We also will highlight use cases of objective outcome measures – including patient-reported outcomes (PROs) and clinician-reported outcomes (ClinROs) – that can be used continuously in trials and clinical practice.

Eileen Mack Thorley, Senior Research Scientist, Patientslikeme

The Outcomes Landscape

Donna Messner, PhD, President and CEO, Center for Medical Technology Policy

Patient Perspective

Jean Rommes, PhD, MS, Patient Representative

2:30-3:00PM Refreshment, Networking, and Exhibits Break

3:00-4:15PM

Session 4: Incorporating Mobile Technologies into Real World Evidence Studies

Session Co-Chairs

Jacqueline Corrigan-Curay, JD, MD, Director, Office of Medical Policy, CDER, FDA

Marni Hall, PhD, MPH, Vice President, Clinical Evidence, IQVIA

This session will explore the use of mobile technologies in generating RWE by examining the types of data that can be captured, e.g. patient reported data versus sensor data and trials designs used. Design features of the FDA MyStudies mobile app design and platform will be presented. Opportunities for integrating data from mobile technologies with other RWD sources, such as sensors, will be examined. Regulatory considerations for incorporating mobile technologies into clinical trials and how mobile technologies can facilitate decentralized trial designs and adherence will be discussed.

Incorporating Mobile Technologies into Real World Evidence Studies

David Martin, MD, MPH, Associate Director for Real World Evidence Analytics, OMP, CDER, FDA

Chris Ceppi, Chief Product Officer, Science 37

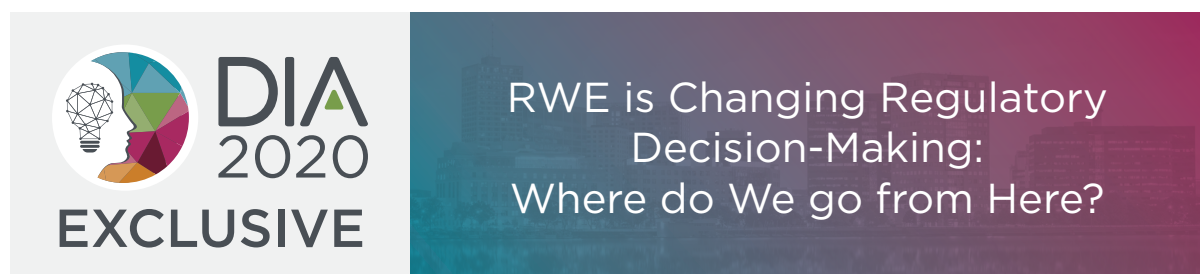
Creating a Path for Decentralized Clinical Trials

Pamela Tenaerts, MD, MBA, Executive Director, Clinical Trials Transformation Initiative (CTTI)

Practical Experience

Norman Stockbridge, PhD, MD, Director, Division of Cardiovascular and Renal Products, OND, CDER, FDA

4:15-6:30PM



Enjoy a complimentary evening of food, drinks, and networking with a multidisciplinary group of colleagues who share your passion to drive innovation from the lab to patients. Also, get an exclusive preview of the exciting content offerings via a fireside chat.

Todd Phillips, PharmD, RAC, Director, Global Regulatory Affairs, Cardinal Health

Alex Mutebi, PhD, MSc, Director, Real World Evidence, Vertex Pharmaceuticals

Jacqueline Corrigan-Curay, JD, MD, Director, Office of Medical Policy, CDER, FDA

This evening is complimentary for all attendees thanks to our sponsor: Cardinal Health

**This complimentary event requires a separate registration. If you have not yet signed up online, please visit the DIA Registration Desk to reserve your seat.*

DAY TWO | NOVEMBER 15

7:00AM-12:30PM **Registration**

7:00-8:00AM **Networking Breakfast and Exhibits**

8:00-8:05AM **Opening Remarks**

8:05-9:25AM

Session 5: Use of Real World Evidence to Support Regulatory Decision-Making for Medical Devices

Session Chair

Paul Coplan, ScD, MBA, FISPE, Vice President, Medical Device Epidemiology, Johnson & Johnson

This session will provide an update on the use of RWE for regulatory decisions for medical devices. Current plans and activities within the FDA's Center for Devices and Radiological Health (CDRH) involving RWE will be presented by a CDRH speaker, including the parallel review program by CDRH for regulatory approval and Centers for Medicaid and Medicare Services (CMS) for coverage decisions. The session will assess methodological challenges with using RWE for regulatory decisions and work that the National Evaluation System for Health Technology (NEST) is doing to improve the methodology. The session will also address innovative developments of RWE within medical device companies and explore whether these can be used for regulatory decisions.

A Multistakeholder Community Approach for Leveraging RWE

Daniel Caños, PhD, MPH, Deputy Director, CDRH, FDA

Methodological Framework for Medical Device Studies Based on RWE

Sharon-Lise Normand, PhD, Professor, Biostatistics and Health Policy, Harvard Y.T. Chen School of Public Health

Use of Healthcare Databases for Medical Device Assessment

Paul Coplan, ScD, MBA, FISPE, Vice President, Medical Device Epidemiology, Johnson & Johnson

9:25-10:40AM

Session 6: New Platforms for Clinical Research Purposes

Session Chair

Debra Schaumberg, ScD, OD, MPH, Vice President, Scientific Affairs Real World Evidence, Evidera

Data from traditional RCT are often insufficient at the time of product approval for considerations concerning patient access, real-world effectiveness, and safety of drugs and devices. The rapid and continuous development of information infrastructures and capabilities has resulted in an explosion in the amount and quality of RWD and linkages that have expanded the possibilities for how RWD can be built into RWE to inform decisions. This session will introduce the rapid emergence of RWD platforms to enable RWE generation from both retrospective and prospective study designs. Speakers will cover how to leverage such resources to build fit-for-purpose evidence to inform decisions by regulators, payers, providers, and patients.

Embrace the RWE Era in China: Trends, Challenges, and Solutions

Tengbin Xiong, Head of RWE Solutions and HEOR, Happy Life Technology

New Platforms for Clinical Research Purposes

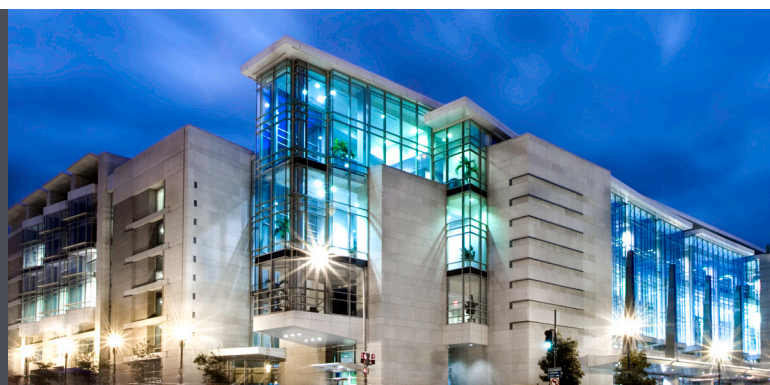
Michelle Longmire, MD, Co-Founder and Chief Executive Officer, Medable

Introduction to the MIT NEWDIGS "LEAPS Project"

Gigi Hirsch, MD, Executive Director, Massachusetts Institute of Technology (MIT) Center for Biomedical Innovation

10:40-11:00AM

Refreshment, Networking, and Exhibits Break



11:00AM-12:15PM

Session 7: What's Next: Real World Evidence in the Development and Access of Novel Therapeutics

Session Co-Chairs

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

James Hartnett, PharmD, MS, Senior Director, Lead, Real World Data and Analytics, Patient and Health Impact

This session will discuss the increasing convergence of industry, payer, and regulator interests in the use of RWD for the generation of evidence on the effectiveness of therapeutic interventions. Opportunities for use of emerging RWD sources and artificial intelligence earlier in the pipeline to identify novel targets, biomarkers, and shape/improve efficiency of clinical trials will be shared. Considerations for application of RWE for supporting confirmation of efficacy in the post-marketing setting and labelling will be discussed leveraging extensive learnings from pharmacovigilance, outcomes research, and early regulatory case studies. The growing importance of RWE for payers in informing reimbursement decisions and realizing future value-based contracting models will be reviewed. Panel members will discuss expected trends for RWD/E for the next three years across industry, payer, and regulators.

Jeremy Rassen, ScD, President and Chief Scientific Officer, Aetion

rwEndpoints Use Case: Assessing Frontline Treatment Regimens in Real-World Patients with Advanced Non-Small Cell Lung Cancer

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

RWE in a US Product Label: Paliperidone Palmitate (Invega Sustenna)

Srihari Gopal, MD, Senior Director, Janssen Research and Development, LLC

Accelerating the Development of Relevant Evidence in Healthcare

Mark Cziraky, PharmD, Vice President, Research, Anthem HealthCore

12:15-12:30PM

Closing Remarks

Session Chair

Nancy Dreyer, PhD, MPH, FISPE, DIA Fellow, Chief Scientific Officer, IQVIA

12:30PM

Conference Adjourns

SAVE THE DATE!

Join Us in San Diego for
the 2020 *Real World
Evidence Conference!*



**November 9-10
San Diego, CA**





Real World Evidence Conference

Exhibitor Directory



Backpack Health, LLC

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Cardinal Health Specialty Solutions

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