Real World Evidence. Real Results.

A virtual learning series: How real world evidence can help you advance to your next milestone.

Across the product lifecycle, real world evidence (RWE) is increasingly impacting healthcare, generating evidence that is augmenting clinical trial programs, driving business strategies, influencing how stakeholders are making decisions, and demonstrating improved patient outcomes.

Get the information you need to better understand how RWE can be leveraged in your business, from pre-clinical and early clinical development, to preparing to partner and commercialize your compound.

IQVIA experts will break down the components of RWE into introductory mini-modules, including a session specific to biotech. Learn about:

- **Building your target product profile with real world data** as the basis for early-stage valuation and long term success
- **Using RWE to understand the patient's journey** when designing your clinical program
- **Demonstrating safety and value for different healthcare stakeholders** to optimize market access and launch success

Ask the experts

IQVIA experts will take your questions at the end of each session. If they are unable to address every question live, they will follow up with an answer individually to ensure you have the information you need.

7 WEBINAR SESSIONS

APRIL 23 – MAY 14, 2020

1. **The Principles of Real World Evidence**
   Thursday, April 23rd
   11:00AM EDT • 4:00 PM BST
2. **Secondary Data First**
   Tuesday, April 28th
   11:00AM EDT • 4:00 PM BST
3. **Innovative Approaches to Generate Real World Evidence**
   Thursday, April 30th
   11:00AM EDT • 4:00 PM BST
4. **Real World Evidence to Support Biotech Companies from Milestone to Milestone** BIOTECH
   Tuesday, May 5th
   11:00AM EDT • 4:00 PM BST
5. **Real World Evidence Strategy for Specific Therapy Areas**
   Thursday, May 7th
   11:00AM EDT • 4:00 PM BST
6. **Real World Evidence to Meet Regulator and Payer Requirements with Confidence**
   Tuesday, May 12th
   11:00AM EDT • 4:00 PM BST
7. **Solutions for Evidence Optimization and Dissemination**
   Thursday, May 14th
   11:00AM EDT • 4:00 PM BST

Full details on pages 2–5

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Topic details

The duration of each webinar is one hour.

1 Thursday, April 23rd
11:00AM EDT • 4:00PM BST

The Principles of Real World Evidence

- **Fundamentals in real world methodology**
  Speaker: Tanja Wagner, Vice President, Head of Evidence Strategy Leads, EMEA

  Learn the key terms and definitions, and the research questions that can be addressed with RWE. Understand how RWE is different from randomized control trials (RCTs). Explore different RWE study types and their applications.

- **Regulatory bodies and the use of real world evidence for decision making**
  Speaker: Matthew W. Reynolds, Vice President, Real World Evidence

  Discover the role of RWE in the regulatory process as acceptance grows. Learn the regulatory definitions and expectations for real world data (RWD) and RWE in a global context. Understand the risks of including RWD in regulatory submissions and how to optimize success through early regulatory engagement approaches. See real case study examples.

- **Speeding up access to medicines for patients with unmet medical need: Integrating evidence and regulatory pathways**
  Speaker: Stella Blackburn, Vice President, Global Head of Early Access & Risk Management, Real World Solutions

  Access to medicines involves different stakeholders making different decisions. Learn about who those stakeholders are and the decisions they make. Understand how conditional authorization in the EU creates opportunities for patients to access medicines which meet an unmet medical need.

- **Industry use of real world evidence, and real world organization and governance structures**
  Speaker: Elizabeth Powers, Vice President and Category Lead, Safety Evidence for Regulators

  Review trends in the real world market and discover what is driving higher adoption of innovative study designs. Learn about organizational approaches for creating and growing a real world department.

2 Tuesday, April 28th
11:00AM EDT • 4:00PM BST

Secondary Data First

- **IQVIA real world data and OHDSI network**
  Speakers: Michèle Arnoe, Head Global Real World Data Assets, and Christian Reich, Vice President, Real World Solutions

  Discover how to extract the value of the IQVIA RWD portfolio which includes databases, data collaborations, and real world networks across the globe. Learn more about the OHDSI network as one example of how to conduct large scale observational research studies.

- **Secondary database studies and their use across the product lifecycle**
  Speaker: Paola Nasuti, Product Strategy Lead, Database Studies

  Get an overview of big healthcare data and how database studies can provide fast and cost effective insights into real life clinical practice. Learn from previously conducted database studies and explore different applications of these data to address potential research and business needs.

- **Privacy in patient data: How to anonymise while preserving value**
  Speaker: Sarah Lyons, General Manager, Privacy Analytics

  Understand the importance of patient privacy when conducting real world research. Get an overview of privacy requirements and how to anonymize data so that it can be safely sourced and linked to gain meaningful insights. Discover how to enable data for secondary use, safeguarding patient privacy while preserving data value and utility.

- **Insights from unstructured data streams (A COVID-19 example)**
  Speaker: Jane Reed, Director Life Sciences, Linguamatics

  How can disease-related evidence be quickly searched and synthesized for insights? By applying natural language processing (NLP), unstructured data streams can be leveraged for evidence-lead decision making. Through a COVID-19 example, discover how to unlock insights with consistent themes from multiple secondary data sources.

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3 Thursday, April 30th
11:00AM EDT • 4:00PM BST

Innovative Approaches to Generate Real World Evidence

- **Introduction to innovative approaches to generate real world evidence**
  Speaker: Andrea Spannheimer, Senior Vice President, Global Head of Real World Solutions, Offerings & Innovation and Partnerships

  A review of innovative approaches to generate RWE, including how and when to choose different study designs. Examples include external comparators, extension studies, pragmatic design, and enriched methodologies, in addition to direct-to-patient and other digital approaches.
- **External comparators**
  Speaker: Joss Warren, Director, External Comparators & Extension Studies

  External comparators, commonly referred to as "synthetic controls" and "external controls", are a prominent use case for the application of RWD in regulatory decision making. Learn how external comparators are currently being used for regulatory and reimbursement decisions and explore important criteria for designing and constructing successful external comparators.
- **Innovative extension studies**
  Speaker: Barbara Arone, Vice President, Medical Affairs, Real World Evidence

  Extension studies, commonly referred to as "rollover studies" and "long-term follow-up studies", provide investigational products to patients who have previously participated in a clinical trial or to collect long-term patient outcomes. While extension studies are commonly used in development programs, they are often designed to look like highly controlled clinical trials. Explore the application of innovative design strategies to simplify extension study programs and reduce the cost of development.
- **Pragmatic studies**
  Speaker: Jenny Christian, Vice President, Clinical Evidence & Epidemiology

  Pragmatic studies randomize patients in routine care to evaluate clinical effectiveness and safety of treatments and devices, and to inform key decision-makers (patients, clinicians, regulators, and payers). Explore when this design option is best applied and how to execute a pragmatic study.
- **Enriched studies**
  Speaker: Jim Coutcher, Senior Director, Global Head of Enriched Studies

  Discover how you can drive value and reduce study burden with innovative, real world enriched study methods. Learn how enriched studies integrate both primary and secondary data collection to build more comprehensive patient records for research. Case studies will be used to explore considerations for when enriched studies are most appropriate for research.

4 Tuesday, May 5th
11:00AM EDT • 4:00PM BST

BIOTECH

Real World Evidence to Support Biotech Companies from Milestone to Milestone

- **Real world data to help build your target product profile (TPP) as the basis for early-stage valuation and long-term success**
  Speaker: Marc Hennebert, Vice President, Consulting Services

  Learn how RWD can support your needs in pre and early clinical development, including how to better understand patient population, market size, unmet needs, treatment dynamics, biomarkers and genomics opportunities, cost of care, and competitive dynamics. Discover how RWD can help select the right indication and define the optimal target product profile for your compound.
- **Real world evidence to understand the patient's journey and help design your clinical program**
  Speaker: Barbara Arone, Vice President, Medical Affairs, Real World Evidence

  Natural history of disease (NHD) studies provide the foundation for optimized interventional trials, particularly in rare disease. A deep understanding of the patient journey, diagnosis, and treatment patterns will help to inform protocol design of phase 2/3 trials. An NHD study can also help identify key sites and KOLs and seamlessly transition to interventional trials. Learn how an NHD cohort can serve as an external comparator arm for a single-arm phase 2 trial.
- **Real world evidence in clinical development to enhance regulatory submission**
  Speaker: Nathalie Horowicz-Mehler, Senior Principal, Head of Real World Evidence Strategy

  Speed, cost, risk, and value are key drivers for any biotech company during clinical development. Discover opportunities to create efficiencies, reduce site and patient burden, and strengthen the submission package of drugs by leveraging RWE. Learn how external comparators, pragmatic trials, and innovative extension studies can help create robust submissions.
- **Safety and value demonstration to optimize market access and launch success**
  Speakers: Elizabeth Powers, Vice President and Category Lead, Safety Evidence for Regulators, and Jacco Keja, Vice President, Consulting Services, Global Category Leader HEOR and HTA

  RWE plays a crucial role in fulfilling regulatory post-authorization safety and efficacy requirements. It is also central to an integrated market access plan on a global and local level. Learn how to better anticipate and manage multiple stakeholder needs, global strategy, and country-specific implementation in a cost-effective manner.

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5 Thursday, May 7th
11:00AM EDT • 4:00PM BST

Real World Evidence Strategy for Specific Therapy Areas

- **Real world data and evidence strategy**
  Speaker: James Anderson, Senior Principal, Integrated Real World Evidence & Solutions

  RWE plans are frequently dispersed across multiple functional areas within the same organization. Discover how these plans can be brought together into a single view that can drive efficient and innovative evidence generation.

- **Real world data for rare diseases**
  Speaker: Ed Drage, Senior Principal, Integrated Real World Evidence & Solutions

  There are opportunities and challenges for leveraging RWD in rare disease. Explore approaches to sourcing and accessing RWD in different rare diseases where existing natural history is sparse. Learn the key differences between approaches for RWE generation in rare vs chronic conditions.

- **Accelerating oncology evidence generation in Europe. Examples in Multiple Myeloma and Non-Hodgkin's Lymphoma**
  Speaker: Finlay MacDougall, Senior Principal, Integrated Real World Evidence & Solutions

  Research in oncology and hematology often requires clinically rich data which can be challenging to access or to generate in Europe. Discover how the formation of dedicated research networks and the use of bespoke analytical tools can expedite access to deep data and rapid insight while driving meaningful partnerships with stakeholders across the healthcare ecosystem.

- **Evidence platforms**
  Speaker: James Anderson, Senior Principal, Integrated Real World Evidence & Solutions

  Increasingly, many organizations are moving from multiple one-off secondary data studies towards standing, multipurpose evidence infrastructures. Learn about the foundation of evidence platforms and why companies are investing in this new type of RWE generation infrastructure. Based on current examples, discover additional use cases these platforms can fulfil in the future.

6 Tuesday, May 12th
11:00AM EDT • 4:00PM BST

Real World Evidence to Meet Regulator and Payer Requirements with Confidence

- **Risk management and PASS**
  Speaker: Stella Blackburn, Vice President, Global Head of Early Access and Risk Management, RWS

  As part of risk management, research can answer questions about safety concerns detailed in a pharmacovigilance plan. Get an overview of definitions and types of post-authorization safety studies contained in the pharmacovigilance plan and the categorization of these studies.

- **Innovation in real world safety: Driving greater value for effort**
  Speaker: Elizabeth Powers, Vice President and Category Lead, Safety Evidence for Regulators

  More and more, drugs are coming to market with less data due to a variety of accelerated approval pathways. In addition to traditional PASS, studies are getting longer and more complex, e.g., pregnancy registries, long-term follow ups, pediatric PASS, vaccine surveillance. However, new data sources and advanced analytics are driving efficiencies. Learn how to anticipate occurrence of adverse events, generating enhanced value for patients, physicians, and sponsors.

- **Market access and the use of real world evidence**
  Speaker: Lisa Taylor, Vice President, European Head of Consulting

  There is continuing pressure on manufacturers to generate RWE to prove product value pre and post launch. RWE has increasingly been part of HTA submissions, especially as extension or observational studies leveraged for internal reimbursement, risk sharing, indication expansion, and re-evaluations. But while payers want to see more evidence, they are not aligned on how to use it to assess value or make decisions. Discover why a direct translation between RWE submissions and outcome of payer decisions is not always clear, how RWE acceptance could change in the future, and how RWE can help ensure optimal access for conditions throughout the lifecycle.

- **Benefits of a holistic approach to HTA at global scale**
  Speaker: Jacco Keja, Vice President, Consulting Services, Global Category Leader HEOR and HTA

  Explore the benefits of centralized governance and harmonized approaches towards early evidence generation from an HTA perspective. Better understand the impact on business needs, such as optimizing spend and resource allocations while providing timely, impactful insights to support local HTAs.

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Real World Evidence. Real Results. A virtual learning series

7 Thursday, May 14th
11:00AM EDT • 4:00PM BST

Solutions for Evidence Optimization and Dissemination

- **The power of genomic data**
  Speaker: Adam Collier, Vice President, Genomic Research Solutions, EMEA

  An introduction to genomics and why this data is increasingly being used to support drug development activities. Case studies will be presented to review how organizations are already benefiting from the use of genomic insights and how they could be applied to other organizations.

- **How to incorporate the patient voice**
  Speaker: Jean Paty, Vice President, Patient Centered Endpoints

  There is a growing focus on more completely understanding the patient experience during and after treatment. From symptom management and side effects, to the impact on family and caregivers, organizations are capturing the real world experience of patients vs. only their in-clinic experience. As new methods, measures, and technologies are being developed, there are both challenges and opportunities to collect, analyze, and interpret RWD. Learn more about these challenges, today's industry advancements, and future opportunities.

- **Machine learning to identify sub-populations of augmented effect**
  Speaker: Kal Chaudhuri, Principal, Sub-Population Optimization Solutions (SOS), R&D Strategy Practice

  Some patients respond to treatment, some don't, and others experience adverse events. This trial and error phase can lead to patients suffering, payers losing money, and a negative reputation for pharma. Identifying sub-populations of augmented effect can reduce potential side effects and ensure effective treatments get to patients in need. Discover how sub-population identification can help in precision medicine, lifecycle management of drug labels, and market access.

- **Evidence dissemination to impact healthcare decisions**
  Speaker: Lynda Parker, Vice President, Medical Sales and Services

  Discover how to improve patient access to medicines through better evidence dissemination. This includes getting scientific evidence effectively disseminated to the right clinicians using the appropriate communication channels. Through effective KOL engagement, learn how to help physicians focus on patient engagement to overcome barriers to uptake. Get insights about medical and patient communications (publications, steering committees, data usage tools, education), medical strategy (KOL engagement) and patient engagement strategies (including patient support services).

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