DIA LEARNING

Understanding Pharmacoepidemiology and Real-World Evidence Studies

14-16 April 2026 | 09:00-13:00 CEST

Overview

Evidence generated from observational studies using real-world data (RWD), outside of clinical trials, known as real-world evidence (RWE), is increasingly being used to inform decision-making regarding the use of medicines.

The use of RWE has gone beyond its usual domains of pharmacovigilance, pharmacoeconomic and outcomes research. RW studies are now conducted during the whole lifecycle of medicines, to enhance drug discovery and development, as well as their contribution to studying post-authorisation safety and effectiveness. The potential for the use of RWE throughout the entire lifecycle of medicines will continue to grow.

Everyone working in biomedical sciences needs to understand the principles, methods and applications of observational RW studies.

Learning Objectives

- Identify the basic principles of real-world studies
- Observational study designs and methods
- Their strengths and weaknesses
- Applications and examples of real-world studies

Key Topics

- The basic principles of studying Real World Data (RWD)
- Strengths of RWD (representing patients in the real world, including large numbers of patients)
- Weaknesses (chance, bias, confounding, missing data, misclassification)
- The differences (and complementarity) between clinical trials and observational studies
- Describe observational study designs (cross sectional, cohort, case-control studies)
- Describe the role of registries in biomedical research
- Examples of observational studies during the whole lifecycle of medicines
- The expansion of RWE and RWD

Who Will Attend

This virtual live training course is designed for professionals with prior experience in biomedical research and clinical trials. Participants mostly to benefit from this course include, but are not limited to, pharmacovigilance executives, study managers, and pharmaceutical physicians seeking to deepen their knowledge and enhance their practical skills.

Faculty

Saad Shakir
Pharmacovigilance Physician and Pharmacoepidemiologist
ADROITVIGILANCE, United Kingdom

Ben Bray
Health data science, Epidemiology, Real world evidence
GenAI, United Kingdom

Xabier Garcia de Albeniz Martinez
Senior Director, Epidemiology
RTI Health Solutions, Spain

Jesper Hallas
Professor, Clinical Pharmacology, Pharmacy and Environmental Medicine
University of Southern Denmark, Denmark

Deborah Layton
Director of Drug Safety
IQVIA, United Kingdom

Andrea Margulis
Senior Director, Epidemiology
RTI Health Solutions, Spain

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DAY 1

09:00 WELCOME AND INTRODUCTION

09:10 SESSION 1

THE VALUE OF REAL-WORLD DATA

Saad Shakir

This session will provide a high-level overview of real-world evidence (RWE) which is the foundation for the following lectures. The critical components of typical RWE studies and their strengths and limitations will be introduced. An overview of randomised controlled trials (RCTs) will be provided, including their different objectives. The differences in internal and external validity between RCTs and RWS will be explained. It will describe the complementary positioning of RWD to RCTs for evidence generation. It will provide a brief overview of how RWD is used in understanding the safety and effectiveness of medicines and vaccines, post-authorisation safety and effectiveness studies (PASS and PAES). The increase in use and importance of RWE across the product lifecycle will be described.

09:40 SESSION 2

BASIC PRINCIPLES OF OBSERVATIONAL REAL-WORLD STUDIES

Saad Shakir and Deborah Layton

This session will build on Session 1 and dive deeper into how the concept of risk can be quantified (basic measures of disease frequency, association and impact) together with assessing uncertainty. The common challenges of RWE studies that affect interpretation will be introduced such as bias, confounding, missing information, and misclassification.

10:30 BREAK

10:50 SESSION 3

BASIC PRINCIPLES OF OBSERVATIONAL REAL-WORLD STUDY METHODS

Deborah Layton

Building further on the first two sessions, the main types of descriptive and comparative study designs will be introduced in the context of safety studies, alongside an overview of general methods on how to handle common challenges. Methods described will be cross sectional, case-control and cohort studies.

11:30 SESSION 4

SELF-CONTROLLED STUDIES

Jesper Hallas

This session will describe the self-controlled designs which are used for investigating associations between treatments and outcomes while automatically controlling for time-invariant confounding, even if unmeasured or unknown.

12:00 BREAK

12:10 INTERACTIVE SESSION

13:00 END OF DAY 1

DAY 2

09:00 INTRODUCTION TO DAY 2

09:05 SESSION 5

SOURCES OF REAL-WORLD DATA

Deborah Layton

This session will describe how RWD are obtained, what are commonly used types of RWD sources and will introduce the concept of "fitness for use" and approaches to ensure data used are reliable, relevant and robust. It will describe the role of registries in generating RWE.

09:40 SESSION 6

FRAMING AND DESIGNING A COMPARATIVE RWE STUDY

Xabier Garcia de Albeniz

This session will introduce causal inference methods, including the Target Trial Emulation approach which provides a framework for causal inference in the non-randomised setting and can be used to design comparative RWE studies.

10:30 BREAK

10:50 SESSION 7

TOOLKIT FOR RWE GENERATION

Xabier Garcia de Albeniz

This session will present the following resources for RWE generation: "SPIFD2" framework (to evaluate RWD fitness for use), "PRINCIPLED" guideline (for the design of studies using RWD), "HARPER" protocol template for RWD studies, "ROBINS-I", a quality-assessment tool to evaluate the risk of bias and the "TARGET" reporting guidelines for target trial emulations.

11:30 INTERACTIVE SESSION

13:00 END OF DAY 2

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DAY 3

09:00 INTRODUCTION TO DAY 3

09:05 SESSION 8

APPLICATIONS OF RWS: RISK MANAGEMENT AND EFFECTIVENESS OF RISK MINIMISATION

Saad Shakir and Xabier Garcia de Albeniz

This session will present regulatory applications to leverage RWD in risk management addressing requests from the European Medicines Agency in different therapeutic areas.

09:50 SESSION 9

APPLICATIONS OF RWS: SAFETY IN PREGNANCY

Andrea Margulis

Pregnant women are usually barely represented in clinical trials. Therefore, RWE has a prominent role in the safety evaluation of drugs taken during pregnancy. This session will review specific challenges of RWE generation in this population and introduce solutions.

10:30 BREAK

10:50 SESSION 10

THE ROLE OF RWE IN OUTCOMES RESEARCH AND HEALTH TECHNOLOGY ASSESSMENT

Ben Bray

How RWE is used in regulatory, payer and clinical decision-making contexts, particularly in outcomes research and comparative effectiveness research studies will be described. The concept of sequential decision making will be explored in relation to how RWE can inform decisions that are made across the lifecycle of a medical product - from development and regulatory approval to payer coverage and clinical implementation. Finally, the increasing use of RWE in supporting expedited authorisations will be described with real world examples presented where RWE has contributed to faster access.

11:30 SESSION 11

RISK BENEFIT BALANCE

Saad Shakir

In this session the concept of risk-benefit (RB) balance will be defined including its role in the whole lifecycle of medicinal products. The principles of causality and causal inference in evaluating adverse events and therapeutic outcomes will be explained through application of the Bradford Hill criteria to assess causal relationships between medicinal products and observed effects. An overview will be provided of the methods for both conventional risk-benefit evaluation and formal semi-quantitative methods for RB evaluation. The evolution of RB evaluation across the lifecycle of products will be described.

12:10 BREAK

12:20 QUESTIONS AND ANSWERS

12:50 CLOSING SESSION

13:00 END OF THE TRAINING COURSE

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Understanding PE and RWE Studies | Virtual Live Training Course # 26592
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Registration fee includes full admission to virtual course, electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

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INDUSTRY/ REPRESENTATIVE	€ 1'215.00 ❑	€ 1'350.00 ❑	€ 1'610.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 675.00 ❑	€ 935.00 ❑
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The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

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