ACQUIRE BUSINESS-CRITICAL MARKET ACCESS COMPETENCIES

LEARN from Pharma's international top experts

Radek Wasiak & Thomas Wilke

Generating RWE for Optimising Market/Patient Access

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CELforPharma
NEVER STOP LEARNING

Generating RWE for Optimising Market/Patient Access

Learn

- The fundamental concepts and principles for utilising Real World Evidence (RWE) towards optimising Market Access.
- The value RWE adds over Randomized Controlled Trials (RCTs) over a product's entire lifecycle.
- The terminology used within the world of RWE, such as the exact difference between Real World Evidence and Real World Data (RWD).
- Why RWE is important to regulators, payers, physicians and pharma and how to tailor the evidence to their specific needs.
- The common sources of data available for RWE and how to assess the robustness of the data.
- The critical success factors when developing a RWE study.
- New developments in RWE.

The Experts

Radek Wasiak & Thomas Wilke

- Thought & business leaders at Cytel, a leading provider of design and implementation services in the field of clinical trials and real-world evidence studies.
- As Head of Real World and Advanced Analytics business unit, Dr. Radek Wasiak oversees a team of 180+ staff who design, execute, and disseminate RWE and HEOR projects.
- Prof. Dr. Thomas Wilke has 20+ years of experience in leading and conducting German and international RWE studies. He is Cytel's Principal Investigator, academic researcher, and author of numerous health economics articles.

Dates & Locations

13 June 2023 *(live online)*
29 November 2023 *(live online)*
28 September 2023 *(live online)*

Visit **www.celforpharma.com** for registration fees and updates.

Additional Benefits

- Radek Wasiak and Thomas Wilke are available for Q&A during breaks and after the course so you can discuss challenges you are facing and get advice from experienced RWE experts.
- Real-life case studies will be used to illustrate the theory and in small groups you will put the key learnings into practice on a real-world case study.

Why You Should Attend This Course

RWE is a critical area of expertise in pharmaceutical companies, engaging various functions such as HEOR, Medical Affairs, R&D and Commercial. There are many challenges in the process of successfully implementing RWE. Executives participating in this open-enrolment course will contribute much more effectively in the cross-functional organisation that RWE requires. This course covers the basics required to understand what RWE is, why it is important, who needs/uses it and how you can utilise it effectively to help your role. The content contains the recent developments on RWE, as well as real life case studies on how RWE can be used and potential challenges that can arise.

Agenda

All courses are held in CET/Brussels Time. Please check the Dates & Locations section on our website for the exact start and end times, or send an email to kealeigh.steel@celforpharma.com.

From RCT to RWD and RWE – A Continuum of Evidence (~1 h)

- RWE defined
- RWD – The reason why we see the explosion of RWE
- The complementary role of RCTs and RWE in drug development

The Role of RWE and Stakeholder Perspectives Throughout the Drug Development Lifecycle (~1 h)

- RWE and the regulatory bodies – The role of RWE during the regulatory process and post launch
- RWE and payers – Pre- and post-launch applications - Global vs. local and how to organise
- Why should HCPs care about RWE?
- 'It's actually my data' – The role of the patient

Typology of RWD Sources: Strengths & Weaknesses (~45 min)

- Existing data sources:
  - Electronic medical records
  - Claims data
  - Healthcare wearables & social media
- Bespoke data sources
  - Patient registries
  - Pragmatic studies
  - Observational studies
  - Surveys
- Geographic differences in access and content across data sources

Lunch Break

Critical Success Factors of a RWE Study (~1 h)

- Define the right questions by considering (and engaging!) stakeholders, their needs and alternative approaches
- Identify the most robust and accessible data source – How to assess the data sources
- Determine a robust data generation methodology
- Use best-practice guidelines on study design
- Ensure you use a pre-specified robust statistical analysis plan
- Effectively communicate RWE to the various stakeholder types

Interactive Group Exercise: How to Build an Effective RWE Generation Plan (~1 h 30 min)

- *Considering a recently launched drug, evaluate how RWE was or could have been used to support the regulatory and reimbursement process.*
- *Group output will be discussed in plenary and experts will close with their expert opinion.*

The Next Frontiers: 'Live RWE' (~30 min)

- Predicting outcomes: The promise of machine learning
- Causal inference: Do drugs really work in real-world treatment populations?

Wrap-Up & Closing (~15 min)

Registration Form

Complete the below form and email to aswaan@celforpharma.com or fax to +32 2 721 13 82 or go to www.celforpharma.com and complete the online registration form.

Questions?

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aswaan@celforpharma.com

Course(s)

Course Title .....

Course Date(s) .....

Registration Fee

Visit our website www.celforpharma.com for information about the early bird fee and full fee, group discounts, etc.

Participant Details

Title .....

First Name .....

Last Name .....

Job Title .....

Email .....

Mobile Number .....

Country of Work .....

Company Details

Company Name .....

VAT Number .....

Invoicing Address:

Street Address .....

City/Province .....

Postcode .....

Country .....

Payment

Payment Method ☐ Bank Transfer (+3%) ☐ Credit Card

PO Number (optional) .....

Confirm Registration

In order to complete the registration, please tick the following box(es):

☐ I, the participant(s), have read and accept CELforPharma's Transfer & Cancellation Policy (www.celforpharma.com/transfer-cancellation-policy) and Privacy Policy (www.celforpharma.com/we-value-your-privacy)

☐ I accept that CELforPharma regularly sends me information by email on topics discussed within their website (www.celforpharma.com) and relevant to my function, under the condition that I can unsubscribe at any time. I accept that relevant personal details are stored in a database for that purpose, as per CELforPharma's Privacy Policy (www.celforpharma.com/we-value-your-privacy), of which I accept the terms.