ACQUIRE BUSINESS-CRITICAL MARKET ACCESS COMPETENCIES

LEARN from Pharma's international top experts

Paul Craddy & Graham Foxon

Generating RWE for Optimising Market Access

The Fundamentals

LEARN from interacting with your industry peers

Up to date with latest developments in different areas as in regulatory, marketing, pricing and reimbursement, digital areas."

Johnson & Johnson
Veronica Zilli
Senior Manager Government Affairs & Policy
Belgium

CELforPharma
NEVER STOP LEARNING

Generating RWE for Optimising Market Access

The Fundamentals

Learn

- The fundamental concepts and principles for utilising Real World Evidence (RWE) towards optimising Market Access.
- The value RWE adds over 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.
- How to effectively incorporate RWE into product launch decisions.

The Experts

Paul Craddy
& Graham Foxon

- Founders of Remap Consulting, a specialist pharmaceutical pricing and market access consultancy.
- Dr. Paul Craddy's expertise in RWE has been gained from many years working in global and European pricing and market access positions in Takeda/Nycomed and IMS/Cambridge Pharma.
- Dr. Graham Foxon's expertise is in developing global launch pricing strategies and producing HTA submissions to address payers' requirements using RWE. His experience includes both consultancy at IMS and Adelphi Values, as well as positions in GSK, Ferring and a start-up biotech.

Dates & Locations

13 October 2020 (live online)

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

Additional Benefits

- To reinforce peer learning, the experts will use a small pre-course questionnaire (by email) and polling during the day to actively engage the whole audience throughout the course.
- Real-life case studies will be used to illustrate the theory and/or to facilitate interactive exercises.

What Participants Say About This Course

Up to date with latest developments in different areas as in regulatory, marketing, pricing and reimbursement, digital areas."

Johnson & Johnson
Veronica Zilli
Senior Manager Government Affairs & Policy
Belgium (November 2019)

Good mix between theory and practical examples."

UCB
France Ferrière
Medical & Science Partner
Belgium (November 2019)

It's been an excellent course, with good insights, excellent content, and slides that will be useful guides when determining franchise strategies."

Novartis
Emma Riley
Medical Science Liaison
United Kingdom
(November 2019)

Agenda

10:00 Welcome & Audience Expectations

10:15 Defining RWE and Its Value Added Over RCTs

- How should we define RWE?
- Although used interchangeably, RWD is not RWE!
- What is the added value of RWE over RCTs?
  - Efficacy vs. effectiveness of a health intervention
  - The distinctive roles of both RTCs and RWE along the product life cycle
- Clarification of key terms used in the world of RWE
- Real-life examples to illustrate what RWE is

11:00 Benefits for Pharma, Regulators, Payers and HCPs

- What are the commercial benefits for pharma?
- Benefits from a regulatory perspective (e.g. indication expansion)
- Benefits from a reimbursement perspective (e.g. evidence development agreements)
- RWE can aid physician decision-making, ultimately increasing uptake
- Challenges and limitations

11:45 Coffee Break

12:00 RWD Sources: What & How – Strengths & Weaknesses – Success Stories

- Patient registries
- Electronic patient records
- Electronic health records & claims data
- Healthcare wearables & social media
- Pragmatic studies
- Observational studies
- Surveys

13:00 Lunch

13:45 Critical Success Factors of a RWE Study

- Strategic decisions: Where in PLC will you gain most from RWE? – Decide how you will use the RWE
- 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 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

15:00 Interactive Group Exercise: Discussing a Real-life RWE Study Case

The audience will be split into groups to discuss the following questions about a real-life case: How to address the problem? – What data sources are most appropriate? – How to set up the RWE study?

Group output will be discussed in plenary and experts will close with their expert opinion.

15:30 Coffee Break

15:45 Incorporating RWE Into Product Launch Decisions

- Who is responsible for RWE in companies?
- Global vs local studies
- Where should RWE be considered in the product's life cycle?
- Challenges for undertaking RWE in practice
- RWE best practices – do's & don'ts

17:15 Summary

17:30 Close

The above agenda is for the face-to-face format. The online version of this course will cover the same modules, but the format and timing will be adapted to suit the online training setting.
Timing of the online course will be: 10-12 AM (CET) + 13-17 PM (CET)

Registration Form

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

Questions?

Inge Cornelis
+32 2 709 01 43
inge@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.