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**Paul Craddy & Graham Foxon**

# Generating RWE for Optimising Market Access

*The Fundamentals*

LEARN from interacting  
with your industry peers



*Great training on ONLY 1 day to better understand the importance of RWE in the new Pharma World. Clear vision of the priorities & the framework to be able to generate RWE with a cross-functional team..."*

**Norgine**

Vincent Verbruggen

**Market Access & Stakeholders**

**Manager BeNeLux**

Belgium



# 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

17 June 2022 (live online)

17 November 2022 (face-to-face)

Visit [www.celforpharma.com](http://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



*Interactive and informative course on RWE. I would recommend it to anyone hoping to gain more insight into the world of RWE!"*

#### GW Pharmaceuticals

Ann Watkins  
Medical Affairs Senior  
Manager  
United Kingdom (June  
2021)



*Very valuable course for RWE beginners or executives with some basic knowledge."*

#### LEO Pharma

Tariq Rehman  
Global Senior Manager  
Market Access  
and Pricing  
United Kingdom  
(June 2021)



*This is a course I would definitely recommend and is perfect for anyone who wants to find tools to support RWE planning and how to present its importance to Leadership Team. The experts shared great examples throughout the day and showed they are clearly experts on the topics presented. I found the interaction with the other participants really useful during discussions and the exercise as we got to learn from each other as well as the experts. Nice job by CELforPharma in preparing and supporting the course, well done!"*

#### Gilead Sciences

Ross Hamilton-Shaw  
Medical Scientist  
United Kingdom  
(June 2021)

# Agenda

Important: all hours are noted in CET/Brussels Time, so carefully convert into your local time zone!

Short breaks will be offered throughout the day.

## 09:30 Welcome & Audience Expectations (~30 min)

### Defining RWE and Its Value Added Over RCTs (~1h)

- 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 RCTs and RWE along the product lifecycle
- Clarification of key terms used in the world of RWE
- Real-life examples to illustrate what RWE is

### Benefits for Pharma, Regulators, Payers and HCPs (~1h)

- 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

### RWD Sources: What & How – Strengths & Weaknesses – Success Stories (~1h)

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

## 13:00 Lunch Break

## 14:00 Critical Success Factors of a RWE Study (~1h)

- 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

### Interactive Group Exercise: Discussing a Real-life RWE Study Case (~45 min)

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.

### Incorporating RWE Into Product Launch Decisions (~1h)

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

### Summary (~15 min)

## 17:00 Close

# Registration Form

Complete the below form and email to [aswaan@celforpharma.com](mailto:aswaan@celforpharma.com) or fax to +32 2 721 13 82 or go to [www.celforpharma.com](http://www.celforpharma.com) and complete the online registration form.



**Questions?**

**Annelies Swaan**  
+32 2 709 01 42  
[aswaan@celforpharma.com](mailto:aswaan@celforpharma.com)

## Course(s)

Course Title .....  
Course Date(s) .....

## Registration Fee

Visit our website [www.celforpharma.com](http://www.celforpharma.com) for information about the early bird fee and full fee, group discounts, etc.

## Participant Details

Title ..... Email .....  
First Name ..... Mobile Number .....  
Last Name ..... Country of Work .....  
Job Title .....

## 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](http://www.celforpharma.com/transfer-cancellation-policy)) and Privacy Policy ([www.celforpharma.com/we-value-your-privacy](http://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](http://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](http://www.celforpharma.com/we-value-your-privacy)), of which I accept the terms.