



ABOUT

Real-world evidence should be incorporated throughout all the product's lifecycle to ensure a significant value during its launch and commercialization. An integrated patient-centric perspective among different stakeholders and a focus on continuous evidence generation is the way forward for the life science industry.

This course will provide methods and hints to successfully:

- identify and prioritize the different RWE needs throughout the product lifecycle.
- apply the observational approach to evaluate "unmet needs" during the clinical development as well as the impact of the drug utilization in the real-world (i.e. patient's perceptions, effectiveness, safety and benefit in diverse environments and specific patients' subset).
- adopt a multidisciplinary approach to design optimized RWE projects that combine multiple stakeholders needs (i.e. Medical Affairs, Market Access and Clinical Development) to generate clinical evidence aligned with the product strategy and its lifecycle stage.
- understanding the methodology behind complex statistical methods used for RWE in published scientific papers.

PROGRAMME

MODULE 1

- 1. Current scenario: introduction to Real World Evidence
- 2. A practical taxonomy of observational research
- 3. RWE strategy and study designs

MODULE 2

- 4. Statistics for RWE: sample size and bias
- 5. Methods for retrospective research
- 6. Best practices for publishing observational studies

MODULE 3

- 7. Understanding propensity score and its uses in RWE generation
- 8. Lies, damned lies and... propensity score: controversies
- 9. Case studies

WHO SHOULD ATTEND

The course is for professionals working in Medical Affairs, Market Access, Drug Development/Clinical Research, Real World Evidence generation, HEOR of pharmaceutical and biotech companies willing to promote, design and manage Real World Evidence project to generate evidence and support the product value.

TEACHING METHODS

Interactive training with practical approach and Q&A sessions

LECTURERS

Paola Tellaroli

Biostatistician and Authoress

Paola Tellaroli holds a masters degree in Biostatistics and Experimental Statistics (University of Milano-Bicocca) and a Ph.D. in Statistical Sciences (University of Padua), during which study she spent one year as visiting scholar at Wayne State University (USA). She worked at the Oncological Institute of the Veneto Region, subsequently she had a Postdoc position at the Department of Cardiac, Thoracic, and Vascular Sciences (Padua) for three years. It was whilst here that she started working on Real World Evidence research focusing on methodology, she was lecturer in university masters and presented her research at both national and international conferences and authored several publications in peer-review scientific journals. Paola has currently found the perfect combination between numbers and words publishing several scientific and nonscientific volumes, combining the roles of Psychometrician and Data Scientist for an editor, handling research at the Department of Surgical Oncological and Gastroenterological Sciences (Padua), and being consultant for companies

AT THE END OF THE TRAINING, YOU WILL BE ABLE TO

- Plan RWD projects able to support the value proposition of your product during the whole lifecycle
- Adopt a tested multi-step technique to design your RWD project, based on the Company's strategy and multi-stakeholders' need leading the entire product development and commercialization

USEFUL INFORMATION

This online training in divided in 3 modules:

- Module 1 | October 16th, 2020 from 09.30 to 12.30 CEST
- Module 2 | October 23th, 2020 from 09.30 to 12.30 CEST
- Module 3 | October 30th, 2020 from 09.30 to 12.30 CEST

After the registration, you will receive all details about the connection.

The course will proceed with a minimum number of participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

REGISTRATION FEE

Early Bird: € 1080,00* (until 2 October 2020)

Ordinary: € 1260,00*

Freelance - Academy - Public Administration: € 663,00*

* for Italian companies: +22% VAT

** Early Bird discount not applicable to Freelance - Academy - Public Administration fee





The fee includes: tuition, teaching materials and attendance certificate that will be sent after the training via e-mail.

SEDE DEL CORSO



Online training - Zoom meetings