epi forum

LIFE SCIENCE ACADEMY

European Epidemiological Forum

The value of Real-World Evidence in Drug Life Cycle: promises, barriers and pathways to success

Date
6 October 2020

Language
English

Location
Online
Virtual Conference

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ABOUT

Regulators, health technology assessment (HTA) bodies, academics, bio-pharmaceuticals companies, payers, and patients are presently rethinking the healthcare ecosystem and facing diverse and increasing challenges at different levels. In this conceptual modelling of the healthcare ecosystem, the potential value of Real-World Data (RWD) for decision making has never been more relevant. Real-World studies seek to provide complementary evidence to that provided by randomized controlled trials. While the latter provide evidence of efficacy, Real-World Data provide information on therapeutic effectiveness in a real-world practice setting.
Pharmaceutical companies need to focus on innovative and targeted therapies both due to the increased competition in the sector, and of the number of better structured and demanding patients' groups or associations. Pharmaceutical companies are presently discussing on:

- How does RWD contribute to translational research?
- Whether there are any companies optimally leveraging RWD and how its application to

biobanks can better advance innovation and discovery of targeted therapies?
- What are the structural and logistical needs for this to be effective?
- What have we already learned about the process?

Regulatory bodies face the challenge of ensuring that only safe and effective medicines reach patients; a decision which so far has only been substantiated upon data from RCTs. They actually need to know:

- Whether other stakeholders can help them in the process and how?
- Where and how do we using RWD in the drug development and approval process?
- What has already been achieved in the field and what the success factors are?

Payers, and HTA bodies want to make sure that the most innovative and novel medicines reach patients who need them most as quickly as possible; and that these medicines provide value for money to all parties: patients and health care systems. They may ask themselves:

- How can sponsors better demonstrate the value of their innovative medicines using RWD?
- How can they work with decision-makers to establish agreed upon standards for RWE research?
- How do recent frameworks (FDA, NICE, etc) help advance RWE research?

What brings all stakeholders at the same level is the need for new paradigms for a more performing healthcare ecosystem that reduce the gap between its representation and its implementation. Emerging e-health models and applications can greatly contribute to it, particularly, if hand-in-hand with Real-World Data Studies. The European Epidemiological Forum will review the progress and perspectives on the value of RWD in the drug life cycle, will discuss what RWD promises, what the barriers may be and what a successful story may look like.

Scientific Board:
Christian Agboton - *Sr Global Brand Medical Director* at Takeda
Maurille Feudjo Tepie - *Observational Research Director* at Amgen
Michele Intorcia - *HEOR Senior Director* at Apellis Pharmaceuticals

Who should attend?
The conference is addressed to professionals with a deep interest in drug development, healthcare decision making, academia and healthcare research, belonging to department such as: Medical Affairs, R&D, HTA/Market access, Medical Informatics, Clinical Operations, Regulatory Affairs, Pharmacovigilance, Biostatistics and Data Management from Pharmaceutical, Biotechnology and Medical Device companies, CROs, Universities/Hospitals, Academic Research, Patient Associations and Healthcare Organizations.

PROGRAMME

All times indicated are Central Europe Summer Time

10:00 **10:20**	**Welcome**

10:20 **10:45**	**Fostering trust among RWE stakeholders: Would medium to long-term partnerships help?** **Maurille Feudjo Tepie** Observational Research Director at Amgen
10:45 **11:10**	**Critical thinking and Real world Evidence** **Elena Peruzzi** Evidence Generation & Data Analytics Head at Novartis
11:10 **11:20**	**Break**
11:20 **11:45**	**NICE Guidance - Widening the evidence base: use of broader data and applied analytics in NICE's work** **Adrian Jonas** Associate Director for Data and Analytics at National Institute for Health and Care Excellence (NICE)
11:45 **12:10**	**HTA, RWD and RWE: Validating and leveraging the different sources of evidence** **Oriol Solà-Morales** CEO at HITT - Health Innovation Technology Transfer
12:10 **12:30**	**What did we learn this morning?**
12:30 **13:50**	**Lunch break**
13:50 **14:15**	**Value Based agreements & Innovative Contracting with Medicines: The value of Real-World Evidence for improving access & reimbursement** **Omar Ali** Visiting Lecturer Value Based Pricing at University of Portsmouth & Former Adviser to NICE
14:15 **14:40**	**Data Transparency and Privacy in Real-World Research** **Raquel Billiones** Subject Matter Expert on Medical/Regulatory/Scientific Writing, Data Disclosure and Protection, Pharma/Medical Devices
14:40 **15:05**	**Digitalization in Data Capturing Impacts Scalability of Patient Recruitment - Using the 2D Matrix Code of Outer Drug Packages as Patient Identifier for ePRO studies – The DePRO study** **Christian Müller** Teamleader Data Generation at Bayer

15:05 **15:15**	**Break**
15:15 **16:15**	**WORKSHOP | Covid-19 Pandemic: RWE, Opportunities and Challenges**
16:15 **16:30**	**Conclusion**

SPEAKERS

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Speaker
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Raquel Billiones
Subject Matter Expert on Medical/Regulatory/Scientific Writing, Data Disclosure and Protection, Pharma/Medical Devices

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Associate Director for Data and Analytics at National Institute for Health and Care Excellence (NICE)

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REGISTRATION FEE

€ 570,00* Early Bird fee until September 17th, 2020
€ 680,00* Ordinary fee
€ 365,00* Freelance, Academy, Public Administration

** for Italian companies: +22% VAT*

Fee includes: access to the virtual conference, organizational support, certificate of attendance, slide presentations in pdf format provided post-event.

SEDE DEL CORSO

Virtual conference with presentations, slots for Q&A and discussion among delegates.
LS Academy will provide the link to join the conference some days before.