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The European Epidemiological Forum

is pleased to announce its 9th Annual Conference:

Tuesday, October 8th, 2019

NEW APPROACHES TO DRUGS VALUE

DEMONSTRATION IN THE AGE OF BIG DATA:

ANATOMY OF A PARADIGM SHIFT

📍 | **Barcelona**

H10 Cubik

Via Laietana, 69 E-08003 - Barcelona

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NEW APPROACHES TO DRUGS VALUE DEMONSTRATION IN THE AGE OF BIG DATA: ANATOMY OF A PARADIGM SHIFT

ABOUT

"IN GOD WE TRUST. ALL OTHERS MUST BRING DATA" | W. Deming

With the development of advanced medical therapies, for targeted or orphan diseases, the need for data generation has never been more important. Payers, HTA bodies and Decision Makers increasingly need evidence beyond Randomized Clinical trials (RCT), an artificial even if rigorous way to demonstrate causality. Hence the efforts to collect data from registries, pragmatic trials, claims databases - to provide real world evidence (RWE) once confined to anecdotal evidence or nice-to-have complementary data.

The real questions are: what is like to bring the evidence needed? Can RWE be label enabling? How to implement this approach in the lifecycle of a product? Recently, regulatory bodies have indicated their interest for non-RCT data, not only for safety purposes but also for establishing effectiveness and the risk-benefit of a medical intervention. One other key aspect, especially for rare diseases that may not have a broad evidence basis at the point of registration is to understand and define the role of real-world evidence data in developing new reimbursement systems that allow or coverage with future evidence development. In the pharmaceutical industry we have witnessed the remarkable advent of new methodologies and statistical approaches to extract data from apparently confusing datasets and to run more sound and reliable comparative analysis. From network meta-analysis to propensity score matching, from disease area models to discrete choice experiments, we have never been more equipped to capture signals from a background noise. Therefore, the need for harmonization, new and better data capturing and analytical technologies as well as more dynamic reimbursement systems that take the evolving evidence base from real life patient experience into consideration, is more and more important as the 21st century medicine is now based on big data rather than only RCTs.

Recent advances and perspectives in this field will be shared during the meeting, with an emphasis on practical aspects and how-tos. Payers, health economists, pharmaceutical physicians, trialists and regulators will share their knowledge with practical examples triggering engaging discussions and guiding participants' efforts in the jungle of methods, designs and analyses that are now available. The objective is to help you finding solutions to the many challenges that a cross-functional development team must solve to maximize the new opportunities ahead of us.

If you'd like to know how RWE can complement RCTs, how NICE is planning to integrate more RWE in their guidance, what's the role of big data in Value-Based Pricing, this event is for you!

Data will be provided Mr. Deming!

Scientific Board



Christian Agboton
Sr Global Brand Medical Director
at Takeda



Michele Intorcia
*Health Economics Outcomes
Research (HEOR) CoE Head*
at Vifor Pharma



Ulf Staginnus
*Senior Vice President, Head Global
Market Access & Pricing*
at Ipsen

Who should attend?

The event is addressed to professionals with a deep interest in drug development, healthcare decision making, academia and healthcare research, belonging to department such as:

- Regulatory Affairs
- HTA/ Market access
- Medical Informatics
- Biostatistics and Data Management
- Medical Affairs
- Pharmacovigilance
- Clinical Operations
- R&D

from Pharmaceutical, Biotechnology and Medical Device companies, CROs, Universities/Hospitals, Academic Research, Patient Associations and Healthcare Organizations.

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- 08:00 - 08:20 **Registration and welcome coffee**
- 08:20 - 08:30 **Welcome from the scientific board**
- 08:30 - 09:10 **What is the value of RWE and why is it needed?**
Michele Intorcchia - *Health Economics Outcomes Research (HEOR) CoE Head* at Vifor Pharma
- 09:10 - 09:50 **Usability and acceptance of different sources in HTA**
Oriol Solà-Morales - *CEO* at HITT - Health Innovation Technology Transfer
- 09:50 - 10:30 **NICE and data analysis – what does the future hold?**
Prof Gillian Leng CBE - *Deputy Chief Executive* at N.I.C.E
- 10:30 - 11:00 **Coffee break**
- 11:00 - 11:40 **Data generation and lifecycle management: towards integrated data evaluation and optimization**
Christian Agboton - *Sr Global Brand Medical Director* at Takeda
- 11:40 - 12:20 **The need and challenges of complementing observed efficacy from RCTs with effectiveness from RWD: The case example of bone therapies in Post-menopausal osteoporosis population**
Maurille Feudjo Tepie - *Director, EU CfOR Head* at Amgen Ltd
- 12:20 - 13:20 **Networking lunch**
- 13:20 - 14:00 **Value Based Pricing & Pay for Performance Agreements with New Medicines - How big data is filling the value gap & value mismatch**
Omar Ali - *Visiting Lecturer Value Based Pricing* at University of Portsmouth & Former Adviser to NICE
- 14:00 - 14:10 **Summary of the First part of the meeting - What did we learn so far?**
- 14:10 - 14:50 **Beyond the price per pill concept. Where do we stand with alternative market access strategies?**
Ulf Staginnus - *SVP Global Market Access & Pricing* at Ipsen Pharmaceuticals
- 14:50 - 15:30 **RWE – Technology Enablers and Data Strategy**
Jordi Gago García - *Senior Principal Business Analyst* at Boehringer Ingelheim
- 15:30 - 16:00 **Coffee break**
- 16:00 - 16:40 **The use of wearables in data generation and to improve patients' life: the POWER study**
Alessandra Ghirardini - *Rare Diseases Medical Unit Head* at Roche
- 16:40 - 16:55 **Steering Committee debate and Q&A**
- 16:55 - 17:00 **Conclusions - Summary of the day and messages to take home**

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HOW TO REACH THE CONFERENCE VENUE

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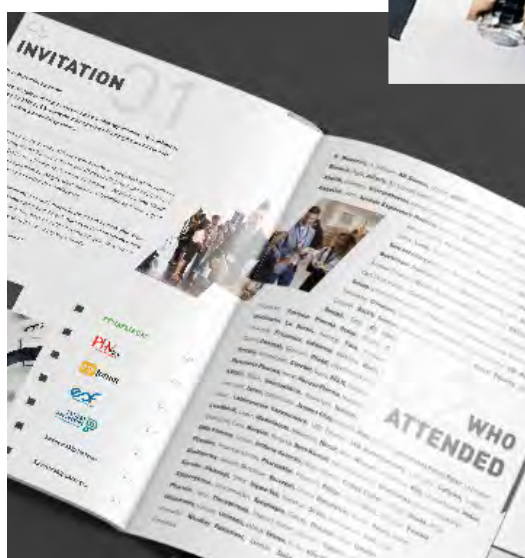
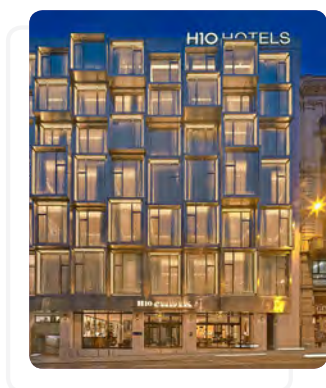
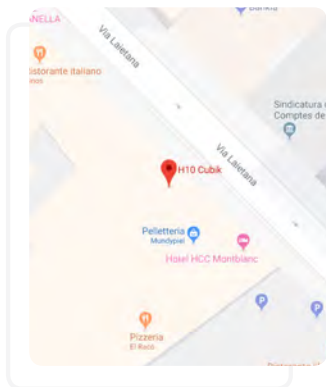
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• By email or fax

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- **€ 670,00 Early Bird fee extended until September 30 2019**
- **€ 790,00** Ordinary fee (after September 30, 2019)
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The fee includes: seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, welcome coffee, networking lunch, coffee break, organisational office assistance, certificate of attendance.

For any additional information, please contact:

Ilaria Butta | ilaria.butta@LSAcademy.com Phone: +39 (0)35.4123594

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