



EUROPEAN EPIDEMIOLOGICAL FORUM

13th October 2014, Milan

Villa Forno Breme, via Martinelli 23, Cinisello Balsamo
(Milan - Italy)

09:30 - 17:25

WWW.EPIFORUM.EU

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INTRODUCTION

In the recent years, clinical observational research has become an essential tool for the development and spread of new health technologies, particularly in the pharmaceutical field.

Within the health systems, the need of a well-documented platform for planning and decision-making is growing and therefore collecting real world data is receiving more and more attention, becoming more and more a strategic choice. According to a recent survey published by the European Commission, an increasing number of countries revisited the relative efficacy and effectiveness of a new treatment as a part of their decision making process for reimbursement and pricing, addressing consistent value to data generated within effectiveness assessment.

As decisions must be taken on an evidence-based foundation where all relevant circumstances and consequences are systematically framed by means of scientific methods, it is essential to put in perspective the data collected under real life practice circumstances.

Due to the many possible study designs in observational research, the proper design is needed to address and answer very different questions:

- descriptive clinical epidemiology
- post-marketing safety studies (PASS)
- comparative effectiveness research
- evaluations on appropriateness of health care interventions, and many others.

This year the 4th EPIFORUM will focus on **the use of epidemiological methods in providing real world evidence (RWE) to document product value in pre and post marketing activities.**

This event aims to bring together experts not only from the world of clinical research but also from academia, public institutions and industry to exchange views and experiences among all the participants, providing networking opportunities and adequate discussion between speakers and audience.

WHO SHOULD ATTEND

The event is addressed to Professionals with a deep interest in drug development and healthcare decision making such as:

Medical Director, Managing Director, Medical Affairs Director, Medical Informatics, R&D Manager, Pharmacovigilance manager, Clinical Operation Manager, Clinical Research Associate, Clinical Project Manager/Clinical Project Leader, Statisticians and Data Managers.

Belonging to Pharmaceutical and Biotechnology company, CROs and University/Hospital, academic research, patient associations, healthcare organisations.

PROGRAMME

- 09:00 - 09:30 **Registration**
- 09:30 - 09:40 **Welcome from the Scientific Board**
Stefano Viaggi, *Director of Marketing and Real World Data Solutions, MediData Observational Research*
Giovanni Corrao, *Dept Statistics & Quantitative Methods, Division of Biostatistics, Epidemiology & Public Health, University of Milano-Bicocca, Milan*
- 09:45 - 10:25 **Real World Data along the drug lifecycle: how pharma companies are embracing the challenge of collecting real world evidence**
Jean-Bernard Gruenberger, *Global HEOR Director, Novartis Pharma AG*
- 10:25 - 11:05 **Real World Experience of Gathering Real World Data – Sometimes painful, take an Aspirin**
Nigel Hughes, *Global Director, Marketing & Health IT Strategy Leader, Janssen Diagnostics BVBA*
- 11:05 - 11:35 **Coffee Break**
- 11:35 - 12:15 **What now? Value and transferability of evidence from regulatory trials**
Lorenzo G. Mantovani, *Senior Researcher, Department of Clinical Medicine and Surgery, Federico II University of Naples*
- 12:15 - 12:55 **Observational Studies and Drugs Assessment: How and Why the Value of a new Drug is not only Determined by Clinical Studies**
Michele Intorcchia, *Health Economics Director, Amgen*
- 12:55 - 13:05 **Discussion**
- 13:05 - 14:05 **Networking Lunch and Exhibitor Area**
- 14:05 - 14:45 **Observational studies in pharmacoepidemiology: Evidence for randomized trials?**
Samy Suissa, *James McGill Professor of Epidemiology, Biostatistics and Medicine, McGill University, Montreal, Canada; Director, Centre For Clinical Epidemiology Lady Davis Research Institute - Jewish General Hospital*
(Via web conference)
- 14:45 - 15:25 **Changing the scale of pharmacoepidemiology: from one database to global studies**
Miriam Sturkenboom, *Professor of Pharmaco-epidemiology, Erasmus MC*
- 15:25 - 15:55 **Coffee Break**
- 15:55 - 16:35 **Challenges of generating real world data for newly marketed drugs**
Dorothee Bartels, *Vice president, Head of Corporate Department Global Epidemiology, Boehringer Ingelheim GmbH*
- 16:35 - 17:15 **An industry epidemiologist's perspective on the design and conduct of observational PASS studies**
Paul Dolin, *Head of Pharmacoepidemiology, Takeda Development Centre Europe*
- 17:15 - 17:25 **Discussion/Conclusion**
Thomas Zwingers, *Senior Director, Consultancy Services, CROS DE GmbH*

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Registration

In order to attend the European Epidemiological Forum, the registration form should be completed and faxed to: **(+39) 035 4501262** or emailed to: segreteria@epiforum.eu or register and pay online: <http://events.lsacademy.it/conferences>

REGISTRATION FEE

€ 580,00* Early Bird fee by 3rd October 2014.

€ 670,00* after 3rd October 2014.

€ 530,00* for Patronage members.

€ 350,00* for Academy, Public Administration, Freelance.

*Only for Italian companies: +22% VAT

*The **fee includes**: seat at the conference, copy of presentations will be made available by Speakers, informative literature for the day, networking lunch, coffee breaks, organisational assistance from registration to event day (travel, accommodation, etc..), certificate of attendance.*

Payment

Payment should be made **online**, or by **bank transfer** (please see details below), or by mailing a **cheque**, along with the registration form. Upon receipt of payment, the registration will be confirmed. Invoice will be sent following receipt of payment. We couldn't accept late registrations or due to limited conference place available or registrations of roles that are not included in the target of the event.

EasyB S.r.l.

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How to reach Villa Forno Breme

For further information, please visit the website:

<https://2014-epiforum.eventify.it/location> or download the document:

http://www.epiforum.eu/EPIforum%202014/documents/Road%20indications%20and%20Hotels_EPI%202014.pdf

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Terms of payment

The registration fee must be paid at the time of registration. Confirmation of event admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants or registrations of roles that are not included in the target of the event.

Cancellation

Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the event date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

Information collection and use

Participants information is collected and utilised by EasyB S.r.l. and sponsor companies in accordance with Italian Legislative Decree 196/2003. Data collected will be used and communicated to third parties for the purposes of event organisation and may be used to communicate future similar initiatives. Participants may at any time verify the accuracy of the information and request changes or deletion.

Date

Signature.....