EMA Information Day on Measuring the Impact of Pharmacovigilance Activities

14 November 2017
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

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Robert Campbell
EURORDIS, France

OVERVIEW

Measuring the impact of pharmacovigilance is essential to allow regulators and pharmaceutical industry to ensure key pharmacovigilance activities are effective and efficient and to support regulatory decisions. Effective risk minimisation balancing benefits and risks of medicines are important tools for patient empowerment and to achieve best public health outcomes.

A workshop organised by the European Medicines Agency (EMA) in 2016 highlighted the need for a sustainable framework, robust scientific methodologies, timely generation of decision-relevant data and clear roles and responsibilities as key pillars of impact research. Based on the workshop's recommendations, the Pharmacovigilance Risk Assessment Committee (PRAC) is revising its strategy to evaluate EU pharmacovigilance activities in a collaborative approach based on clearly defined process indicators and measures of patient health outcomes.

The objective of this information day is to take stock of the implementation of the strategy, to discuss enablers and barriers, to impact and to foster collaboration and sharing of information amongst stakeholders.

KEY TOPICS

- Framework for impact evaluation
- Systematic collection of impact relevant data
- Methodologies for measuring health impacts of pharmacovigilance activities
- Collaboration with novel information technology providers
- Active engagement and capacity building of patient communities and healthcare professional bodies to support impact research
- Implementing a process to identify intended (and unintended) public health outcomes of regulatory decisions

TARGET AUDIENCE

Stakeholders of pharmacovigilance including pharmaceutical industry, regulators, patients and consumers and their organisations, healthcare professionals and their organisations; academia.

DETAILS OF THE INFORMATION DAY

Location: European Medicines Agency
30 Churchill Place
Canary Wharf, London E14 5EU
United Kingdom

Capacity: The event is limited to 110 participants

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

AGENDA

08:00 **REGISTRATION**

08:45 **WELCOME NOTE**

Xavier Kurz, European Medicines Agency (EMA)

08:50 – 10:20 **SESSION 1**

THE REGULATORY FRAMEWORK FOR IMPACT EVALUATION OF PHARMACOVIGILANCE ACTIVITIES

This session will provide an overview of the updated framework for the evaluation of the impact of regulatory decisions in pharmacovigilance based on workshop recommendations and practical experience.

Session Co-Chairs: Marieke De Bruin, University of Copenhagen, and Kaisa Immonen-Charalambous, European Patients Forum

08:50 – 09:15	**Revised PRAC Strategy for measuring impact of regulatory decisions** June Raine, MHRA
09:15 – 09:40	**Impact evaluation of pharmacovigilance activities – industry perspective** Vickie Edwards, AbbVie, Inc. On behalf of EFPIA
09:40 – 10:05	**A conceptual framework for the evaluation of effectiveness of risk minimisation: Experience at the Danish Medicines Agency** Mona Vestergaard Laursen, Danish Medicines Agency
10:05 – 10:20	**Panel discussion**

10:20 – 10:40 **COFFEE BREAK**

10:40 – 12:10 **SESSION 2**

GETTING IT RIGHT: SYSTEMATIC COLLECTION OF IMPACT RELEVANT DATA THROUGHOUT THE PRODUCT LIFE-CYCLE

This session looks at the generation of impact relevant data as a systematic process considering the need for, the nature of and the approach to data collection throughout a product's life-cycle.

Session Co-chairs: June Raine, MHRA, and Vicki Edwards, AbbVie Inc.

10:40 – 11:05	**Framework for utilising data to support decision-making - industry experience** Emma Du Four, AbbVie Inc. On behalf of EFPIA
11:05 – 11:30	**How could novel technologies and access to real world data facilitate impact research?** Alison Cave, European Medicines Agency (EMA)
11:30 – 11:55	**Patients' involvement in generating impact relevant data** Kaisa Immonen, European Patient`s Forum
11:55 – 12:10	**Panel discussion**

12:10 – 13:00 **SANDWICH LUNCH**

13:00 – 14:30 **SESSION 3**

METHODOLOGIES FOR IMPACT EVALUATION

This session focuses on the validated methods for evaluating the impact of regulatory actions in terms of public health outcomes and what can we learn from case examples.

Session Co-chairs: Bruce Guthrie, University of Dundee, and Mona Vestergaard Laursen, Danish Medicines Agency

13:00 – 13:25	**Methodological approaches to assessing risk minimisation interventions – study design, target population, data source, and outcome measures** Christine Hallgreen, Copenhagen Centre for Regulatory Science
13:25 – 13:50	**Time series regression as analytical approach – case examples** Daniel Morales, European Medicines Agency (EMA)
13:50 – 14:15	**Outcome measures to evaluate the effectiveness of risk minimisation in EU PAS studies: A quantitative review** Nawab Qizilbash, OXON Epidemiology
14:15 – 14:30	**Panel discussion**

14:30 – 14:50 **COFFEE BREAK**

14:50 – 16:20 **SESSION 4**

WHAT DO TO WITH THE RESULTS OF IMPACT EVALUATIONS – ARE WE READY FOR THE CHANGE?

This session will provide the opportunity to discuss amongst all stakeholders the future direction of pharmacovigilance with the aim to focus resources on those activities where impact research provides the required evidence for change.

Session Co-Chairs: Emma Du Four, AbbVie Inc., and Gonzalo Calvo-Rojas, EACPT

14:50 – 15:15	**Patient and healthcare professional engagement in impact evaluation of regulatory decision-making** Priya Bahri, European Medicines Agency (EMA)
15:15 – 15:40	**Impact of regulatory risk communication on public health outcomes – challenges and opportunities** Bruce Guthrie, University of Dundee
15:40 – 16:05	**Outline of a process to identify intended (and unintended) public health outcomes of regulatory decisions** Sue Jordan, Swansea University
16:05 – 16:20	**Panel discussion** Discussant: Robert Campbell, EURORDIS
16:20	**Closing remarks** Marieke De Bruin, University of Copenhagen

16:45 **END OF INFORMATION DAY**

REGISTRATION FORM

ID #17598

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SEND YOUR COMPLETED REGISTRATION FORM TO DIA EUROPE, MIDDLE EAST & AFRICA CONTACT CENTRE TEAM,
E-mail: basel@DIAglobal.org Fax: +41 61 225 51 52 For more information please call +41 61 225 51 51

Registration fees*	Fees
Industry	500.00 EUR ❑
Government/Academia/Charitable/Non-Profit (full time)	250.00 EUR ❑

*Registration fee includes: refreshments, sandwich lunch and electronic access to delegate material

Payment is due 30 days after registration and must be paid in full by commencement of the event.

HOTEL INFORMATION

Participants are kindly requested to make their own hotel reservation.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA EMEA.**

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Date	Signature

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- Government/Academia/Charitable/Non-Profit (full time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
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