EMA EudraVigilance & Signal Management Information Day

Event #18593
16 March 2018
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Paolo Alcini, Head of Data Standardisation and Analytics Service, EMA, EU
Peter Arlett, Head of Pharmacovigilance and Epidemiology Department, EMA, EU
Sabine Brosch, Principal Scientific Administrator, EMA, EU
Georgy Genov, Head of Signal and Incident Management Service, EMA, EU
Anja van Haren, EudraVigilance Coordinator, Medicines Evaluation Board (MEB), NL
Margaret Walters , Deputy EU Qualified Person for Pharmacovigilance, MSD, UK

FACULTY

Gaby Danan, Pharmacovigilance expert, France
Francois Domergue, Business Project Manager, EMA, EU
Julie Durand, Scientific Administrator, EMA, EU
Nick Halsey, Scientific Administrator, EMA, EU
Claudia Lehmann, Head Global Pharmacovigilance Operations, Boehringer Ingelheim International GmbH, DE
David Lewis, Global Head of Pharmacovigilance, Novartis Pharma AG, CH
Subhash Mistry, Manager, GSK, UK
Attila Olah, Head Global Pharmacovigilance, EU-QPPV, Gedeon Richter PLC, HU
Nils Opitz, Head of PV System Management and Analytics, Bayer AG, DE
Tom Paternoster-Howe, Scientific Administrator , EMA, EU
Rodrigo Postigo, Scientific Administrator , EMA, EU
Gilles Touraille, Pharmacovigilance and Risk Management, EMA, EU
Menno Van der Elst, Alternate PRAC member, Medicines Evaluation Board (MEB), NL
Mona Vestergaard Laursen, Chief Advisor, Danish Medicines Agency, DK
Magnus Ysander, EU QPPV, AstraZeneca, SE
Freia Zude, Head GPV Operations Excellence and Innovation, Boehringer Ingelheim International GmbH, DE

OVERVIEW

The new and enhanced EudraVigilance system became operational on 22 November 2017 and brought about significant changes to electronic reporting requirements and access to reports of suspected adverse reactions related to medicines by marketing authorisation holders in the EEA.

In addition, EMA and the European Commission have agreed transitional arrangements to streamline the monitoring of EudraVigilance by marketing authorisation holders. During a pilot period of one year, which will start on 22 February 2018, MAHs of the active substances included in the list published in October 2017, will have to monitor them in EudraVigilance.

This EudraVigilance Information Day provides a forum to discuss the initial experience of stakeholders with the new EudraVigilance system functionalities focusing on procedural, technical and data quality aspects and the use of the new ICH E2B(R3) standard. In addition, this Information Day will allow the audience to interact with signal management experts from EMA and national Competent Authorities and to learn from the approach of marketing authorisation holders involved in the pilot.

The faculty invites participants to submit related questions by 23 February 2018 latest to emaevents@diaglobal.org.

KEY TOPICS

- EudraVigilance achievements to date and next steps
- Access to EudraVigilance and impact on stakeholders
- Procedural aspects under discussion by the Pharmacovigilance Business Team
- Signal management pilot
- Use of EVDAS in support of signal management
- Frequently asked questions and points to consider

TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs)
- Sponsors of clinical trials
- Individuals involved in pharmacovigilance, safety database, signal management and information management
- IT system developers and data managers

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

08:00 **REGISTRATION**

08:50 **WELCOME NOTE**

Peter Arlett, Head of Pharmacovigilance and Epidemiology Department, EMA, EU

09:00 **SESSION 1**

Session chairs: **Anja van Haren**, MEB and **Sabine Brosch**, EMA

OPERATIONAL EXPERIENCE WITH EUDRAVIGILANCE (PART I)

This session provides an overview of the initial experience gained with the operation of the new and enhanced EudraVigilance system as well as the use of the new ICH E2B(R3) ICSR format. Aspects addressed will include an overview of data processed and accessed so far as well as key features of release 5 of EudraVigilance. Lessons learned in using the new ICSR format will be shared. Process related aspects in the context of the EudraVigilance download of ICSRs will be discussed based from a MAH perspective. The panel will be available to address questions from the audience.

EudraVigilance Achievements to Date and Next Steps
Francois Domergue, EMA

Operational Experience With EudraVigilance – a MAH Perspective
Margaret Walters, MSD

Implementing the ISO/ICH E2B(R3) Standard in a Pharmacovigilance System – Challenges and Lessons Learned
Claudia Lehmann, Boehringer Ingelheim

Q&A/Panel Discussion
Freia Zude, Boehringer Ingelheim, Subhash Mistry, GSK, Gaby Danan, Pharmacovigilance Expert, Attila Olah, Gedeon Richter, Nick Halsey, EMA, Gilles Touraille, EMA

10:30 **COFFEE BREAK**

11:00 **SESSION 2**

OPERATIONAL EXPERIENCE WITH EUDRAVIGILANCE (PART II)

Session chairs: **Anja van Haren**, MEB and **Sabine Brosch**, EMA

This session provides the opportunity to discuss with an expert from a national Competent Authority the simplified reporting rules and frequently identified issues related to ICSRs reported by marketing authorisation holders. Furthermore, key topics discussed by the Pharmacovigilance Business Team as regards procedural and regulatory aspects will be highlighted. The session will conclude with a dedicated question and answer session for which participants are invited to send questions by 23 February 2018 to emaevents@diaglobal.org

The new EudraVigilance System – the Experience from an NCA Perspective
Mona Vestergaard Laursen, Danish Medicines Agency

Dos and Don'ts in Using EudraVigilance
Anja van Haren, MEB and **Sabine Brosch**, EMA
Frequently asked questions (questions submitted by attendees)

Q&A/Panel Discussion
Paolo Alcini, EMA, Nick Halsey, EMA, Tom Paternoster-Howe, EMA, Gilles Touraille, EMA, Gaby Danan, Pharmacovigilance Expert, Subhash Mistry, GSK, Attila Olah, Gedeon Richter

12:30 **SANDWICH LUNCH**

13:30 **SESSION 3**

SIGNAL MANAGEMENT (PART I)

Session chairs: **Georgy Genov**, EMA and **Menno van der Elst**, MEB

This session will provide a summary of the key processes related to signal management by marketing authorisation holders introduced by GVP Module IX and the main principles applicable to the signal management pilot. The importance of the signal management activities from a scientific and public health perspective will be addressed by a member of PRAC. The experience in working with the eRMR and the new EVDAS tools will be presented from a marketing authorisation holder perspective.

Pilot on Signal Detection in EudraVigilance by MAHs
Julie Durand, EMA

PRAC Recommendations on Signals
Menno van der Elst, MEB

First Experience in Working with the Electronic Reaction Monitoring Report (eRMR) and the EVDAS tools
Nils Opitz, Bayer

Q&A/Panel Discussion
David Lewis, Novartis, Attila Olah, Gedeon Richter, Rodrigo Postigo, EMA, Gaby Danan, Pharmacovigilance Expert, Magnus Ysander, AstraZeneca

15:00 **COFFEE BREAK**

15:30 **SESSION 4**

SIGNAL MANAGEMENT (PART 2)

Session chairs: **Georgy Genov,** EMA and **Menno van der Elst**, MEB

The signal management session will continue with a presentation on the processes put in place by a marketing authorisation holder involved in the signal management pilot. Signal management key performance indicators (KPIs) from an industry perspective will be also discussed. The session will conclude with a dedicated question and answer session for which participants are invited to send questions by 23 February 2018 to emaevents@diaglobal.org

MAHs Processes as Part of the Signal Management Pilot
Magnus Ysander, AstraZeneca

Signal Management KPIs from an Industry Perspective
David Lewis, Global Head of Pharmacovigilance, Novartis Pharma
Frequently asked questions (questions submitted by attendees)

Q&A/Panel Discussion
Julie Durand, EMA, David Lewis, Novartis, Attila Olah, Gedeon Richter, Rodrigo Postigo, EMA, Gaby Danan, Pharmacovigilance Expert

16:45 **END OF INFORMATION DAY**

REGISTRATION FORM

ID #18593

Joint EudraVigilance & Signal Management Information Day

16 March 2017 | European Medicines Agency | London, United Kingdom

SEND YOUR COMPLETED REGISTRATION FORM TO DIA 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 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.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Event ID #18593 as well as the invoice number to ensure correct allocation of your payment.

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.**

By signing below, I confirm that I agree with DIA Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- 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 reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA 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.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Photography and Video Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA 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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