EMA EudraVigilance & Signal Management Information Day

Event #18588
07 December 2018
Hilton Canary Wharf, London, United Kingdom

PROGRAMME COMMITTEE

Paolo Alcini, Head of Data Standardisation and Analytics Service, EMA, EU

Sabine Brosch, Principal Scientific Administrator, EMA, EU

Gaby Danan, Pharmacovigilance expert, France

Anja van Haren, EudraVigilance Coordinator, Medicines Evaluation Board (MEB), NL

David Lewis, Global Head of Pharmacovigilance, Novartis, CH

Attila Olah, EU-QPPV, Gedeon Richter PLC, HU

Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, MSD, UK

FACULTY

Vicki Edwards, Vice President & QPPV, AbbVie Inc., UK

Elsa Ferrao, Inspector, INFARMED, PT

Judy Harrison, Chief Medical Officer, MedDRA Maintenance and Support Service Organisation (MSSO), US

Andreas Iwanowitsch, Head Global Pharmacovigilance Unit, EU, Stada, DE

Calin Lungu, Lead Trainer EudraVigilance training programme, DDCS, LU

Christiane Michel
Global Head Safety Signal Detection, Novartis, CH

Alexandra Szabó, Head of Signal & Risk Management, Gedeon Richter PLC, HU

Kiernan Trevett, Senior Pharmacovigilance Inspector, MHRA, UK

Dionne Usher, Senior Specialist, EU QPPV Office, Merck, Sharp & Dohme Ltd (MSD), UK

OVERVIEW

EudraVigilance is a cornerstone for the conduct of pharmacovigilance in the EU. The new EudraVigilance system, which was subject to an independent audit in 2017, is now operational for almost one year. Based on the anniversary, this Information Day will provide a platform to exchange operational experience in using the new system functionalities and applying the simplified adverse reaction reporting rules. As regards signal management using EudraVigilance, a phased approach in the EU was agreed in the form of a pilot, which started in February 2018 involving a limited number of active substances selected based on the list of medicinal products subject to additional monitoring. In August this year, EMA announced the extension of the pilot beyond February 2019 to allow for additional experience to be gained. As part of a dedicated signal management session, pragmatic approaches and lessons learned so far will be discussed at this Information Day. The event will conclude with an outlook of current and future challenges in pharmacovigilance focusing on the impact of the coming into force of the General Data Protection (GDPR) Regulation in May 2018, the latest developments as regards MedDRA and a proposed pharmacovigilance vision for the next years to come.

KEY TOPICS

- The new EudraVigilance system - one year of operation
- New EMA Access and Account Management
- EudraVigilance Do's and Dont's - status update
- Processes for signal management and eRMR assessment
- How does GDPR impact on safety reporting?
- Latest MedDRA initiatives and developments
- Outlook for new approaches on data collection and safety monitoring

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:
Hilton Canary Wharf
Marsh Wall
South Quay Square
London E14 9SH
United Kingdom

Capacity: The event is limited to 150 participants

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

08:00 **REGISTRATION**

08:50 **WELCOME NOTE**

09:00 **SESSION 1**

THE NEW EUDRAVIGILANCE SYSTEM - ONE YEAR ANNIVERSARY (PART I)

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

This session will provide a summary of the industry's operational experience with EudraVigilance following the launch of the new system functionalities in November 2017. Following the integration of EudraVigilance with the new identity and access management of users and organisations in July 2018, an update will be provided on the achievements and challenges. The coding of medicinal product information reported in Individual Case Safety Reports (ICSRs) is based on the data provided by marketing authorisation holders (MAHs) as part of their Article 57 data submissions to the XEVMPD. The impact of the data coding on the ICSR download and the analysis in EVDAS will be explained. Questions from the audience will be addressed by the expert panel.

Industry Feedback on EudraVigilance New Functionalities
Margaret Walters, MSD

Identity and Access Management (IAM) Integration with EudraVigilance
Dionne Usher, MSD

Interplay of EudraVigilance and the XEVMPD - Why Does it Matter?
Sabine Brosch, EMA

Discussants:
Attila Olah, Gedeon Richter, **Calin Lungu**, DDSC, **Andreas Iwanowitsch**, Stada, **Gaby Danan**, Pharmacovigilance Expert

10:30 COFFEE BREAK

11:00 **SESSION 2**

THE NEW EUDRAVIGILANCE SYSTEM - ONE YEAR ANNIVERSARY (PART II)

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

This session will start with observations from a pharmacovigilance inspections perspective based on the application of the simplified reporting rules by MAHs in the EU. Taking into account the importance of high quality of data in EudraVigilance, initiatives to strengthen and improve the quality of ICSRs will be summarised. Frequently asked questions will be addressed based on a new set of do's and don't's for EudraVigilance.

The expert panel will address further questions from the audience on the topics presented.

Simplified reporting rules and interaction with EudraVigilance Pharmacovigilance inspector's perspective

Elsa Ferrao, INFARMED, PT
Kiernan Trevett, MHRA, UK

Initiatives to strengthen the quality of ICSR data
Sabine Brosch, EMA

EudraVigilance Dos' and Dont's – New Aspects to be Aware of
Anja van Haren, MEB

Panel Discussion:
Margaret Walters, MSD, **Gaby Danan**, Pharmacovigilance Expert, **Andreas Iwanowitsch**, Stada, **Attila Olah**, Gedeon Richter

12:20 LUNCH

13:20 **SESSION 3**

SIGNAL MANAGEMENT USING EVDAS (GVP MODULE IX)

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

Taking into account the phased implementation of the EudraVigilance signal management by MAHs, which started in February 2018 in the form of a pilot focusing on a limited number of active substances of medicinal products subject to additional monitoring, EMA announced in August the extension of the pilot beyond February 2019 to allow for additional experience to be gained. This session is dedicated to discuss how industry has approached the new signal management and eRMR assessment and the lessons learned so far.

Experience with the EudraVigilance signal detection pilot from an industry perspective
Alexandra Szabo, Gedeon Richter

How to approach the eRMR assessment for innovative medicines?
Christiane Michel, Novartis

eRMR assessment for generics
Andreas Iwanowitsch, Stada

Panel Discussion:
Margaret Walters, MSD, **Gaby Danan**, Pharmacovigilance Expert, **Attila Olah**, Gedeon Richter, **Calin Lungu**, DDCS

14:50 COFFEE BREAK

15:20 **SESSION 4**

CURRENT AND FUTURE CHALLENGES IN PHARMACOVIGILANCE

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

In May 2018 the GDPR became applicable in the EU. The session will inform about the impact and challenges in the area of pharmacovigilance from a MAH perspective. Furthermore, new initiatives and developments as regards MedDRA will be summarised. The Information Day will conclude with an industry vision proposed for pharmacovigilance for the next years to come focusing on new technologies and new approaches to data management.

The Impact of GDPR in Pharmacovigilance
Dave Lewis, Novartis

MedDRA – what's new?
Judy Harrison, MedDRA MSSO, US

New approaches on data collection and safety monitoring
Vicky Edwards, AbbVie, UK

16:40 **END OF INFORMATION DAY**

REGISTRATION FORM

ID #18588

EMA EudraVigilance & Signal Management Information Day

7 December 2018| Hilton Canary Wharf| 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*

*(Direct E-mail Adress required for Presentation Access)

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.**

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

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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. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click here.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click here. You agree that your personal data will be transferred to DIA in the US.

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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