Signal Detection and Management Information Day

Key Principles, Processes and Responsibilities

2 December 2016

European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

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Statistician, Pharmacovigilance Department, EMA, EU

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Antoni Wisniewski
Systems Area Lead, Patient Safety Analytics, AstraZeneca, UK

Cosimo Zaccaria
Signal Management Lead, Pharmacovigilance Department, EMA, EU

DETAILS OF THE INFORMATION DAY

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

OVERVIEW

This Information Day will review signal detection and management activities essential to the overall risk management process of a medicinal product. We will drill down to uncover what the impact of the implementation of the 2010 pharmacovigilance legislation are, with a strong focus on signal detection and management within the EU, and emphasis on the requirements to be implemented in 2017.

KEY TOPICS

- Different tools to support signal detection and safety monitoring (EudraVigilance access, electronic reaction monitoring reports, emerging safety issues)
- Implementation of the pharmacovigilance legislation
- Scope and objectives of GVP module IX
- Stakeholders' involvement in signal detection and management (role of the Pharmacovigilance Risk Assessment Committee (PRAC), member state and pharmaceutical industry perspective
- New approaches to signal management)
- MAH access to EudraVigilance
- Benefits of ICH E2B R3
- Evidence from PROTECT on signal detection practices

TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs)
- Professions involved in Signal Detection and Management
- Individuals involved in clinical development, information management, safety databases
- PV Information Technology Professionals

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA DEVELOP INNOVATE ADVANCE

08:30 REGISTRATION

08:45 WELCOME NOTE

Peter Arlett, EMA

09:00 SESSION 1

SIGNAL DETECTION AND MANAGEMENT WITHIN THE EU

Session Chairs:
Georgy Genov, EMA, and Sabine Straus, MEB

This session will provide an overview of the signal management procedure and the impact of the implementation of the 2010 pharmacovigilance legislation with emphasis on the requirements to be implemented in 2017 driven by the EV auditable requirements project and the EV access policy (revision 2).

The scope and objectives of GVP module IX as well as a summary of the enhancements as part of revision 1 will be presented.

Various training possibilities to support MAHs in meeting their pharmacovigilance obligations will be presented. This includes the use of online learning (user manuals), upcoming webinars and other training opportunities.

EU Signal management procedure: implementation of the pharmacovigilance legislation
Rodrigo Postigo, EMA

GVP Module IX – Signal Management: scope of revision, feedback from the public consultation and next steps
Julie Durand, EMA

Emerging Safety Issues (ESIs) and how they should be used
Irina Caplanusi, EMA

Panel Discussion/Q&A

10:30 COFFEE BREAK

11:00 SESSION 2

STAKEHOLDER INVOLVEMENT IN SIGNAL DETECTION AND MANAGEMENT

Session Chairs:
Georgy Genov, EMA, and Sabine Straus, MEB

Member States' perspective on signal management and a general overview of the perspectives and involvement of NCAs in signal detection and management will be presented.

The session will focus on signal detection and management approach of MAHs and their interactions/involvement with EMA and NCAs.

The role and responsibilities of the PRAC in signal management as well as the interaction with MAHs and the public will be outlined taking into account the publication of PRAC recommendations.

Member States' perspective on signal management
Ulla Wändel-Liminga, MPA

Signal detection and management: a pharmaceutical industry perspective and future approaches
David Lewis, Novartis

PRAC involvement in signal management
Sabine Straus, MEB

Panel Discussion/Q&A

12:30 SANDWICH LUNCH

13:30 SESSION 3

TOOLS TO SUPPORT SIGNAL DETECTION AND SAFETY MONITORING

Session Chairs:
Georgy Genov, EMA and Sabine Straus, MEB

This session will provide an overview of the use of EVDAS by MAHs to perform signal detection. It will cover an overview of the EVDAS dashboards, the eRMR, line listings, active substance groupings and the process for requesting access to case narratives.

Furthermore the design of an eRMR and a description of the structure and how it can be used to perform signal detection in EVDAS will be explained.

An overview on emerging safety issues will be provided: what constitutes an ESI, how to report them and how they are by the Agency in collaboration with the EU network.

MAHs access to EudraVigilance
Rodrigo Postigo, EMA

The electronic reaction monitoring report (eRMR) as a tool for signal detection in EVDAS
Cosimo Zaccaria, EMA, and Gianmario Candore, EMA

Training possibilities to support pharmacovigilance obligations
Francois Domergue, EMA

Panel Discussion/Q&A

15:00 COFFEE BREAK

15:30 SESSION 4

NEW APPROACHES TO SIGNAL MANAGEMENT

Session Chairs:
Georgy Genov, EMA, and Sabine Straus, MEB

The essential improvements introduced with the use of the ICH E2B R3 standard as well as the benefits of using ICH E2B R3 in signal detection and management will be discussed.

The main research questions for signal detection addressed in PROTECT and the recommendations for pharmacovigilance professionals to improve signal detection practices will be summarised.

Benefits of ICH E2B R3 in signal detection and management
Nicole Lang, Ratiopharm GmbH

Recommendations on signal detection practices - evidence from PROTECT
Antoni Wisniewski, AstraZeneca

Areas of uncertainty in signal detection in spontaneous reports and future research
Jim Slattery, EMA

Panel Discussion/Q&A

17:00 END OF THE INFORMATION DAY

REGISTRATION FORM

Signal Detection and Management Information Day
Key principles, processes and responsibilities of Marketing Authorisation Holders
2 December 2016 | European Medicines Agency, London, United Kingdom

ID #16599

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

Registration fees*	Fees
Industry	400.00 EUR ❑
Government/Academia/Charitable/Non-Profit (full time)	200.00 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.
Recommended hotel close to the EMA:

Novotel London Canary Wharf, 40 Marsh Wall , E14 9TP, London, UK
Tel: +44 871 66 30 624 Email: H9057@accor.com

DIA has blocked a limited number of hotel rooms for the course participants from 01 to 02 December 2016 (1 night) at the rate of GBP 175.00 per superior double room for single use including Full English Breakfast, taxes and service fee.

In order to book a hotel room, please fill in the booking form available on www.diaglobal.org/signalinfoday and send it to the hotel directly.

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 #16599 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 EMEA.**

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

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA EMEA 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 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.

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 EMEA office of any such substitutions as soon as possible.

Photography 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 EMEA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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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