EudraVigilance Information Day

Event #17591
19 September 2017
European Medicines Agency, London, United Kingdom

FACULTY

David Bosque Villaverde
Project Manager of Information Technology, EMA, EU

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Martin Hofstaetter
Project Manager, Change Manager, Austrian Agency for Health and Food Safety (AGES), Austria

David J Lewis
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Scientific Administrator, Clinical & Non-clinical Compliance Department, EMA, EU

Subhash Mistry
Manager (Applications Development and Support), GSK, United Kingdom

Nils Opitz
Head of PV System Management and Analytics, Bayer AG, Germany

Rodrigo Postigo
Signal Management Lead, Pharmacovigilance Department, EMA, EU

Gilles Touraille
Pharmacovigilance and Risk Management, EMA, EU

Margaret Walters
Director & Deputy EU Qualified Person for Pharmacovigilance, Merck, Sharp & Dohme Ltd, United Kingdom

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

NEED FOR THIS EUDRAVIGILANCE INFORMATION DAY

The new and enhanced EudraVigilance functionalities will go live on 22 November 2017, which will trigger a number of business process and technical changes which impact national Competent Authorities, marketing authorisation holders and sponsors of clinical trials. This EudraVigilance Information Day provides a forum to discuss the final steps in preparation of the simplified adverse reaction reporting, the new signal management for marketing authorisation holders in the EEA as well as the initial testing experience by stakeholders.

More specifically, the focus of this Information Day will be on the EudraVigilance go-live planning and the preparations and actions required by national Competent Authorities in the EEA, marketing authorisation holders and sponsors of clinical trials. The Information Day will also serve as a platform to experts to share their testing experience based on the use of the new EudraVigilance XCOMP (test) environment, which was released on 26 June 2017 and to raise specific process related and technical questions.

Other topics include the finalisation of the revision of the Guideline on Good Pharmacovigilance Practices (GVP) Module IX – Signal management and practical arrangements for the new signal management process for marketing authorisation holders. There will be further an opportunity to raise GVP Module VI – Management and reporting of adverse reactions to medicinal products related questions and questions in relation to reporting of suspected unexpected serious adverse reactions (SUSARs) for clinical trials.

KEY TOPICS

- EudraVigilance auditable requirements project – go-live planning
- Revision of the GVP module IX and how MAHs should prepare for signal management
- Lessons learned from the XCOMP testing activities by NCAs and MAHs
- Preparing for business change – frequently asked questions

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

PROGRAMME COMMITTEE

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

Sabine Brosch, Principal Scientific Administrator, Pharmacovigilance and Epidemiology Department, EMA, EU

Georgy Genov, Head of Signal and Incident Management and Acting Head of Pharmacovigilance and Epidemiology Department, EMA, EU

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

08:00 **REGISTRATION**

08:50 **WELCOME NOTE**

Georgy Genov, EMA

09:00 **SESSION 1**

EUDRAVIGILANCE – HOW TO PLAN FOR THE GO-LIVE

Session Chairs: Sabine Brosch, EMA, and Anja van Haren, MEB

This session will focus on the discussion of the detailed steps to be followed by national Competent Authorities, marketing authorisation holders and sponsors of clinical trials in preparation of the launch of the new and enhanced EudraVigilance functionalities on 22 November 2017. This will include the process to be followed for the switch from the interim to the simplified reporting rules of suspected adverse reactions related to medicines and address technical considerations.

EudraVigilance Go Live Planning
Francois Domergue, EMA

EudraVigilance Go Live Planning – preparations from an MAH and sponsor point of view
Margaret Walters, Merck, Sharp & Dohme Ltd

EudraVigilance Go Live Planning – arrangements by an NCA
Speaker invited

Q&A/Panel Discussion
Discussants: Nick Halsey, EMA, Nils Opitz, Bayer, and David Bosque Villaverde, EMA

10:30 COFFEE BREAK

11:00 **SESSION 2**

ICH E2B(R3) ICSR IMPLEMENTATION IN THE EU AND TESTING WITH THE NEW EUDRAVIGILANCE XCOMP ENVIRONMENT

Session Chairs: Sabine Brosch, EMA, and Anja van Haren, MEB

On 26 June 2017, the new EudraVigilance XCOMP (test) environment has been released for testing purposes, which serves all stakeholders to perform interoperability testing of their local systems including the use of the new ICH E2B(R3) ICSR format. The aim of this session is to share experience gained during the first 12 weeks of testing.

EudraVigilance XCOMP stakeholder testing – observations by the EMA
Francois Domergue, EMA, and Nick Halsey, EMA

EudraVigilance XCOMP Marketing Authorisation Holder testing
Speaker invited

EudraVigilance XCOMP National Competent Authority testing
Martin Hofstaetter, AGES, presenting remotely

Q&A/Panel Discussion
Discussants: Margaret Walters, Merck, Sharp & Dohme Ltd, Nils Opitz, Bayer, and David J Lewis, Novartis Pharma AG

12:30 SANDWICH LUNCH

13:30 **SESSION 3**

SIGNAL MANAGEMENT

Session Chairs: Georgy Genov, EMA, and Anja van Haren, MEB

The session will update on revision 1 of GVP Module IX "Signal Management", which is planned to be published before the go live as well as transitional arrangements for a pragmatic implementation. The approach taken by a marketing authorisation holder to implement the new signal management process will be also presented.

GVP Module IX "Signal Management" - a pragmatic implementation approach
Julie Durand, EMA

The new signal management in the EU - a MAH perspective
David J Lewis, Novartis Pharma AG

Q&A/Panel Discussion
Discussants: Margaret Walters, Merck, Sharp & Dohme Ltd, Nils Opitz, Bayer, and Subhash Mistry, GSK

14:45 COFFEE BREAK

15:15 **SESSION 4**

QUESTIONS AND ANSWERS IN PREPARING FOR THE CHANGES TO COME

Session Chairs: Sabine Brosch, EMA, and Anja van Haren, MEB

Participants will be able to raise specific technical and business process related questions. The topics include the implementation of the clinical trials regulation and the reporting of SUSARs, the use of the new ICH E2B(R3) format, the simplified reporting of suspected adverse reactions, registration and testing procedures and signal detection and management activities. Experts from EMA and medicines regulatory authorities will be available to answer to your questions.

Note: Participants are invited to send their questions by 6 September to eudravigilance@diaglobal.org. Alternatively, questions can be raised during the Information Day.

Q&A/Panel Discussion
Discussants: Sophia Mylona, EMA, Francois Domergue, EMA, Nick Halsey, EMA, Rodrigo Postigo, EMA, Julie Durand, EMA, Gilles Touraille, EMA, David Bosque Villaverde, EMA, and Nils Opitz, Bayer

16:45 **END OF INFORMATION DAY**

REGISTRATION FORM

ID #17591

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19 September 2017 | European Medicines Agency | London, United Kingdom

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	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 #17591 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

TERMS AND CONDITIONS

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 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 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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