EudraVigilance Information Day

21 June 2016
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Paolo Alcini
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Member of the EudraVigilance Expert Working Group (EV-EWG)

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

This EudraVigilance Information Day provides a forum to update stakeholders about latest developments with regard to EudraVigilance in the context of the implementation of the pharmacovigilance legislation. It further aims to facilitate change management as part of the Agency's pharmacovigilance programme and the planning of modifications to business processes by medicines regulatory authorities and pharmaceutical companies.

Other topics to be addressed include the revision of the Guideline on Good Pharmacovigilance Practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products with main focus on the transition to the ISO/ICH E2B(R3) format as well as updates on MedDRA provided by the Maintenance Support Service Organisation (MSSO).

The Information Day will conclude with a summary of the first year of the operation of the medical literature monitoring and ICSR reporting by the Agency.

KEY TOPICS

- Adverse reaction reporting and analysis, EudraVigilance system changes to come
- Definitions, principles, processes and reporting of ICSRs in R3 format: what will change with the revision of GVP Module VI?
- Preparing for business change from a medicines regulatory authority and pharmaceutical industry perspective
- One year of medical literature monitoring performed by the Agency – achievements and lessons learned
- MedDRA – latest developments from a user's perspective

TARGET AUDIENCE

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA DEVELOP INNOVATE ADVANCE

REGISTRATION FORM

EudraVigilance Information Day
21 June 2016 European Medicines Agency, London, United Kingdom

ID #16524

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.

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

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❑ **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 #16524 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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