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
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*

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*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.

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DIA reserves the right to include your name and affiliation on the attendee list.

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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.

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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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