EMA EudraVigilance & Signal Management Information Day

24 November 2021
13:30 - 17:30 CEST | Virtual Event

| PROGRAMME COMMITTEE

Paolo Alcini
Head of Data Standardisation and Analytics Service
European Medicines Agency (EMA), EU

Georgy Genov
Head of the Pharmacovigilance Office
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Rodrigo Postigo
Pharmacovigilance Office,
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Gilles Touraille
Pharmacovigilance Office,
European Medicines Agency (EMA), EU

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

| SPEAKERS & PANELISTS

Vicki Edwards
Vice President, Pharmacovigilance Excellence and International QPPV
AbbVie, UK

Nick Halsey
Scientific Administrator, Data Analytics and Methods, Task Force - Healthcare Data, European Medicines Agency, EU

Tom Paternoster-Howe
Scientific Administrator, Data Analytics and Methods, Task Force - Healthcare Data, European Medicines Agency, EU

Florence van Hunsel
Head Signal Detection
The Netherlands Pharmacovigilance Centre Lareb, NL

| OVERVIEW

Based on a Pharmacovigilance Risk Assessment Committee (PRAC) recommendation, the EMA Management Board confirmed and announced the mandatory use of the ISO Individual Case Safety Report (ICSR) standard (ISO 27953-2:2011) based on the ICH E2B(R3) modalities as of 30 June 2022 for all reporting to EudraVigilance. Furthermore, the ISO terminology on pharmaceutical dose forms and routes of administration, (ISO 11239:2012), will also become mandatory at the same time.

This information day will highlight the necessary technical adaptation and implications for the use of the EDQM (European Directorate for the Quality of Medicines & HealthCare) terms to implement the pharmaceutical dose forms and routes of administration.

The COVID-19 pandemic and the authorisation of the vaccines against COVID-19 have a major impact on EudraVigilance and the database plays a crucial role on the signal detection and management activities for the vaccines. The impact on the database and the network together with the main signal management activities and achievements will be also outlined.

An update of the existing ICH E2D (Post Approval Safety Data Management: Definitions and Standard for Expedited Reporting) guideline is proposed to clarify the management of post-approval safety information from new or increasingly used data sources. The revision of the E2D guideline will be an important opportunity to improve the generation of information related to safety and the problem statement together with the objectives will be explored.

Other aspects and milestones in the EudraVigilance operational workplan will be summarised.

| KEY TOPICS

- Mandatory use of ICH-E2B(R3). Implementation of ISO Individual Case Safety Report standard and ISO terminology on pharmaceutical dose forms and routes of administration.
- COVID-19 vaccines. Impact on EudraVigilance and Signal Management.
- Revision of ICH- E2D. Problem statement and objectives
- EudraVigilance Operational Workplan – Key milestones

| TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs)
- Sponsors of Clinical Trials
- Individuals involved in clinical development, information management, safety databases and safety assessment.
- Pharmacovigilance Information Technology Professionals

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

AGENDA | WEDNESDAY, 24 NOVEMBER 2021 | 13:30 – 17:30 CET

13:30 **LOG IN TO VIRTUAL PLATFORM**
WELCOME NOTE
Session Chairs: Georgy Genov & Paolo Alcini, EMA, EU

13:45 **EUDRAVIGILANCE OPERATIONAL PLAN – MILESTONES 2020-2022**
Speaker: Anja van Haren, EudraVigilance Coordinator, MEB, NL

MANDATORY USE OF THE ISO INDIVIDUAL CASE SAFETY REPORT (ICSR) STANDARD AND THE ISO TERMINOLOGY ON PHARMACEUTICAL DOSE FORMS AND ROUTES OF ADMINISTRATION – STAKEHOLDERS CHANGE MANAGEMENT
Speaker: Nick Halsey, EMA, EU

14:45 Q&A with speakers and panelists

15:00 BREAK

15:15 **REVISION OF ICH E2D – SCOPE AND STATUS UPDATE**
Speaker: Vicki Edwards, Abbvie, UK

THE NEW CLINICAL TRIAL LEGISLATION - IMPACT ON EUDRAVIGILANCE
Speaker: Nick Halsey, EMA, EU

16:00 Q&A with speakers and panelists

16:15 BREAK

16:30 **COVID 19 VACCINES – IMPACT ON EUDRAVIGILANCE, CODING GUIDELINES AND TRANSPARENCY ASPECTS**
Speakers : Gilles Touraille & Rodrigo Postigo, EMA, EU

COVID 19 VACCINES ICSRS – A NATIONAL COMPETENT AUTHORITY (NCA) PERSPECTIVE
Speaker: Florence van Hunsel, Lareb, NL

17:15 Q&A with speakers and panelists

17:30 END OF THE INFORMATION DAY

| Disclosure Policy
Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice.

REGISTRATION FORM | ID# 21525

EMA EudraVigilance and Signal Management Virtual Information Day
24 November 2021 13:30 - 17:30 CET | VIRTUAL EVENT

You can register online at www.diaglobal.org/EMA/conference-listing

CATEGORY

Industry (or Representative)*	€ 350.00 ❑
Government/Patients/Academia/Non-Profit (Full-Time)	€ 175.00 ❑

A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA in Basel for more information.

*All fees are subject to the applicable VAT. Payment due 30 days after registration and must be paid in full by commencement of the event.

TOTAL AMOUNT DUE: € _____

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- Tutorial cancellation: € 50.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled, 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.

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The DIA will be pleased to assist you with your registration from Monday to Friday between 08:30 and 17:00 CET.

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