VIRTUAL EVENT

EMA EudraVigilance Information Day

02 December 2020
13:30 - 17:30 CET | Virtual Event

PROGRAMME COMMITTEE

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Gilles Touraille
Scientific Administrator, Pharmacovigilance Office
European Medicines Agency, EU

| Details of Information Day

Date: 02 December 2020
Time: 13:30 – 17:30 hrs CET
Venue: Virtual Event

OVERVIEW

This Information Day will provide an update of some key elements and activities that will impact EudraVigilance and its stakeholders in the coming years. The objective is to outline technical and operational activities with anticipated timelines and to highlight how the database and the users that interact with the system will be affected.

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 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. Guidance on the necessary technical adaptation and implications including updates of the guidelines will be highlighted.

The quality of the ICSRs and the implications on the data analysis will be discussed, in light of the publication of the detailed guide regarding the EudraVigilance data management activities by the European Medicines Agency. In this context, the activities triggered by the COVID-19 pandemic will also be outlined.

After the withdrawal of the UK from the European Union and the foreseen termination of the transition period by end of 2020, the impact of Brexit in the submission of ICSRs and the subsequence database access and outputs will be highlighted.

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.
- Update of the EU ICSR implementation guide
- ICSR quality and guide regarding the EudraVigilance data management activities by the European Medicines Agency. COVID-19 related activities.
- The Brexit impact on EudraVigilance

TARGET AUDIENCE

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

AGENDA | WEDNESDAY, 2 DECEMBER 2020

13:30 LOG IN

13:35 WELCOME NOTE BY THE SESSION CHAIRS

13:45 SESSION 1

MANDATORY USE OF THE ISO ICSR STANDARD AND THE ISO TERMINOLOGY ON PHARMACEUTICAL DOSE FORMS AND ROUTES OF ADMINISTRATION

Session Chairs:
Georgy Genov, Head of Pharmacovigilance Office, EMA, EU
Paolo Alcini, Head of Healthcare Data, EMA, EU

Update of the EU Individual Case Safety Report (ICSR) Implementation Guide (Revision 2)
Anja van Haren, EudraVigilance Coordinator, MEB, NL

Marketing Authorisation Holder's Experiences and Preparedness for the Mandatory Use ICH-E2B (R3) Submissions
Denny Lorenz, PV Digital Program Delivery Lead, Bayer Healthcare AG, Germany

Q&A and Panel Discussion including:
Rodrigo Postigo, Scientific Administrator, Pharmacovigilance Office, EMA, EU
Gilles Touraille, Scientific Administrator, Pharmacovigilance Office, EMA, EU

15:00 BREAK

15:15 SESSION 2

QUALITY OF ICSRS AND DETAILED GUIDE REGARDING THE EUDRAVIGILANCE DATA MANAGEMENT ACTIVITIES BY THE EMA

Session Chairs:
Georgy Genov, Head of Pharmacovigilance Office, EMA, EU
Paolo Alcini, Head of Healthcare Data, EMA, EU

Eudravigilance Data Management Activities Performed by the EU Network Including Activities to Enhance Monitoring of the Covid-19 ICSRs
Tom Paternoster-Howe, Scientific Administrator, Data Analytics and Methods, Task Force - Healthcare Data, EMA, EU

ICSRs Data Quality and Impact on Data Analysis and Safety Monitoring
Majella Quinn, Pharmacovigilance Compliance Assessor, Health Products Regulatory Authority, Ireland

Q&A and Panel Discussion including:
Rodrigo Postigo, Scientific Administrator, Pharmacovigilance Office, EMA, EU
Gilles Touraille, Scientific Administrator, Pharmacovigilance Office, EMA, EU

16:30 BREAK

16:45 SESSION 3

IMPACT OF BREXIT AND THE NORTHERN IRELAND PROTOCOL ON EUDRAVIGILANCE

Session Chairs:
Georgy Genov, Head of Pharmacovigilance, EMA, EU
Paolo Alcini, Head of Healthcare Data, EMA, EU

Impact of Brexit and the Nothern Ireland Protocol on EudraVigilance
Nick Halsey, Scientific Administrator, Data Analytics and Methods, Task Force - Healthcare Data, EMA, EU

Q&A and Panel Discussion including:
Rodrigo Postigo, Scientific Administrator, Pharmacovigilance Office, EMA, EU
Gilles Touraille, Scientific Administrator, Pharmacovigilance Office, EMA, EU

17:30 END OF THE VIRTUAL INFORMATION DAY