



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance project: Launch of the new system

12th industry stakeholder platform – 24 November 2017

Francois Domergue – EudraVigilance business project manager



Project milestones

- Independent audit report completed in February/April 2017
- Favourable PRAC recommendation in May 2017
- Confirmation and announcement by the EMA Management Board that full functionality of the new EudraVigilance database has been achieved on 22 May 2017
- Transition period for the launch of the new system: 8 November to 21 November 2017
- **Go-live of the new EV system: 22 November 2017**

EudraVigilance go-live activities

- Transition period for the launch of the new system:
 - 8 November to 21 November 2017
- Scheduled EudraVigilance downtime was communicated to all stakeholders.
- EudraVigilance go-live plan and technical note were published on 4 October.
- EMA project team completed the activities for the system installations and data migration according to plan.
- Key decision points were set-up during this process to
 - ensure control/checks;
 - decide to communicate to NCAs/MAHs in case of delays/issues.

EudraVigilance go-live

- As of 22 November the new EudraVigilance System is live



- It was a major undertaking
- It was a joint effort between all stakeholders
- There was/is excellent collaboration with NCA experts in Member States and pharmaceutical industry
- It is a really great team that delivered



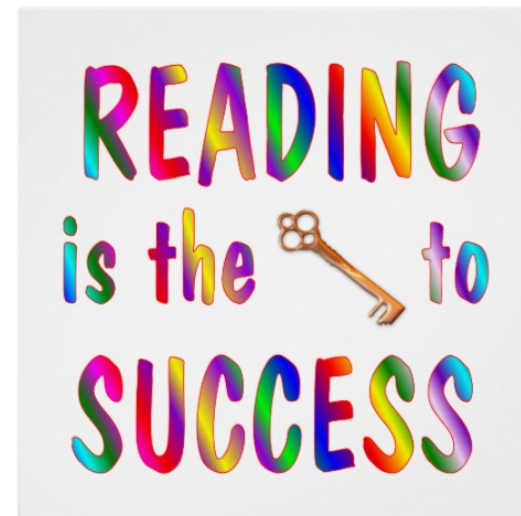


Expected benefits

New feature	Benefit
<ul style="list-style-type: none">Enhanced signal-detection and data-analysis tools to support safety monitoring directly by Member States and marketing authorisation holders	<ul style="list-style-type: none">Better detection of new or changing safety issues, enabling rapid action to protect public health
<ul style="list-style-type: none">Improved quality and completeness of ICSR data	<ul style="list-style-type: none">Better searchability and more efficient data analysis
<ul style="list-style-type: none">Enhanced scalability of the EudraVigilance system	<ul style="list-style-type: none">Able to support an increased number of ICSRs due to the new requirement to report non-serious cases to EudraVigilance
<ul style="list-style-type: none">Simplified reporting of ICSRs to EudraVigilance and the rerouting of ICSRs to Member States	<ul style="list-style-type: none">Reduced duplication of effortsMarketing authorisation holders no longer have to provide ICSRs to national competent authorities, they have to submit these to EudraVigilance only
<ul style="list-style-type: none">EMA will provide data to the World Health Organization (WHO) Uppsala Monitoring Centre directly from EudraVigilance	<ul style="list-style-type: none">Enhanced collaboration between EMA and WHOMember States will no longer need to carry out this task

Stakeholder support and training (1/4)

- e-learning/technical documentation/revised change management plan/user guides/Q&A published on EMA website;
- Recent additions:
 - ADR website user guide – new
 - EVWEB release notes – new
 - XCOMP release notes (updated)
 - EudraVigilance EVWEB user manual (updated)
 - EVDAS user manual for MAHs – new
 - EVDAS release notes for MAHs – new



Stakeholder support and training (2/4)



- ICSR submission face-to-face training courses
 - To be continued in 2018, with increased frequency
- Monthly technical and pharmacovigilance related support webinars in support of MAHs
 - To be continued in 2018

Please consult the ["EudraVigilance training and support"](#) webpage

Stakeholder support and training (3/4)

EudraVigilance training: Face to face training

The new EudraVigilance System and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format: hands-on training course

Email Print Help S

Details

Documents

Multimedia

Title The new EudraVigilance System and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format: hands-on training course

Date 20/11/2017 - 22/11/2017

Location European Medicines Agency, London, UK

Summary The European Medicines Agency (EMA) will launch a new EudraVigilance system with enhanced functionalities for reporting and analysing suspected adverse reactions in November 2017. The system will make use of the individual case safety report (ICSR) standards developed by the International Organization for Standardization (ISO), in collaboration with the International Council for Harmonisation of Technical

Registration


► Places limited

Related content

► EudraVigilance training

Contact point:

Malgorzata Durka-Grabowska
malgorzata.durka-
grabowska@ema.europa.eu



The NEW EudraVigilance System and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format: Hands-on Training Course

Duration: 3 days
Location: European Medicines Agency (EMA)
20 Chancery Place
Canary Wharf
E14 4EU London, UK

OVERVIEW
EudraVigilance is the system for managing and analysing information on suspected adverse reactions to medicines, which have been authorised in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network and will launch a new EudraVigilance system with enhanced functionalities for reporting and analysing suspected adverse reactions in November 2017. The system will make use of the individual case safety report (ICSR) standards developed by the International Organization for Standardization (ISO) in collaboration with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

This hands-on training course covers the functionalities of the new EudraVigilance web application (EudraVigilance) and includes practical examples for creating, sending and accessing ICSRs in the new ISO/ICH E2B(R3) format. It covers reporting principles in accordance with the guidance on good pharmacovigilance practices (GVP) Module VI 'Management and reporting of adverse reactions to medicinal products' and explanations on how to comply with the EudraVigilance business rules and the EudraVigilance Access Policy.

The training course includes a knowledge evaluation for which participants, who pass the evaluation, will receive a notification from the EMA, organisations, which are to use a ICSRs to start the electronic reporting of ICSRs to EudraVigilance for the first time, need to provide such notification for at least one user to be able to successfully register with the EudraVigilance production environment. For more information on the registration process, please consult the EMA website.

LEARNING OBJECTIVES
By the end of this training course, participants should be able to:

- Describe the EudraVigilance system components
- Apply ISO/ICH E2B(R3) rules to safely reporting based on practical examples for initial and follow-up reports, amendment and notification reports, iterations and planned re-submissions, and reports from studies
- Understand how to use EudraVigilance to create, send and access ICSRs and acknowledgements
- Describe the principles of GVP and access by MAHs to use electronic Reaction Monitoring Reports (e-RMRs), the listings and eCSR forms
- Query data faster and download ICSRs using the EudraVigilance ICSR Download functionality, which provides access by marketing authorisation holders (MAHs) to ICSRs submitted by national Competent Authorities (NCAs) in the EEA.

TARGET AUDIENCE
Users of EudraVigilance – New users and users already trained on working with EudraVigilance including:

- Professionals of Marketing Authorisation holders
- Spouses on a licence holder
- National Competent Authorities or those acting on their behalf, in charge of pharmacovigilance and drug safety with obligations to report suspected adverse reactions related to medicines


BACKGROUND KNOWLEDGE
Participants are expected to have prior background knowledge of:


- The EU pharmacovigilance legislation
- GVP Module VI – Management and reporting of adverse reactions to medicinal products
- Customer documents related to the monitoring or safety or efficacy issue of ICSRs
- GVP Module IX – Signal management and related guidance on statistical methods

Further information on the new EudraVigilance system training can be found on the dedicated EMA EudraVigilance training page.

COURSE DATES:

- 17-18 June 2017
- 14-16 June 2017
- 15-17 September 2017
- 19-21 June 2017
- 21-23 June 2017
- 26-28 June 2017
- 4-6 September 2017
- 6-8 September 2017
- 13-15 September 2017
- 18-20 September 2017
- 19-21 September 2017
- 20-22 September 2017
- 9-11 October 2017
- 11-13 October 2017
- 16-18 October 2017
- 18-20 October 2017
- 19-21 November 2017
- 19-21 November 2017
- 20-22 November 2017
- 22-24 November 2017


EudraVigilance





Stakeholder support and training (4/4)

EudraVigilance Information Days

- 15 December 2017
- 16 March 2018
- 7 December 2018

Dec 2017 Info Day presents new EV and signal management activities & results from the IMI WEB-RADR project & social media analytics in phv



EMA EudraVigilance Information Day

Event dates: 15 December 2017
European Medicines Agency, London, United Kingdom

FACULTY

Gaby Grasse, Pharmacovigilance expert, France
John Eklund, Team Manager, Research, Uppsala Monitoring Centre (UMC), Sweden
Linda Hammarik, Netherlands Pharmacovigilance Centre (LNC), The Netherlands
David J Lewis, Global Head of Pharmacovigilance, Novartis Pharma AG, Switzerland
Brian Makiel, Professor of Autonomous Systems, University of Liverpool, United Kingdom (UK)
Sallybeth Mistry, Manager Operations Development and Support, GSK, UK
Joel Rubin, Director - VEH4 Medicines and Healthcare products Regulatory Agency (MHRA), UK, MHRA Chair
Phil Theagance, Signal Management Unit Manager, MHRA, UK
Margaret Walters, Director & Deputy to Quoted Person for Pharmacovigilance, Merck, Sharp & Dohme (MSD), UK

OVERVIEW

The go-live of the new and enhanced EudraVigilance system is a major milestone based on the updated European Union (EU) pharmacovigilance legislation, which brought about significant changes to electronic reporting requirements for suspected adverse reactions to support better safety monitoring for medicines and a more efficient system for stakeholders.

EMA published a first version of the EudraVigilance Change Management Plan in 2015 to assist national Competent Authorities, marketing authorisation holders and sponsors of clinical trials in preparing for the necessary IT changes and business processes.

This EudraVigilance information day provides a forum to discuss the very initial experience of stakeholders with the new EudraVigilance system functionalities following its launch in November 2017: the use of the new ICH Q12 (2015) standard, the improved adverse reaction reporting and the data analysis outputs. The information day will also serve as a platform to experts to raise questions on the practical application of the recently revised GVP Module VI and IX.

In addition, a session is dedicated to summarise the results and achievements of the Innovative Medicines Initiative (IMI) WEB-RADR project, which looked at the development of a dedicated mobile app for patients and healthcare professionals to report suspected adverse reactions to national EU regulators and investigating the potential for publicly available social media data for identifying drug safety issues.

KEY TOPICS

- EudraVigilance auditable requirements project – first go live experience
- The new simplified reporting rules and impact on stakeholders
- Signal management using VIGAS
- Frequently asked questions on the application of GVP Module VI and IX
- IMI WEB-RADR project – achievements and next steps

TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs)
- Sponsors or clinical trials
- Individuals involved in pharmacovigilance, safety databases, signal management and information management
- IT system developers and data managers

PROGRAMME COMMITTEE

Patricio Aliste, Head of Data Standardisation and Analytics Services, European Medicines Agency (EMA), European Union (EU)
Sabine Broth, Principal Scientific Administrator, Pharmacovigilance and epidemiology Department, EMA, EU
Georgy Gerasimov, Head of Signal and Incident Management Service, EMA, EU
Arjo van Haren, EudraVigilance Coordinator, Medicines Evaluation Board (MEB), The Netherlands

DETAILS OF THE INFORMATION DAY
Location: European Medicines Agency
30 Churchill Place
Canary Wharf, London E14 6LL, United Kingdom
Capacity: The event is limited to 100 participants

EUROPEAN MEDICINES AGENCY
EMA

DIA





Stakeholder testing

EudraVigilance **test environment** (XCOMP) remains **available** to support:

- Interoperability testing
- Testing of transition to ICH E2B(R3) format
- Testing of major system changes

EudraVigilance post-go-live



- Increased monitoring of the system and support to users
- An additional EudraVigilance release (release 5) is planned for February 2018 to address potential bugs/issues identified after 22 Nov 2017; any downtime for release 5 is expected to be minimal and of similar nature to previous routine updates
- EudraVigilance operational plan is under development in consultation with the PhV Business Team and PRAC



Thank you for your attention

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU •
United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660
5555

Send a question via our website www.ema.europa.eu/contact

Follow us on  **@EMA_News**