22 November 2017
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Information Management Division

EudraVigilance auditable requirement project

EudraVigilance training plan (version 5)

Project Maintenance Group 1 consultation	11 December 2015
Eudravigilance Expert Working Group consultation	14 December 2015
Pharmacovigilance Risk Assessment Committee (PRAC) consultation	14 December 2015
European Risk Management Facilitation Group (ERMS-FG) adoption	04 February 2016
Heads of Medicines Agency information	16-18 February 2016

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5560
Send a question via our website www.ema.europa.eu/contact

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Versions

Date	Version number	Summary of changes
5 April 2016	1.0	First version of the document
11 August 2016	2.0	Second version of the document. This has been updated in light of the go-live timelines of the EudraVigilance Auditable requirements project. Updates include: • Indication of published modules during the first release, marked as 'Available now'; • Update of publication timelines for user manuals.
05 January 2017	3.0	Third version of the document. This has been updated to reflect changes to the availability timelines of various training modules. Updates include: • Indication of published modules during the first release, marked as 'Available now'.
23 June 2017	4.0	Forth version of the document. Updates include: • Timelines for the publication of user manuals and additional training modules; • Dates of support webinars and technical support webinars marked as 'Dates available now'; • Hands-on training courses on the "NEW EudraVigilance System and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format".
22 November 2017	5.0	Fifth version of the document. Updates include: • Timelines for the publication of user manuals and additional training modules.

1. About this document

1.1. Background

The 'EudraVigilance functionalities to be audited' document, endorsed by EMA Management Board in December 2013, defines the functionalities of EudraVigilance in relation to the key deliverables set out in the pharmacovigilance legislation listed below that will be the subject of an independent audit as referred to in Article 24, paragraph 2 of Regulation (EC) 726/2004.

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- Directive 2001/83/EC on the Community code relating to medicinal products for human use.
- Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.

Based on an independent audit report that takes into account the recommendations of the Pharmacovigilance Risk Assessment Committee (PRAC), the EMA Management Board has confirmed and announced on 22 May 2017 when full functionality of the EudraVigilance database has been achieved and the system meets the defined functional specifications. The new EudraVigilance system was released to all stakeholders/users on 22 November 2017.

1.2. Scope of document

This document details the training curriculum that will be released to all EudraVigilance Stakeholders to prepare them on the changes introduced by the 'EudraVigilance Auditable Requirements' project in the EudraVigilance system.

The intended audience is National Competent Authorities (NCAs), Marketing Authorisation Holders (MAHs) and Sponsors of Clinical Trials

This document details all the training planned at stakeholder level.

The training are organised around 3 areas:

- pharmacovigilance operations;
- EudraVigilance operations;
- IT Systems operations.

Each training area is supported either by:

- e-learning;
- face to face training;
- guidance documents;
- support webinars.

This document has been built in consultation with members of the Project Maintenance Group 1, EudraVigilance Expert Working Group and the Pharmacovigilance Risk Assessment Committee (PRAC), and adopted by the European Risk Management Facilitation Group.

All training materials are published on the EudraVigilance training and support webpage on the EMA website.

2. Training curriculum

2.1. Pharmacovigilance Operations:

2.1.1. **E-learning**

Table 1. Pharmacovigilance Operations: E-learning

Module	Training Topic	Training sub-topic	Learning Objectives	Target audience	Reference documentation	Publication date
PhV-M0	**Introduction to training offering by the EMA**	N/A	This module provides an overview of all training offerings planned by EMA in the area of EudraVigilance, ADR reporting and signal management providing learning paths for new and existing users.	NCAs, MAHs, Sponsors of Clinical Trials	EV Auditable Requirements Training plan	Available now
PhV-M1	**New EudraVigilance functionalities and the 2010 pharmacovigilance legislation – preparing for change**	N/A	This module provides an overview of the pharmacovigilance legislation, which formed the basis for new or enhanced EudraVigilance functionalities. It outlines what steps need to be taken to prepare for changes in business processes and provides an overview of the key milestones and timelines that should be adhere to.	NCAs, MAHs, Sponsors of Clinical Trials	Stakeholder change management plan	Available now
PhV-M2	**Implementing ISO ICSR / ICH E2B(R3)**	a: Key changes for	This module outlines the key principles of the ISO/ICH	NCAs, MAHs, Sponsors of	ICH E2B(R3) Implementation Guide	Available now

Module	Training Topic	Training sub-topic	Learning Objectives	Target audience	Reference documentation	Publication date
		pharmacovigilance	E2B(R3) ICSR standard and guideline and the impact on the collection, reporting and processing of adverse reactions reports. It further highlights the specific EU requirements and the business rules to be adhered to when reports are submitted to EudraVigilance.	Clinical Trials	EU ICSR Implementation Guide	
		b: Backwards and forwards conversion - impact on adverse reaction reporting	This module summarises the key principles to be taken into account as part of the conversion between the two formats during a transitional period and the potential impact on the operation of pharmacovigilance.	NCAs, MAHs, Sponsors of Clinical Trials	ICH E2B(R3) Implementation Guide EU ICSR Implementation Guide Conversion tool and mapping documentation	Available now
PhV-M3	**How to prepare for simplified adverse reaction reporting in the EU**	N/A	This module provides an overview of the principles of the simplified adverse reaction reporting in the EU, how to prepare and the processes that should be discontinued.	NCAs, MAHs, Sponsors of Clinical Trials	REG (EC) 726/2004 GVP Module VI	Available now
PhV-M4	**Revised EudraVigilance Access Policy – how does it impact stakeholders**	N/A	This module provides an overview of the main characteristics of the revised EudraVigilance Access Policy, how stakeholders obtain access to EudraVigilance data in support	NCAs, MAHs, Sponsors of Clinical Trials	Revised EudraVigilance Access Policy REG (EC) 726/2004	Available now

Module	Training Topic	Training sub-topic	Learning Objectives	Target audience	Reference documentation	Publication date
			of their pharmacovigilance obligations. It also outlines the key requirements for personal data protection.			
PhV-M5	**Revised GVP guidelines - updates and impact**	a: Revision of GVP Module VI – what's new	This module describes the updates to GVP Module VI and the impact on the pharmacovigilance activities.	NCAs, MAHs	Revised GVP Module VI ICH/EU ICSR Implementation Guide	Q1 2018
		b: Signal detection methods in EudraVigilance- an introduction to the main principles	This module provides a summary of the key principles of the signal detection methods applied in EudraVigilance.	NCAs, MAHs	Revised Signal detection guideline	Cancelled
		c: Revised GVP Module IX- signal detection and validation by MAHs including EV data	This module describes the requirements and processes for signal detection and management for MAHs based on the principles set out in the revised module of GVP IX.	MAHs	Revised GVP Module IX Commission IR 520/2012	Cancelled
		d: Revised GVP Module IX- signal management by NCAs	This module summarises the key changes introduced by the revised module of GVP IX processes for signal detection and management for NCAs.	NCAs	Revised GVP Module IX	Cancelled

2.1.2. **Guidance documents**

Table 2. Pharmacovigilance Operations: Guidance documents

Module	Training Topic	Learning Objectives	Target audience	Reference documentation	Publication date
PhV-G1	**Methodological guidance for Signal Detection**	This will cover methodological aspects of Signal detection for Spontaneous reports. This will be formed by 2 different documents: 1) Addendum to the GVP Module IX called "Methodological Aspects of Signal Detection from Spontaneous Reports. 2) Screening for Adverse Drug Reactions in EudraVigilance (describing the rationale of the assumptions that are reflected in the eRMR such as: ROR, thresholds).	NCAs, MAHs, Sponsors of Clinical Trials	N/A	Available now

2.1.3. **Webinars**

Table 3. Pharmacovigilance operations: webinars

Module	Training Topic	Learning Objectives	Target audience	Reference documentation	Publication date
PhV-W1	**Operational pharmacovigilance and EudraVigilance webinars**	The webinars will focus on: • Operation of pharmacovigilance with main focus on the latest revision of GVP Modules VI "Management and reporting of adverse reactions to medicinal	NCAs: • Experts with obligations to report suspected adverse reactions related to medicines and to perform	N/A	Dates available now

Module	Training Topic	Learning Objectives	Target audience	Reference documentation	Publication date
		products" and IX "Signal management" • Procedural and implementation planning questions related to the launch of the new EudraVigilance System, including the use of the new ICH E2B(R3) Individual Case Safety Report (ICSR) format, the use of EVDAS for signal detection, organisation and user registration, and EudraVigilance Access Policy.	signal management • Users of EudraVigilance (EVWEB and EVDAS)		
PhV-W2	**Operational pharmacovigilance and EudraVigilance webinars**	The webinars will focus on: • Operation of pharmacovigilance with main focus on the latest revision of GVP Modules VI "Management and reporting of adverse reactions to medicinal products" and IX "Signal management" • Procedural and implementation planning questions related to the launch of the new EudraVigilance System, including the use of the new ICH E2B(R3) Individual Case Safety Report (ICSR) format, the use of EVDAS for signal detection, organisation and user registration, and EudraVigilance Access Policy.	MAHs, Sponsors of Clinical Trials: • Experts with obligations to report suspected adverse reactions related to medicines and to perform signal management • Users of EudraVigilance (EVWEB and EVDAS)	N/A	Dates available now

2.2. EudraVigilance Operations

2.2.1. **E-learning**

Table 4. Eudravigilance Operations: E-Learning

Module	Training Topic	Training sub-topic	Learning Objectives	Target audience	Reference documentation	Publication date
EV- M1	**How to register with EudraVigilance and EVDAS**	N/A	This modules explains the steps and process to be followed to register with EudraVigilance and EVDAS and to how to maintain the registered user information.	NCAs, MAHs, Sponsors of Clinical Trials	Registration instructions	Available now
EV-M2	**Introduction to EV system components and system functionalities**	N/A	This module outlines the EV system components and system functionalities.	NCAs, MAHs, Sponsors of Clinical Trials	EVWEB user guide	Available now
EV-M3	**Reporting of ICSRs for EV users**	a: EV-Gateway, WEB-Trader and EV-Post functions	This module describes the EudraVigilance Gateway, and how different EudraVigilance users interact can interact with the gateway in fulfilling their pharmacovigilance obligations.	NCAs, MAHs, Sponsors of Clinical Trials	EVWEB user guide	Available now
		b: Introduction to EVWEB	This module provides instructions on accessing the EudraVigilance web reporting application (EVWEB) and provides an introduction to the functionality that can be accessed via the EVWEB application.	NCAs, MAHs, Sponsors of Clinical Trials	EVWEB user guide	Available now

Module	Training Topic	Training sub-topic	Learning Objectives	Target audience	Reference documentation	Publication date
		c: Export functions in EVWEB	This module provides detailed information regarding the ICSR export tool available via the EudraVigilance web reporting application (EVWEB). It also outlines how the EudraVigilance Access Policy is implemented within the EVWEB application, and how the ICSR export tool can be used to obtain information from the database in accordance with this policy.	NCAs, MAHs, Sponsors of Clinical Trials	EVWEB user guide	Available now
		d: Create and send ICSRs using EVWEB	This module provides detailed information regarding the functionality available in the “create and send ICSRs” section of the EudraVigilance web reporting application (EVWEB). It also provides instructions on carrying out core EVWEB activities in this section, including the creation, validation and submission of ICSRs in EVWEB.	NCAs, MAHs, Sponsors of Clinical Trials	EVWEB user guide	Available now
		e: Special reporting scenarios in	This module provides detailed information regarding specific	NCAs, MAHs, Sponsors of	EVWEB user guide	Available now

Module	Training Topic	Training sub-topic	Learning Objectives	Target audience	Reference documentation	Publication date
		EVWEB	reporting scenarios including: • Patient death cases –related & unrelated deaths • SUSARs reporting • Nullifications and Amendments • Parent child reports • Creating follow-ups	Clinical Trials		
EV-M5	**EVDAS training**	a: EVDAS Training for MAHs	This module is targeted at MAHs focusing on EVDAS functionalities they can use in support of their pharmacovigilance obligations and the use of the EVDAS outputs such as line listings and ICSR forms.	MAHs	EVDAS Report manual	Available now
		b: EVDAS training for NCAs	This module is targeted at NCAs focusing on EVDAS functionalities they can use in support of their pharmacovigilance obligations and the use of the EVDAS outputs such as line listings and ICSR forms.	NCAs	EVDAS Report manual	Available now
EV-M6	**ADRreports.eu**	N/A	This module provides an overview of the ADRreports.eu	Public		Available now

Module	Training Topic	Training sub-topic	Learning Objectives	Target audience	Reference documentation	Publication date
	portal		portal, which provides public access to reports of suspected side effects submitted to the EudraVigilance system by national medicines regulatory authorities and pharmaceutical companies that hold marketing authorisations for medicines in the European Economic Area. In addition to outlining the utility of the portal, this module also details the enhancements that will be made to the portal starting from November 2017.			
EV-M7	**Medical Literature Monitoring by EMA**	N/A	This module provides an overview of the changes to the MLM service.	MAHs		Available now

2.2.2. **Face to Face**

Table 5. Eudravigilance Operations: Face to Face

Module	Training Topic	Training sub-topic	Learning Objectives	Target audience	Reference documentation	Publication date
EV-F1	**EVDAS train the trainer course (Face to face) for NCAs**	N/A	This training course will provide participants hands-on experience to familiarise with the new functionalities and is	NCAs: • Users of EudraVigilance	EVDAS Report manual	Dates available now. Registration via EU Network Training Centre

Module	Training Topic	Training sub-topic	Learning Objectives	Target audience	Reference documentation	Publication date
			aimed at competent EVDAS users (preferably), who have attended previous EVDAS training and/or have practical experience.	(EVDAS)		Learning Management System (LMS)
EV-F2	**The NEW EudraVigilance System and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format** **(Face to Face)**	N/A	This hands-on training course covers the functionalities of the new EudraVigilance web application (EVWEB). It includes practical examples for creating, sending and accessing ICSRs in the new ISO/ICH E2B(R3) format.	NCAs, MAHs, Sponsors of Clinical Trials: • Users of EudraVigilance (EVWEB and EVDAS)		Dates available now

2.2.3. **Guidance documents**

Table 6. Eudravigilance Operations: Guidance documents

Module	Training Topic	Learning Objectives	Target audience	Reference documentation	Publication date
EV-G1a	**MAH's level 1 access via EVDAS**	To describe how MAHs can access EVDAS to run eRMR reports, line listing and ICSR forms.	MAHs		Available now
EV-G1b	**eRMR for NCA; structure and key activities in screening**	To describe how NCAs can access EVDAS to run eRMR reports, line listing and ICSR forms.	NCAs		Available now

Module	Training Topic	Learning Objectives	Target audience	Reference documentation	Publication date
EV-G2	**EVDAS Report Manual**	Detailed guide to support EVDAS users and describing OBIEE functionalities (run, save, export reports in EVDAS) and key EVDAS functionalities. The manual will describe functionality common to every report in EVDAS as well as information specific to individual reports covered in annexes for the following: • Annex 1: ROR reports • Annex 2: eRMR reports • Annex 3: Data quality reports • Annex 4: Art.57 reports • Annex 5: Signal detection (general) • Annex 6: PSUR simplified reports • Annex 7: Creation of report by NCAs in EVDAS	NCAs, MAHs		Available now
EV-G3	**ADR website user guide**	Update of guidance document published on ADR website.	NCAs, MAHs, Sponsors of Clinical Trials		Available now
EV-G6	**ICSR form user manual**	To describe the new ICSR form, replacing the existing CIOMS I form.	NCAs, MAHs, Sponsors of Clinical Trials		Available now
EV-G7	**EVWEB User Guide**	Guide to support users of the EVWEB application.	NCAs, MAHs, Sponsors of Clinical Trials		Available now

2.2.4. **Webinars**

Eudravigilance Operations: Webinars

Module	Training Topic	Learning Objectives	Target audience	Reference documentation	Publication date
EV-W1	**Operational pharmacovigilance and EudraVigilance webinars**	The webinars will focus on: • Operation of pharmacovigilance with main focus on the latest revision of GVP Modules VI "Management and reporting of adverse reactions to medicinal products" and IX "Signal management" • Procedural and implementation planning questions related to the launch of the new EudraVigilance System, including the use of the new ICH E2B(R3) Individual Case Safety Report (ICSR) format, the use of EVDAS for signal detection, organisation and user registration, and EudraVigilance Access Policy.	NCAs: • Experts with obligations to report suspected adverse reactions related to medicines and to perform signal management • Users of EudraVigilance (EVWEB and EVDAS)	N/A	Dates available now
EV-W2	**Operational pharmacovigilance and EudraVigilance webinars**	The webinars will focus on: • Operation of pharmacovigilance with main focus on the latest revision of GVP Modules VI "Management and reporting of adverse reactions to medicinal products" and IX "Signal management" • Procedural and implementation planning questions related to the launch of the new EudraVigilance System, including the use of the new ICH E2B(R3) Individual Case Safety Report	MAHs, Sponsors of Clinical Trials: • Experts with obligations to report suspected adverse reactions related to medicines and to perform signal	N/A	Dates available now

Module	Training Topic	Learning Objectives	Target audience	Reference documentation	Publication date
		(ICSR) format, the use of EVDAS for signal detection, organisation and user registration, and EudraVigilance Access Policy.	management • Users of EudraVigilance (EVWEB and EVDAS)		

2.3. IT system Operations:

2.3.1. **E-learning**

Table 7. IT system Operations: E-learning

Module	Training Topic	Learning Objectives	Target audience	Reference documentation	Publication date
IT-M1	**ISO ICSR standard implementation for IT system developers**	This module is focusing on the ISO ICSR standards implementation with main focus on IT systems	NCAs, MAHs, Sponsors of Clinical Trials	ICH/EU ICSR Implementation Guide and XML sample instances	Available now
IT-M2	**Instructions on how to test ICSR submissions to EV**	This module outlines the approach as how testing should be performed for the new ISO ICSR format.	NCAs, MAHs, Sponsors of Clinical Trials	Testing instructions	Available now

2.3.2. Webinars

Table 8. IT system Operations: Webinars

Module	Training Topic	Learning Objectives	Target audience	Reference documentation	Publication date
IT-W1	**Technical support webinars**	Webinar to support users, with main focus on IT system implementation/upgrade, pharmacovigilance/safety databases and testing performed with the new EudraVigilance test environment (XCOMP).	NCAs: • IT experts responsible for adaptations of national pharmacovigilance/safety system	N/A	Dates available now
IT-W2	**Technical support webinars**	Webinar to support users, with main focus on IT system implementation/upgrade, pharmacovigilance/safety databases and testing performed with the new EudraVigilance test environment (XCOMP).	MAHs, Sponsors of Clinical Trials: • IT experts responsible for adaptations of national pharmacovigilance/safety system	N/A	Dates available now