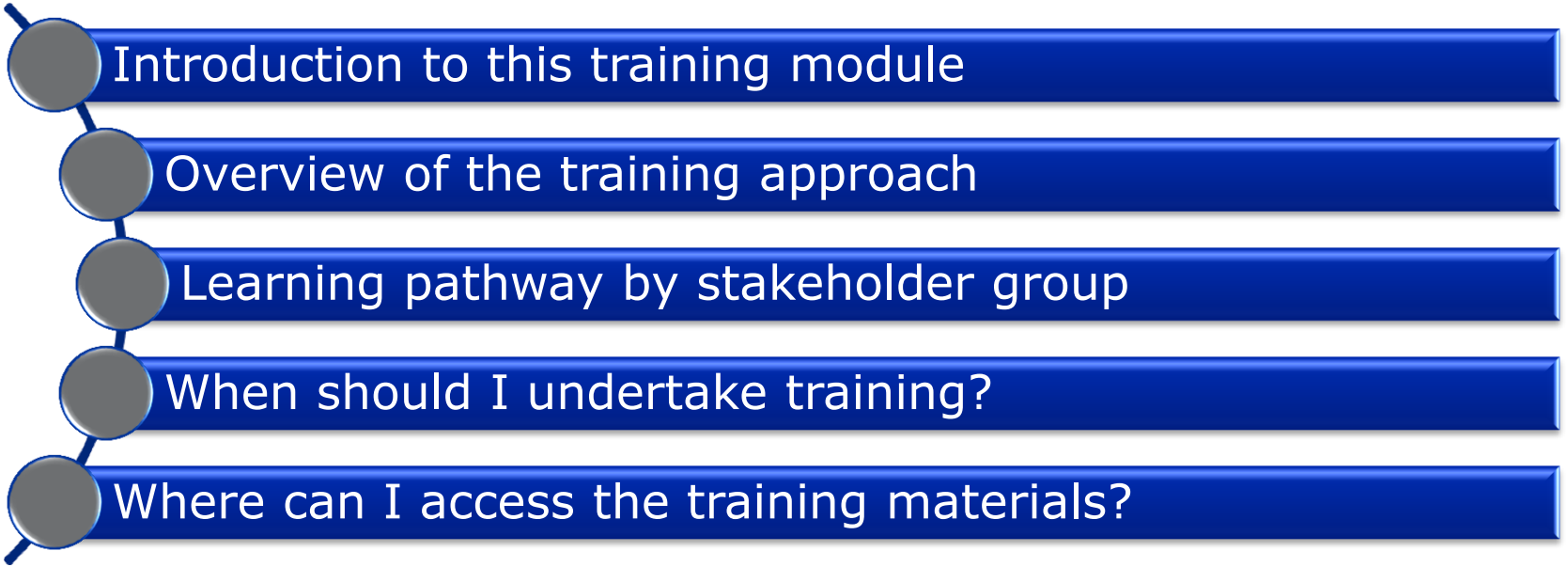
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction to training offering by EMA

Training Module PhV-M0
This module provides an overview of all training offerings planned by EMA in the area of EudraVigilance, EVDAS, ADR reporting and signal detection providing learning paths for new and existing users

Overview of Module PhV-M0



- Introduction to this training module
- Overview of the training approach
- Learning pathway by stakeholder group
- When should I undertake training?
- Where can I access the training materials?

Introduction: Audience

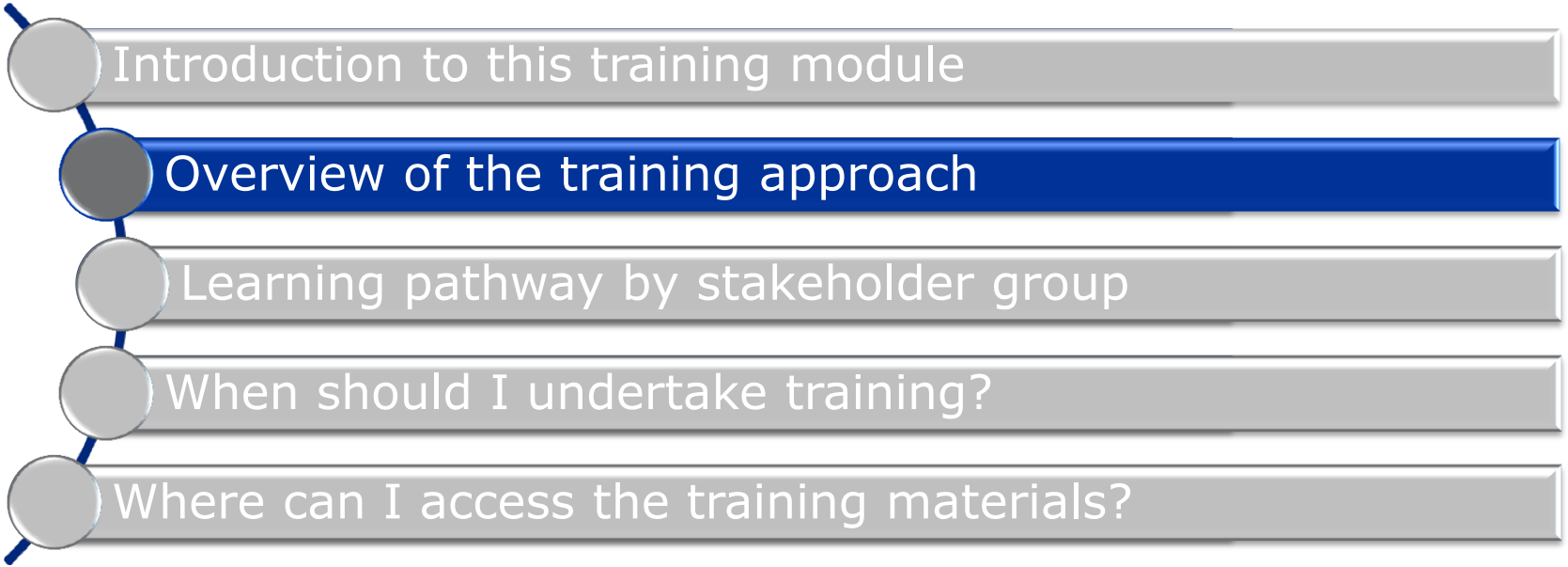
Target audience for this training module:

- National Competent Authorities (NCAs) in the European Economic Area (EEA)
- Marketing authorisation holders (MAHs)
- Sponsors of Clinical Trials

Introduction: Learning Objectives

At the end of module PhV-M0 you should be able to:

- Understand the training offerings by the EMA in the area of EudraVigilance, EVDAS, ADR reporting, signal detection
- Apprehend which training modules are relevant from the perspective of an NCA, MAH, Sponsor of clinical trial
- Understand where to access the training materials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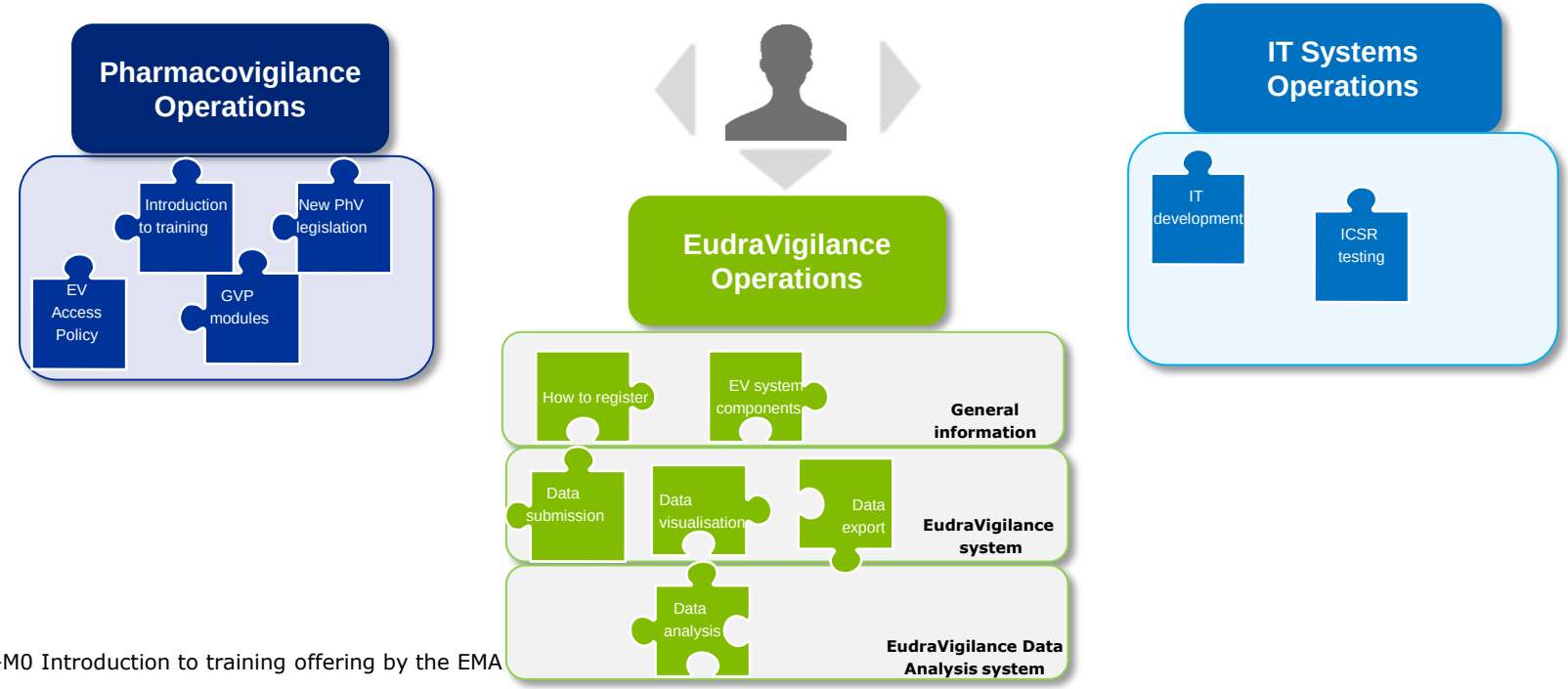
Training curriculum areas (1 of 2)

Training is organised by subject matter around three areas:

Pharmacovigilance Operations	Modules detailing the key changes in pharmacovigilance legislation, standards and guidelines and the impact of these on pharmacovigilance activities
EudraVigilance Operations	Modules describing the EudraVigilance and EVDAS functionalities and components, as well as the various data analysis, submission, visualisation and reporting options
IT Systems Operations	Modules providing instructions on the modifications required to prepare internal systems for the EudraVigilance system enhancements

Training curriculum areas (2 of 2)

Training areas are organised against the following learning needs:



Training delivery methods

Support through E-Learning
Training is predominately delivered through narrated information videos hosted on the EMA corporate website.

- Optional quizzes are provided for all E-learning modules to enhance user understanding.
- For new users, a mandatory competency assessment will have to be undertaken upon completion of the training courses

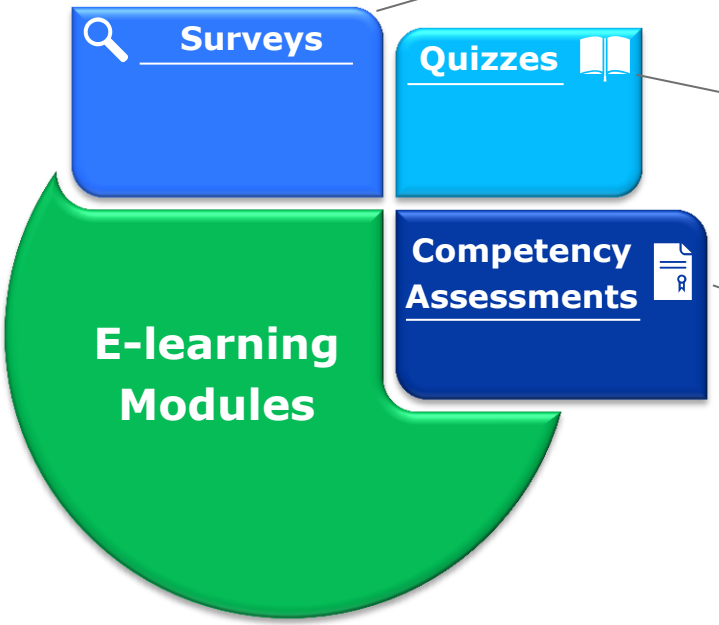
Support through face to face
Face to face training will have limited availability and will be mainly targeted at new users

Support through guidance documentation
Detailed guidance documentation and user manuals will be produced to explain the functionality of each component of the EV system detailing step by step how the system should be used.

In addition, 'contextual help' information will be available online in the new EVWEB interface.

Support through webinars
A series of webinars will be organised over the course of 2017 targeted at NCAs and MAHs. Participants will be reminded 4 days in advance to provide questions (this will help us to start the webinar session) and they will have the opportunity to ask questions during the webinars.

Training module evaluation



Surveys

Feedback on E-learning modules and their attendant user manuals can be submitted via the survey link found on all training materials.

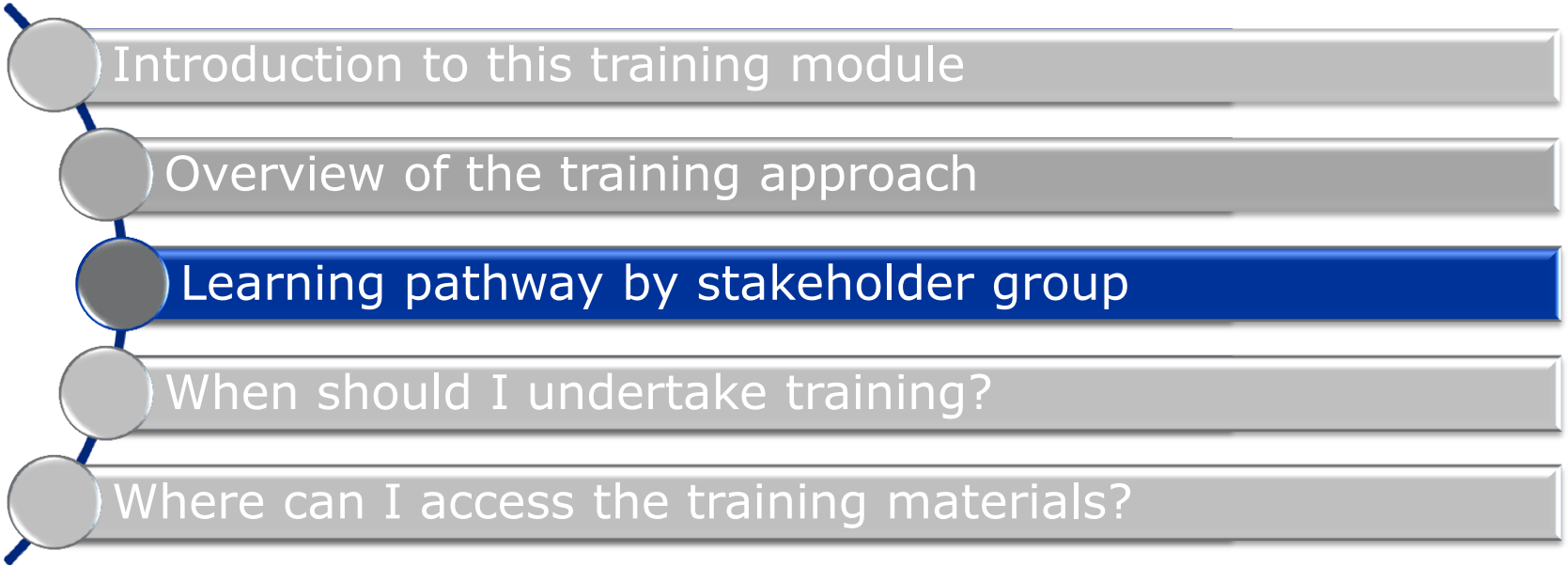
Quizzes

Optional multiple choice quizzes are provided for most E-learning modules to enhance content understanding. These can be accessed via the EudraVigilance training page.

Competency Assessment

A mandatory competency assessment will be undertaken by **new** users.

- One user per organisation will undertake the assessment, who should share acquired knowledge to relevant colleagues within their organisation.
- The assessment will consist of a multiple choice test and assessed simulation of submitting an ICSR.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NCA Learning Pathway

Pharmacovigilance Operations

- New EV functionalities and 2010 pharmacovigilance legislation
- Implementing ISO ICSR/ICH E2B R3
- How to prepare for simplified adverse reaction reporting in the EU
- Revised EV Access policy – impact on stakeholders
- Revised GVP guidelines – updates and impact
- Methodological guidance for Signal Detection
- Revised GVP Module VI
- Revised GVP Module XI
- Pharmacovigilance Operations support webinar

EudraVigilance Operations

- How to register with EudraVigilance and EVDAS
- Introduction to EV system components and system functionalities
- Reporting of ICSRs for EV users
- EudraVigilance export manager and ICSR download
- EVDAS training for NCAs
- EVDAS Report Manual
- EVWEB User Manual
- Patients ADR Website
- EV/EVDAS Functionalities webinar
- EV training on electronic reporting of ICSRs in the EEA (new users)

IT Systems Operations

- ISO ICSR standard implementation for IT system developers
- Instructions on how to test ICSR submissions to EV

Recommended learning

Supporting learning

MAH Learning Pathway

Pharmacovigilance Operations

- New EV functionalities and 2010 pharmacovigilance legislation
- Implementing ISO ICSR/ICH E2B R3
- How to prepare for simplified adverse reaction reporting in the EU
- Revised EV Access policy – impact on stakeholders
- Revised GVP guidelines – updates and impact
- Methodological guidance for Signal Detection
- Revised GVP Module VI
- Revised GVP Module XI
- Pharmacovigilance Operations support webinar

EudraVigilance Operations

- How to register with EudraVigilance and EVDAS
- Introduction to EV system components and system functionalities
- Reporting of ICSRs for EV users
- EudraVigilance export manager and ICSR download
- EVDAS training for MAHs
- Medical Literature monitoring service
- EVWEB User Manual
- MAH Level 1 Access to EVDAS
- EVDAS Report Manual
- Patients ADR Website
- EV/EVDAS Functionalities webinar
- EV training on electronic reporting of ICSRs in the EEA (new users)

IT Systems Operations

- ISO ICSR standard implementation for IT system developers
- Instructions on how to test ICSR submissions to EV

Recommended learning

Supporting learning

Sponsors of Clinical Trials Learning Pathway

Pharmacovigilance Operations

- New EV functionalities and 2010 pharmacovigilance legislation
- Implementing ISO ICSR/ICH E2B R3
- How to prepare for simplified adverse reaction reporting in the EU
- Revised EV Access policy – impact on stakeholders
- Methodological guidance for Signal Detection
- Revised GVP Module XI

EudraVigilance Operations

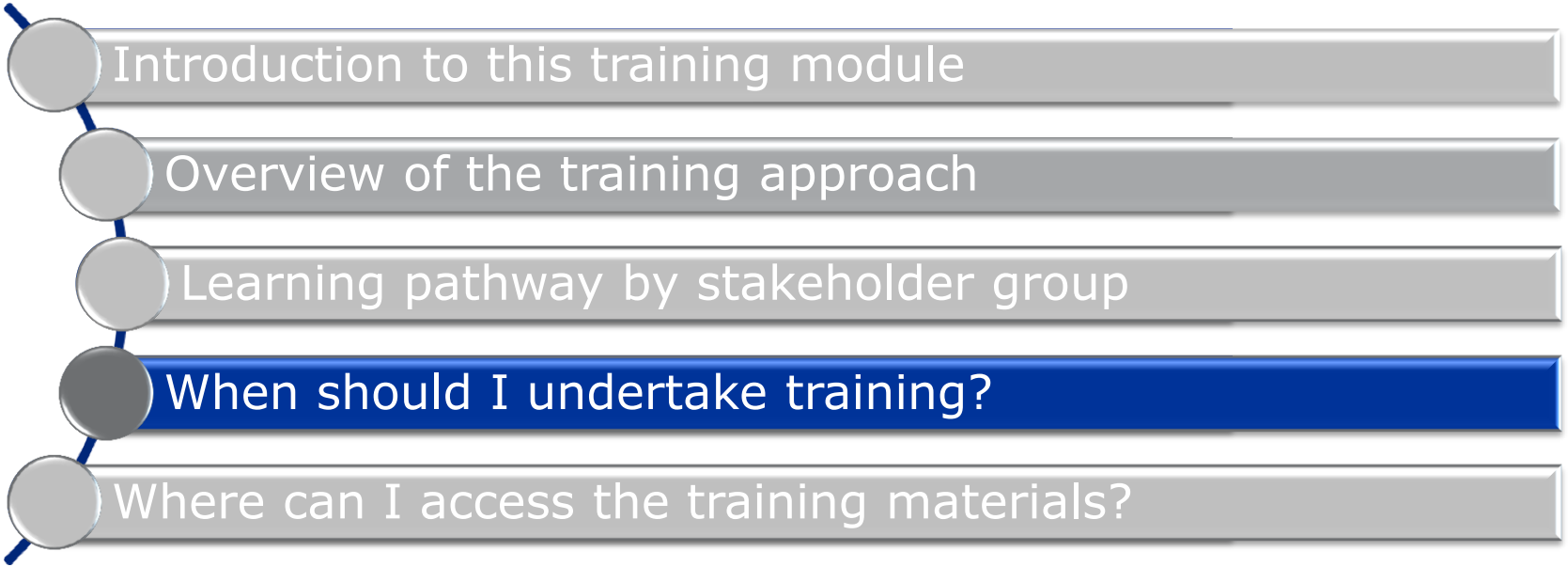
- How to register with EudraVigilance and EVDAS
- Introduction to EV system components and system functionalities
- Reporting of ICSRs for EV users
- EVWEB User Manual
- EudraVigilance export manager and ICSR download
- Patients ADR Website
- EV training on electronic reporting of ICSRs in the EEA (new users)

IT Systems Operations

- ISO ICSR standard implementation for IT system developers
- Instructions on how to test ICSR submissions to EV

Recommended learning

Supporting learning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Stakeholder training planning

Stakeholders are advised to start training well in advance of the new system being implemented with regular, refresher training ahead of the move to simplified reporting.

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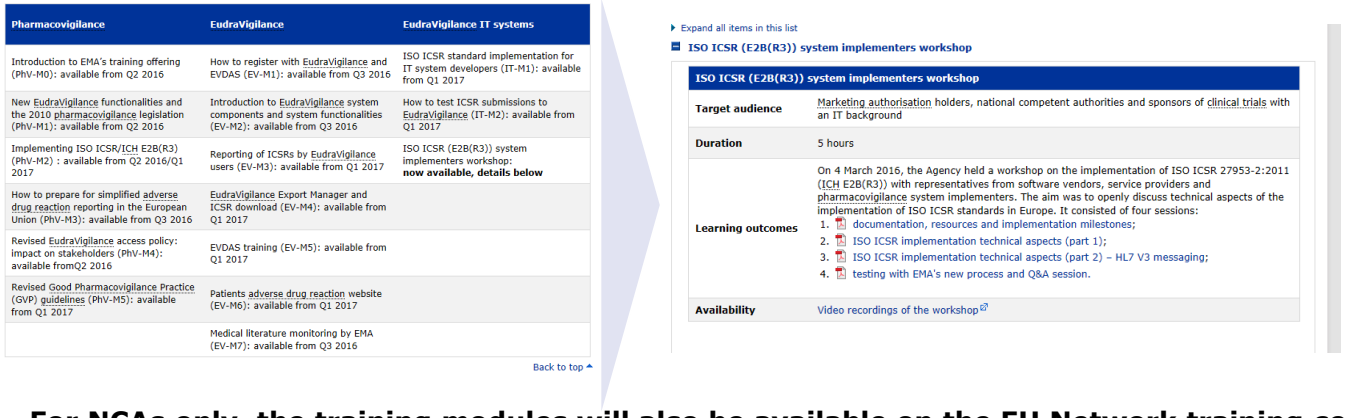
EudraVigilance Training Page

All training modules can be accessed via the EudraVigilance Training Page.

EMA Website -> Human Regulatory ->Pharmacovigilance -> EudraVigilance -> Training page

The e-learning modules are listed as clickable links in the table at the top of the webpage in a navigable table.



Pharmacovigilance	EudraVigilance	EudraVigilance IT systems
Introduction to EMA's training offering (PhV-M0): available from Q2 2016	How to register with EudraVigilance and EVDAS (EV-M1): available from Q3 2016	ISO ICSR standard implementation for IT system developers (IT-M1): available from Q1 2017
New EudraVigilance functionalities and the 2010 pharmacovigilance legislation (PhV-M1): available from Q2 2016	Introduction to EudraVigilance system components and system functionalities (EV-M2): available from Q3 2016	How to test ICSR submissions to EudraVigilance (IT-M2): available from Q1 2017
Implementing ISO ICSR/ICH E2B(R3) (PhV-M2) : available from Q2 2016/Q1 2017	Reporting of ICSRs by EudraVigilance users (EV-M3): available from Q1 2017	ISO ICSR (E2B(R3)) system implementers workshop: **now available, details below**
How to prepare for simplified adverse drug reaction reporting in the European Union (PhV-M3): available from Q3 2016	EudraVigilance Export Manager and ICSR download (EV-M4): available from Q1 2017	
Revised EudraVigilance access policy: impact on stakeholders (PhV-M4): available fromQ2 2016	EVDAS training (EV-M5): available from Q1 2017	
Revised Good Pharmacovigilance Practice (GVP) guidelines (PhV-M5): available from Q1 2017	Patients adverse drug reaction website (EV-M6): available from Q1 2017	
	Medical literature monitoring by EMA (EV-M7): available from Q3 2016	

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ISO ICSR (E2B(R3)) system implementers workshop

ISO ICSR (E2B(R3)) system implementers workshop	
Target audience	Marketing authorisation holders, national competent authorities and sponsors of clinical trials with an IT background
Duration	5 hours
Learning outcomes	On 4 March 2016, the Agency held a workshop on the implementation of ISO ICSR 27953-2:2011 (ICH E2B(R3)) with representatives from software vendors, service providers and pharmacovigilance system implementers. The aim was to openly discuss technical aspects of the implementation of ISO ICSR standards in Europe. It consisted of four sessions: 1. documentation, resources and implementation milestones; 2. ISO ICSR implementation technical aspects (part 1); 3. ISO ICSR implementation technical aspects (part 2) – HL7 V3 messaging; 4. testing with EMA's new process and Q&A session.
Availability	Video recordings of the workshop

Modules will generally contain

- ❑ A summary of learning objectives
- ❑ Target audience
- ❑ E-learning video link
- ❑ Downloadable e-learning slides
- ❑ Supporting materials relevant to the module
- ❑ Quiz link

For NCAs only, the training modules will also be available on the EU Network training centre: http://euntc.eudra.org

Summary of PhV-M0

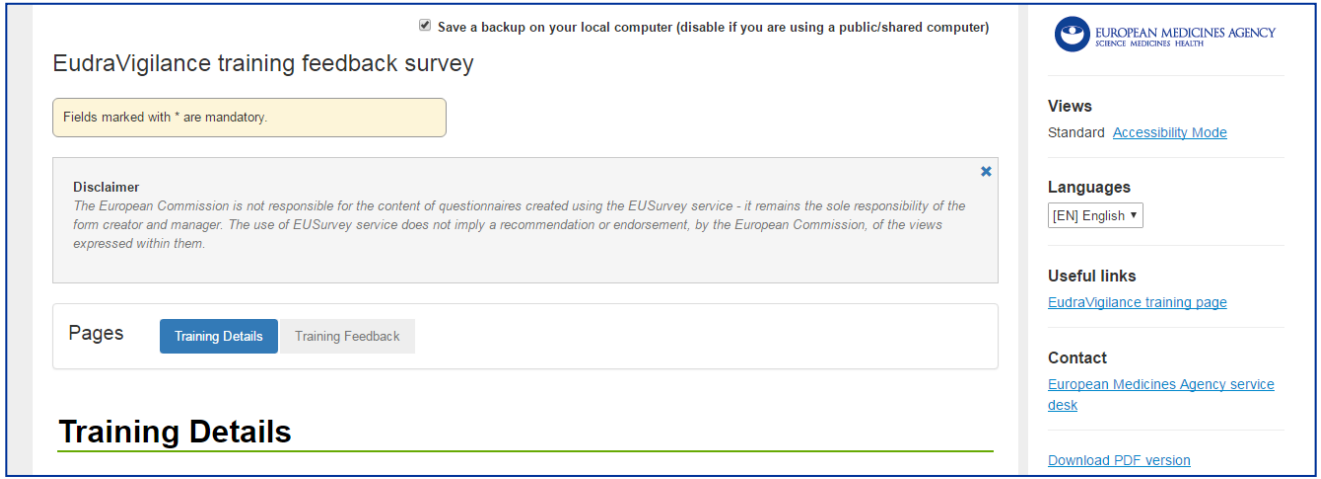
We are now at the end of the training module PhV-M0, which provided you to basis for:

- Understanding the training offerings by the EMA in the area of EudraVigilance, EVDAS, ADR reporting, signal detection
- Apprehending which training modules are relevant from the perspective of an NCA, MAH, Sponsor of clinical trial
- Understanding where to access the training materials and when to start training

Feedback

- Please provide us with feedback on this E-learning module and any attendant guidance documents you have viewed by taking the EMA training survey.

- The survey is accessible via this link.



Acronyms (1)

Acronym	Description
EV	EudraVigilance
EVCTM	EudraVigilance Clinical Trials Module
EVDAS	EudraVigilance Data Analysis System
EVWEB	EudraVigilance Web Application
GVP	Guideline on good pharmacovigilance practices
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICSR	Individual Case Safety Report

Acronyms (2)

Acronym	Description
MAH	Marketing authorisation holder
NCA	National competent authority
PhV	Pharmacovigilance

Thank you for your attention

Further information:
https://servicedesk.ema.europa.eu

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