



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EV Reporting process for users: EV Gateway, WEB-Trader, EV-Post functions

Training Module EV-M3a





Content Summary



A vertical table of contents graphic on the left side of the slide. It consists of a dark blue vertical line with six white circular markers. Each marker is connected to a horizontal bar. The top bar is dark blue with white text, while the others are light gray with white text.

- Introduction
- EudraVigilance Gateway
- Gateway Organisations
- WEB Trader – Post Function Traders
- WEB Trader – EVWEB
- Summary



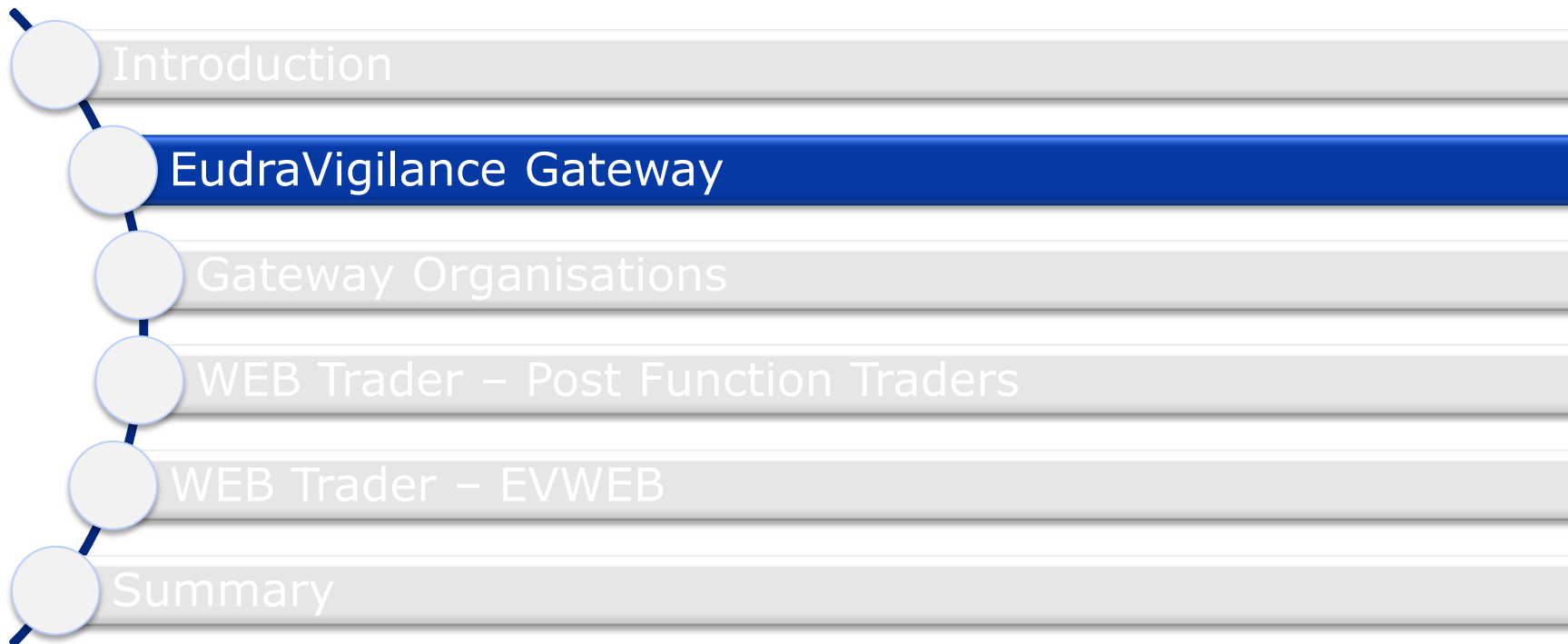
Introduction: Target audience

- Target audience for this training module:
 - National Competent Authorities (NCAs) in the European Economic Area (EEA)
 - Marketing authorisation holders (MAHs)
 - Sponsors of clinical trials (Sponsors)
 - Research institutions/Academia

Introduction: Learning objectives

Following the completion of EV-M3a training module you should be able to understand:

- EudraVigilance Gateway
- EudraVigilance User Types:
 - Gateway organisations
 - WEB Traders - Post Function Users
 - WEB Traders - EVWEB Users

A vertical navigation menu on the left side of the slide, consisting of a dark blue line with six white circular nodes. Each node is connected to a horizontal bar representing a slide topic. The second bar, 'EudraVigilance Gateway', is highlighted in dark blue, while the others are light gray.

- Introduction
- EudraVigilance Gateway**
- Gateway Organisations
- WEB Trader – Post Function Traders
- WEB Trader – EVWEB
- Summary

EudraVigilance Gateway

- Is a hub that has connections for Marketing Authorisation Holders, commercial and non-commercial sponsors and National Competent Authorities.
- All Safety and Acknowledgment Messages are re-routed by the gateway to the appropriate receiver specified in the message.
- When a successful connection has been established, Safety and Acknowledgment Messages can be successfully transferred among all business partners connected to the gateway.



EudraVigilance Gateway

- Provides Secure Messaging
 - Privacy, authentication, integrity and non-repudiation of all transactions
 - Data Encrypted
 - Messages Routed



EudraVigilance Gateway Transmission Protocols

- AS1 – e-Mail based protocol
- AS2 – HTTP based protocol preferred transmission protocol
- Preparing for E2B(R3)
 - The EU Implementation Guide allows for XML E2B(R3) files to be up to 20Mb in file size. Current E2B(R2) are not normally greater than 2Mb.
 - Organisations using AS1 will need to ensure that the e-mail server used by the gateway allows 20Mb file attachments.
 - Note: An email containing a 20Mb attachment will be slightly larger than 20Mb
 - Organisations using AS2 should not be affected by the increase in file sizes



Gateway Trading Partner Configuration for E2B(R3)

Gateway settings used to identify Gateway trading partners

Direct path for sender and receiver IDs:

ICSR/Ack Sender: /MCCI_IN200100UV01/sender/device/id/@extension

ICSR/Ack Receiver: /MCCI_IN200100UV01/receiver/device/id/@extension

Relative path for sender and receiver IDs:

ICSR/Ack Sender: /*/sender/device/id/@extension

ICSR/Ack Receiver: /*/receiver/device/id/@extension



Gateway Trading Partner Configuration for E2B(R3)

- Organisations using the AS1 protocol for their gateway connection should note that they may need to change settings of the e-mail server used by the AS1 protocol in order to allow E2B(R3) XMLs up to 20Mb in size to be sent.
- As the e-mails include headers and routing information in addition to the XML attachment it is recommended to set the e-mail maximum size to at least 25Mb.



WEB Trader Functions

- Is an integrated part of the EudraVigilance Gateway that supports the secure electronic transmission of Safety and Acknowledgment Messages.
- Allows organisations without an automated local gateway solution to send and receive Safety and Acknowledgment Messages through the use of an Internet Browser securely to the EudraVigilance and other registered organisations.



WEB Trader Function

Two forms of WEB Trader are available:

- Sending complete XML files generated by the sender's local pharmacovigilance system (WEB Trader Post Function)
- Creating ICH ICSRs through the EVWEB application and subsequent sending through the WEB Trader Outbox



WEB Trader Functions

Accessible through EVWEB

- Inbox
 - Contains all Safety and Acknowledgment messages that other organisations have sent to the WEB Trader. All messages received, will be displayed in the Inbox
- Outbox
 - Displays the messages the WEB Trader has sent to other organisations (Safety Messages and/or Acknowledgment Messages)



- Introduction
- EudraVigilance Gateway
- Gateway Organisations**
- WEB Trader – Post Function Traders
- WEB Trader – EVWEB
- Summary



Gateway Traders

- **Prerequisites for a Gateway Trader:**
 - Can create E2B(R2/R3) XML ICSRs from their pharmacovigilance database
 - Have an ESTRi compliant automated gateway software solution for exchanging ICSRs and acknowledgments with the EudraVigilance Gateway
- **Gateway Traders:**
 - Have access to EudraVigilance via EVWEB but can not send ICSRs and acknowledgments using EVWEB
 - Can submit Product Messages and Reports using EV-Post or through their own automated gateway



Gateway Organisations

- Gateway submission validation
 - All submissions to the gateway are checked to ensure that they are valid XML E2B(R2) or E2B(R3) files. Invalid XML files or non-XML files are rejected and not processed further.
 - The EudraVigilance system will return an E2B(R3) acknowledgement with error code "AR" for invalid XML files or non-XML files received by the gateway
 - Note: Organisations using EVWEB and EVPOST will not be able to make a invalid submission that could result in an error "AR" acknowledgment being returned

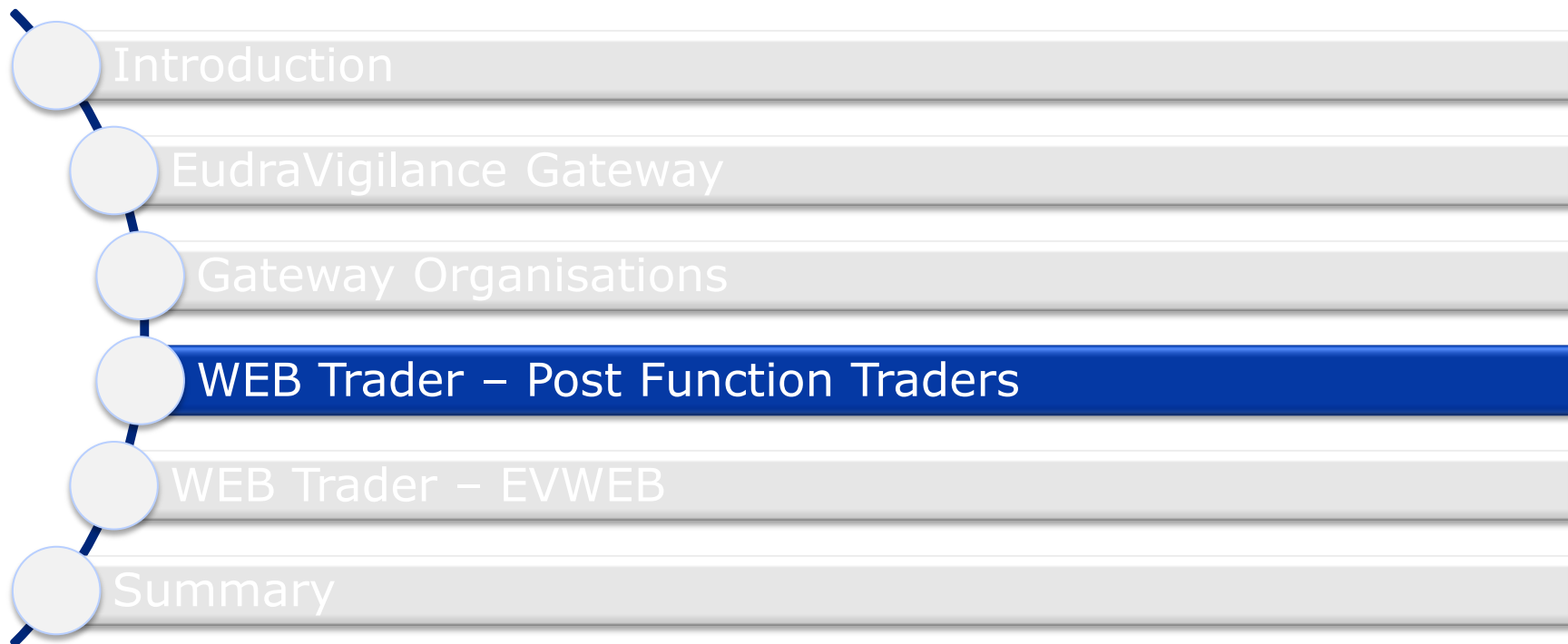
EudraVigilance Acknowledgments

- After the gateway level validation, valid XML file submissions sent to EudraVigilance will go through business rule checks to ensure the data content of the files meet the EU requirements for a valid submission.
- An E2B(R2) acknowledgement will be returned for E2B(R2) ICSRs and an E2B(R3) acknowledgement will be returned for E2B(R3) ICSRs
 - Note: Organisations are permitted to return either E2B(R2) or E2B(R3) acknowledgements for ICSR received in either E2B(R2) or E2B(R3) formats. Therefore, when sending to other organisations you will need to be able to process both Acknowledgement formats. The EU Backwards Forwards Conversion tool can also convert acknowledgements.

EudraVigilance Acknowledgments – Gateway configuration

- In order for organisations sending E2B(R2) ICSRs to be able to process E2B(R3) acknowledgements configuration changes to the sender's gateway maybe required.
- If changes are to be made to an organisation's gateway some communication testing with EVTEST (XCOMP) is strongly encouraged. This should be conducted between June 2017 and October 2017 in order to give time to resolve any issues.
- Full QAT Testing is not required for gateway communication testing, if any issues are encountered during your testing please contact the EMA service desk

<http://servicedesk.ema.europa.eu/>

A vertical table of contents on the left side of the slide. It consists of a dark blue line with six white circular nodes. Each node is connected to a horizontal bar that contains a text label. The bars are light gray with a slight 3D effect, except for the fourth bar, which is dark blue with white text. The labels are: Introduction, EudraVigilance Gateway, Gateway Organisations, WEB Trader – Post Function Traders, WEB Trader – EVWEB, and Summary.

- Introduction
- EudraVigilance Gateway
- Gateway Organisations
- WEB Trader – Post Function Traders**
- WEB Trader – EVWEB
- Summary



WEB Trader – Post Function

- **Prerequisite for Post Function:**
 - Can create XML ICSRs from their E2B compliant pharmacovigilance database
 - Don't have an automated Gateway solution
- **Post-Function Users:**
 - Can send XML ICSRs and acknowledgments using the Post Function
 - Receive ICSRs and acknowledgments through the WEB Trader in EVWEB

WEB Trader – Post Function

- The post function is fully integrated into the EVWEB application
- It allows E2B(R2) or E2B(R3) to be sent to EudraVigilance or other Organisations connected to the gateway
- The post function will prevent XML files being sent if they are invalid format, contains an invalid Message receiver or the Message sender does not match the organisation logged on.
- It will not prevent submissions that do not meet the EudraVigilance business rule requirements



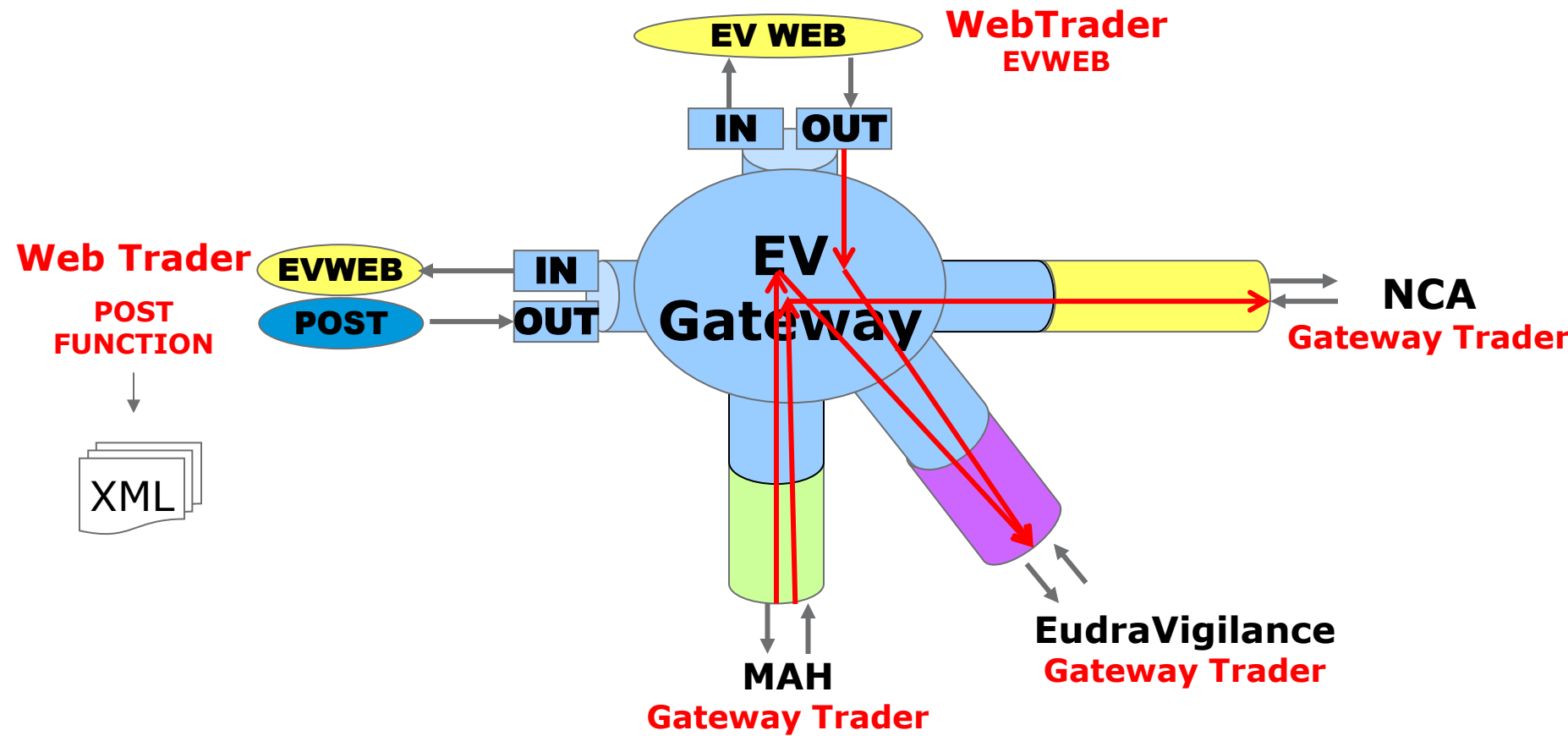


WEB Trader – EVWEB

- EVWEB is an interactive tool that allows the 'manual' creation of E2B(R3) safety messages and either E2B(R2) or E2B(R3) acknowledgement messages using a web browser.
- It is specifically designed for Small and Medium Size Enterprises (SMEs) and non-commercial sponsors, which do not have a fully ICH E2B (R2) or E2B(R3) compliant pharmacovigilance system in place.

A vertical table of contents on the left side of the slide. It consists of a dark blue line with six white circular nodes. Each node is connected to a horizontal bar. The bars are light gray with a slight 3D effect, except for the bottom one which is dark blue. The text on the bars is white. The bottom bar, labeled 'Summary', is highlighted in dark blue.

- Introduction
- EudraVigilance Gateway
- Gateway Organisations
- WEB Trader – Post Function Traders
- WEB Trader – EVWEB
- Summary**





What type of user is my organisation?

Do you have an ESTRIM compliant gateway?	Do you have pharmacovigilance system that can produce E2B(R2) or E2B(R3) files?	User Type
YES	YES	Gateway Trader
NO	YES	Web Trader: Post-Function
NO	NO	Web Trader: EVWEB



Summary

- EudraVigilance Gateway
- EudraVigilance User Types:
 - Gateway organisations
 - WEB Traders - Post Function Users
 - WEB Traders - EVWEB Users



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](#).

Save a backup on your local computer (disable if you are using a public/shared computer)

EudraVigilance training feedback survey

Fields marked with * are mandatory.

Disclaimer

The European Commission is not responsible for the content of questionnaires created using the EUSurvey service - it remains the sole responsibility of the form creator and manager. The use of EUSurvey service does not imply a recommendation or endorsement, by the European Commission, of the views expressed within them.

Pages [Training Details](#) [Training Feedback](#)

Training Details

EUROPEAN MEDICINES AGENCY
SCIENCE. MEDICINES. HEALTH.

Views
Standard [Accessibility Mode](#)

Languages
[EN] English ▾

Useful links
[EudraVigilance training page](#)

Contact
[European Medicines Agency service desk](#)

[Download PDF version](#)

Acronyms (1/2)

Acronym	Description
AS1	Applicability Statement 1
AS2	Applicability Statement 2
ESTRI	Electronic Standards for the Transfer of Regulatory Information
EV	EudraVigilance
HTTP	Hypertext Transfer Protocol
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICSR	Individual Case Safety Reports



Acronyms (2/2)

Acronym	Description
ISO	International Organization for Standardization
MAH	Marketing authorisation holder
NCA	National competent authority
XML	Extensible Markup Language



Thank you for your attention

Further information/ **Contact information**

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**

