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

**Training Module EV-M3a**

# Content Summary

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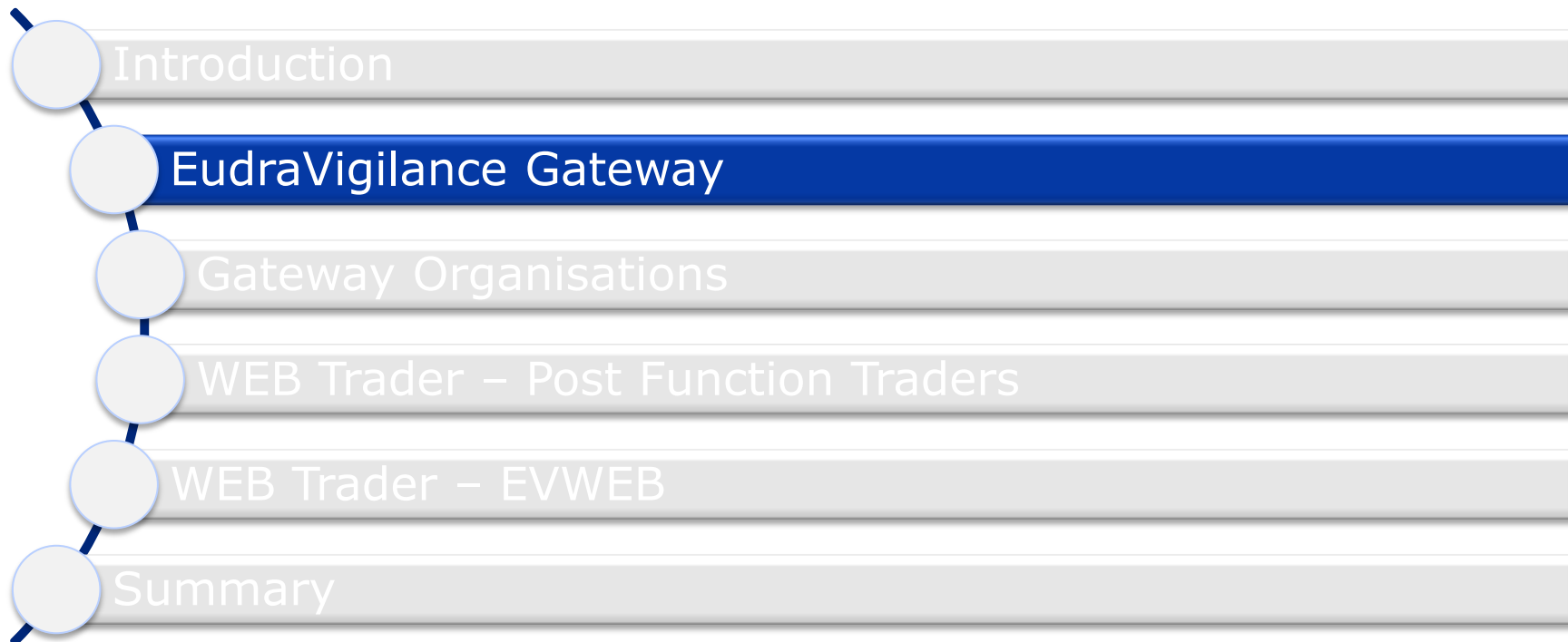
WEB Trader – EVWEB

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

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.
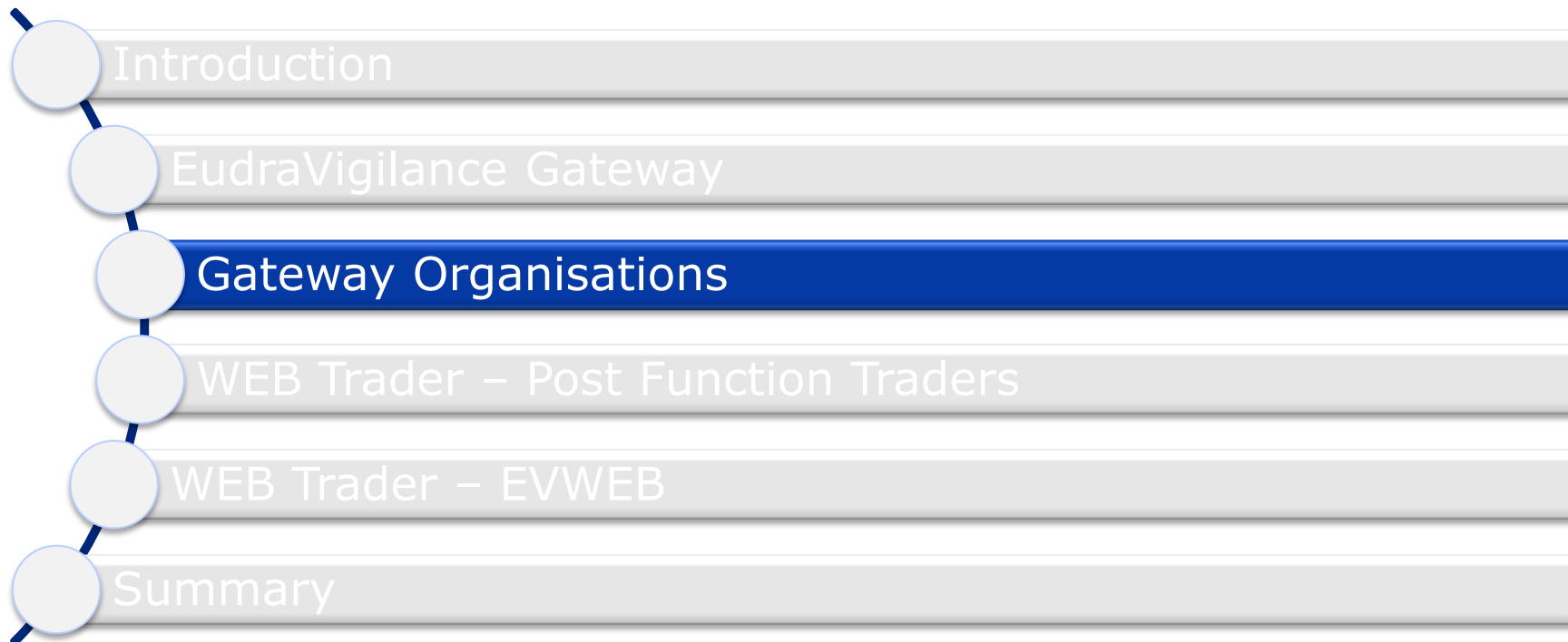
# WEB Trader Function

**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)

# 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
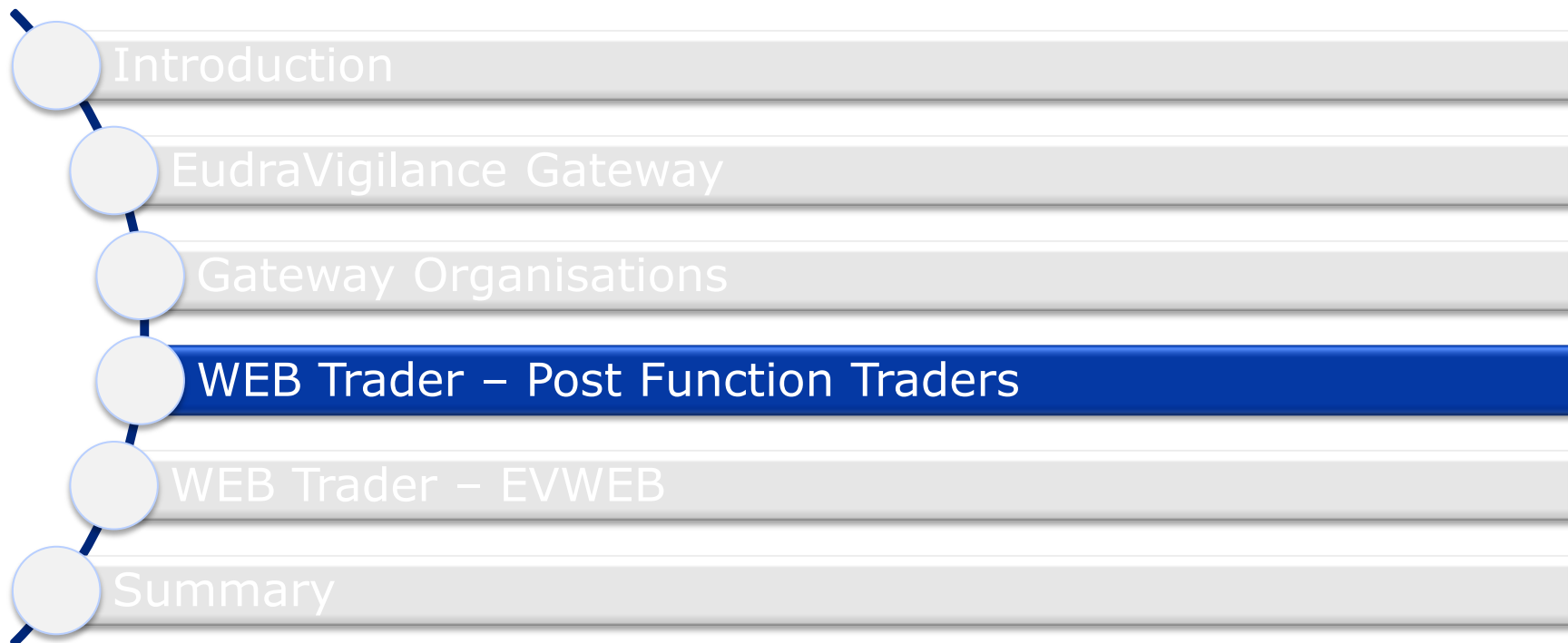
# EudraVigilance Acknowledgments

- 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/

# 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

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

# 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.

Introduction

EudraVigilance Gateway

Gateway Organisations

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WEB Trader – EVWEB

Summary

# What type of user is my organisation?

| Do you have an ESTRI 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.

# 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

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