



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Testing the electronic reporting of ICSRs/SUSARs to EudraVigilance

Training module IT-M2

Instructions on how to test the electronic transmission of
E2B(R3) and E2B(R2) ICSRs/SUSARs to EudraVigilance





Overview Module IT-M2





Version 1.0



Overview Module IT-M2





Introduction: IT-M2

- This training module is intended for EudraVigilance (EV) stakeholders who have to test the E2B (R3)/(R2) compliance of their database in order to use it in production with EudraVigilance
- Organisations (Pharmaceutical companies, Sponsors and National Competent Authorities) that want to register as Gateway or EVPOST user in EV or upgrade their database have to perform the E2B(R3) or (R2) XML testing
- The testing is not required for EVWEB users



Introduction: Learning Objectives

- At the end of the module IT-M2, you should be able to:
 - Register with EudraVigilance
 - Book a test slot
 - Understand what testing to do before testing with the EMA
 - Download test E2B(R3) or E2B(R2) XMLs for testing
 - Perform E2B(R3) or E2B(R2) XML testing
 - Request for your Production profile to be activated



- Introduction
- Registration with EudraVigilance**
- Booking a testing slot
- Gateway Certification and communication/development/validation testing
- E2B(R3) and E2B(R2) XML testing
- Summary

Registration with EudraVigilance (1)

Registration in EV test opened up to all relevant parties:

- NCAs, MAHs, MAAs & Sponsors are able to register individually for both test and production
 - You can register for production at the same time as test, but your production profile will not be activated until testing is complete
 - Registering for both environments at once is strongly advised to minimise any post-testing delays
- PV database developers & PV service providers will also be able to register for testing
 - If you are a CRO/PV database provider & you wish to perform testing directly, email VendorTesting@ema.europa.eu to request that a EudraVigilance test profile is configured
 - When a test profile has been configured, to initiate the testing process you will need to email gattesting@ema.europa.eu with the subject line "Service provider testing request"



Registration with EudraVigilance (2)

- There are different types of electronic exchange solution that an organisation can opt to use:
 - 'Gateway' or 'EV Post' function: new organisations need to register separately to use the external compliance testing environment (XCOMP) and the production environment
 - EVWEB: users (also known as WEB traders) will be registered in the production environment only, unless they also request to use the XCOMP environment
- XCOMP mirrors the EudraVigilance production environment and allows organisations to test the submission of ICSRs and SUSARs
- The testing process is mandatory for organisations submitting safety reports using a gateway solution or the EV Post function

Registration with EudraVigilance (3)

For further information, please refer to:

- Training Module EV-M1: How to register with EudraVigilance and EVDAS
 - Available from the [EV training page](#) on the EMA website
- [EudraVigilance: how to register](#) page on the EMA website

Human Regulatory > Research and development > Pharmacovigilance > EudraVigilance > Registration > EudraVigilance: how to register

EudraVigilance: how to register

Pharmaceutical companies holding or applying for a marketing authorisation in the European Economic Area (EEA), sponsors of clinical trials and national competent authorities in the EEA need to register with **EudraVigilance for the electronic data interchange of pharmacovigilance information. The registration process is a prerequisite for **electronic reporting**.**



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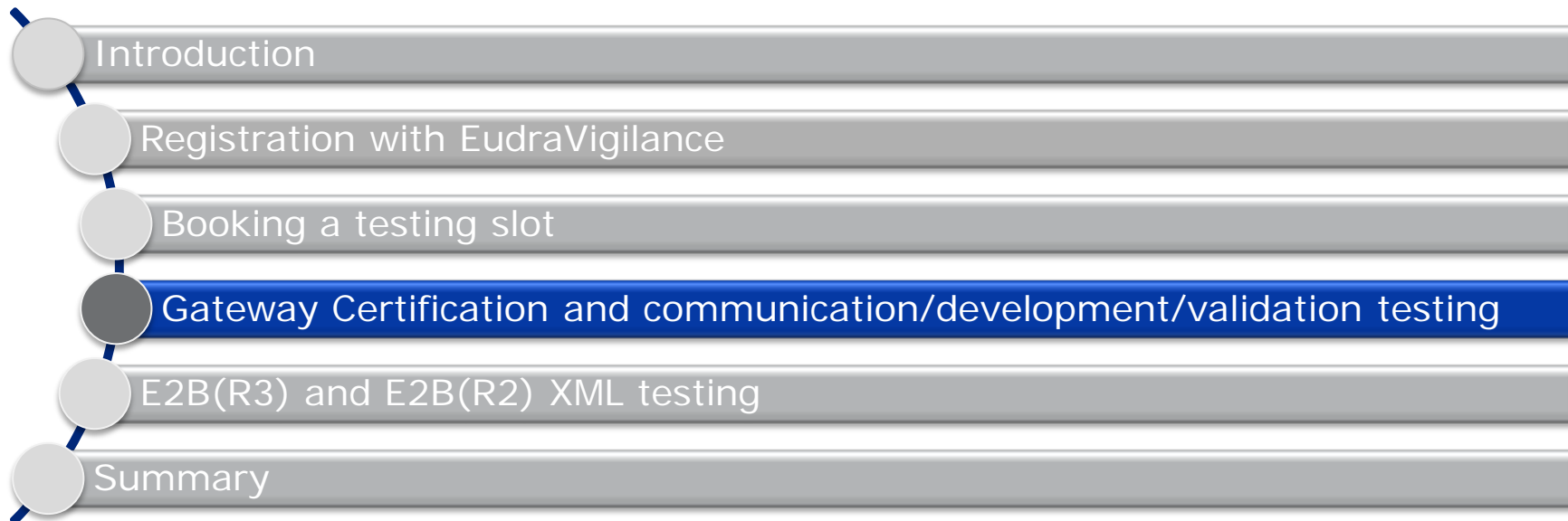


Booking a testing slot

Starting from June 2017:

- Once you are registered in EV test (XCOMP), you may book your test slot
- Numbers will be limited per month & allocated on a first come, first served basis
- All testing will be performed in your allocated window
- Process for booking a slot will be published on the EMA website in June 2017
 - Subscribe to EMA [RSS](#)/[Twitter](#) feeds to ensure you are informed the moment it is published

You can book a test slot at any time before XML testing starts, but if you delay then your desired timeslot may not be available.





Gateway Certification

- Organisations wanting to use the EV Gateway need to confirm that their system is compatible with the EudraVigilance Gateway
- The EMA does not mandate any particular software for the e-reporting of ICSRs/SUSARs, however, the software needs to adhere to the standards outlined in the [EU ICSR Implementation Guide](#)



Communication test

The process of establishing the connection requires several steps:

- Document Transport Choice
- Exchange of Profile Information
- Exchange of Public keys for encryption
- Testing the Connection
 - Testing is accomplished by sending an encrypted Safety Message to the EudraVigilance Gateway, where it is unencrypted, checked for basic accuracy, then re-encrypted and sent to EV



Development & validation testing

- Once connected, organisations have full access to send data to EV in the test environment
- Since XCOMP is a copy of production, including the parser and the MLM environment for downloading, you can use this to validate that your cases meet the EV business rules
- The EMA will not assess the cases you use for validation – you can use this environment as you wish for any development or validation activities
- It is at your discretion if you wish to perform any such validation, however it is strongly recommended that this is done in order to ensure the XML testing runs smoothly



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E2B(R3) and E2B(R2) XML testing (1)

From June 2017 all organisations will be able to begin E2B(R3) testing, including PV database vendors & CROs

- System testing for PV database vendors & CROs
 - Vendors & CROs will be able to perform testing for a specific version & build of their system
 - EMA will confirm if that precise version of the database has passed testing
 - New versions of the system may require re-testing
 - If you are a CRO or a PV database provider you should provide a copy of the relevant tested version to your clients for their registration with EudraVigilance
 - Full testing will NOT be required for organisations using the tested version and configuration
 - If changes are made to the tested version and its configuration for a specific client and if these changes will affect the generation of the XML and/or its contents, the normal testing process will be required for that client



E2B(R3) and E2B(R2) XML testing (2)

- During testing organisations will be required to inform the EMA of the precise version & build of their system
- This information will be held by the EMA & upon request will be passed to Pharmacovigilance inspectors in advance of an inspection



E2B(R3) and E2B(R2) XML testing (3)

- Organisations should note that XCOMP is a shared system used by many registered organisations. Therefore, organisations should ensure that large volumes of data should not be sent to XCOMP in short periods of time.
- Organisations causing issues for other users of XCOMP such as submitting large volumes of data (hundreds of ICSRs/day) are likely to have their access revoked



E2B(R3) and E2B(R2) XML testing (4)

- You should download the test cases, import them into your database, make appropriate changes (see next slide) & transmit the cases to EV
- Please follow the instructions on the [EMA testing webpage](#) on the EMA corporate website in order to obtain either the E2B(R2) or E2B(R3) XMLs needed for your testing

Human Regulatory > Research and development > Pharmacovigilance > EudraVigilance > Electronic reporting > EudraVigilance: electronic reporting

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EudraVigilance: electronic reporting



E2B(R3) and E2B(R2) XML testing (5)

- Change the receive & receipt dates for all cases to the day you downloaded them
- Change the safety report IDs
- If necessary change the drug called “Spare drug” to one of your company’s drugs
 - You can change any of the populated fields, but please do not add data in any other fields
- For the cases with “followmeup” or “nullifyme” in the case number, make the same changes as above & send an initial version, then follow the instructions in the senders comment field (before sending the follow-up versions)
- Send the cases to EVTEST or EVCTMTEST as applicable



E2B(R3) and E2B(R2) XML testing (6)

- Receive and check ACK
- Email gattesting@ema.europa.eu informing them of the Safety Report IDs of the test cases and your sender identifier/organisation name
- EV QA testing team will validate test cases were transmitted successfully and inform you if there are any errors to be corrected or any issues to be fixed



E2B(R3) and E2B(R2) XML testing (7)

Once you have completed testing, you will receive confirmation from the EMA that the specific version & build of your PV database has completed testing & can be used in production

- If you are an MAH, MAA, Sponsor or NCA then you must include this when you contact the EV registration team to activate your production profile
- If you are a CRO/database provider you should provide a copy of this to your clients for their registration
- The confirmation provided upon completion of the testing process through the EudraVigilance test system (XCOMP) is for information purposes only, and does not entail any implicit or explicit recommendation or endorsement by EMA. The electronic data interchange partner is restricted from using this confirmation as an endorsement by EMA.



E2B(R3)/E2B(R2) XML testing for accepted database (1)

If you are purchasing & installing, without customisation, a database that has already passed testing, then there are 5 steps to reporting to EudraVigilance:

1. [Register with EudraVigilance](#)
2. Obtain EudraVigilance Gateway certification (for internet communication)
3. Communication test (to assure successful Gateway to Gateway communication)
4. Single case test (see following slide)
5. Production

Please note that if there is customisation to a purchased database, then full re-testing as on the previous slides will be required.



E2B(R3)/E2B(R2) XML testing for accepted database (2)

- Send a **single case** to EV (EVTEST or EVCTMTEST as applicable)
- Receive and check ACK
- Email gattesting@ema.europa.eu informing them of the single test case's safety report ID & your sender identifier and organisation name
- EV QA testing team will validate the case was transmitted successfully with correct sender ID & case numbers and confirm that the tested PV database can be used in production
 - If you are an MAH, MAA, Sponsor or NCA then you must include this along with the email you received from your CRO or database provider when you contact the EV registration team to activate your production profile



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Summary of IT-M2

We are now at the end of the training module IT-M2, which provided you instructions on how to test the electronic transmission of E2B(R3)/(R2) ICSRs and SUSARs to EudraVigilance

If you are amending your database or if you wish to start electronic transmission of ICSRs for the first time, you should now be able to:

- Register with EudraVigilance and book a test slot
- Understand what to do before formal E2B(R3)/(R2) XML testing
- Download E2B XMLs and perform testing
- Perform XML testing for accepted database
- Request your Production profile to be activated



Further guidance

- [EU Individual Case Safety Report \(ICSR\) Implementation Guide](#) (for R3 XML)
- [Note for guidance – EudraVigilance Human – Processing of safety messages and individual case safety reports \(ICSRs\)](#) (for R2 XML)
- [GVP Module VI – Management and reporting of adverse reactions to medicinal products](#)
- [E2B\(R3\) ICSR Specification and Related Files](#)
- [EudraVigilance support guide](#) (EV Helpdesk)



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.

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Abbreviations/Acronyms (1)

Abbreviation/Acronym	Description
ACK	Acknowledgment message
CRO	Clinical Research Organisation
EMA	European Medicines Agency
EVCTMTEST	EudraVigilance Clinical Trial test module
EVPOST	EudraVigilance Post function
EVTEST	EudraVigilance Post-Authorisation test module
EVWEB	EudraVigilance Web application

Abbreviations/Acronyms (2)

Abbreviation/Acronym	Description
ICSR	Individual Case Safety Report
MAA	Marketing Authorisation Applicant
MAH	Marketing Authorisation Holder
MLM	Medical Literature Monitoring
NCA	National Competent Authority
PV	Pharmacovigilance
SUSAR	Suspected Unexpected Serious Adverse Reaction



Thank you for your attention

Further 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

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