



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session 4

Testing with EMA new process

Workshop on the implementation of ISO standard for ICSRs

Presented by Tom Paternoster-Howe on 4 March 2016
Data Standardisation and Analytics





Agenda

Current process

- 6 steps to e-reporting

New process

- 7 steps to e-reporting
- Alternate process for those using a pre-approved database

Steps you can take right now



Current process



Current process

6 steps to reporting to EudraVigilance:

1. [Register with the EMA](#)*
2. Obtain EudraVigilance Gateway certification (for internet communication)[†]
3. Communication test (to assure successful Gateway to Gateway communication)[†]
4. Development and Validation testing[‡]
5. XML test phase with submission of 10 sample cases**
6. Production*

* [EV registration team](#)

† [EV Gateway team](#)

‡ No interaction with EMA staff – at organisation's discretion

** [EV QA Testing team](#)



Current process: registration

Both test & production registration only open to those with an obligation to transmit ICSRs/SUSARs:

- Nation Competent Authorities (NCAs)
- Marketing Authorisation Holders (MAHs)
- MA Applicants (MAAs)
- Sponsors



Current process: XML testing

Drawbacks of current process:

- Ad-hoc: first-come, first-served basis
 - Can lead to a delay if there is a glut of testing
- No guaranteed response time
- Multiple testing of the same database for different users
- Senders often provide cases
 - Incomplete control of testing of all data fields
- Highly manual:
 - Slow
 - Room for inconsistency



Current process: XML testing

Current testing cannot be performed between 16 May & 31 August 2016 as test environment is reconfigured for new system



New process



New process

7 steps to reporting to EudraVigilance:

1. [Register with the EMA](#)
2. Book a test slot
3. Obtain EudraVigilance Gateway certification (for internet communication)
4. Communication test (to assure successful Gateway to Gateway communication)
5. Development and Validation testing
6. XML test phase with downloading, importing & resubmission of 8 cases
7. Production



New process: registration

Registration in test opened up to all relevant parties:

- NCAs, MAHs, MAAs & Sponsors still 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 the same time 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 gattesting@ema.europa.eu with the subject line "Service provider testing request" and when the relevant profiles have been created you will be assigned one



New process: booking a test slot

Starting from July 2016:

- Once you are registered, book your test slot
- Number 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 EV & EMA websites before July
 - Subscribe to EMA [RSS](#)/[Twitter](#) feeds to ensure you are informed the moment it's published

You can book a test slot at any time before XML testing starts, but if you delay then your desired timeslot may be gone



New process: Gateway certification

Organisations wanting to use the EV Gateway need to obtain a EudraVigilance Gateway certification

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 chapter IV of the [Note for guidance for the Regulatory Electronic Transmission of Individual Case Safety Reports in Pharmacovigilance](#)



New process: 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

New process: development & validation testing

Once connected, organisations have full access to send data to EVWEB in the test environment

Since test 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, but it is strongly recommended to ensure the XML testing runs smoothly

New process: XML testing 1

New process (to start from September 2016):

- Database testing
 - Vendors & CROs can perform testing for a specific version & build of their database
 - EMA will confirm if that precise version of the database passes testing
 - Any changes to the database will require re-testing with the EMA before rolling-out to users
- During testing you will have to inform the EMA of the precise version & build of your database
 - This information will be held by the EMA & will be passed to PV inspectors in advance of any inspection

New process: XML testing 2

8 cases will be provided by the EMA

Users should download the cases (see below for the current process), import them into your database, make appropriate changes (see next slide) & transmit the cases to EV

Download XMLs from test [ICSR Export Manager](#) ([user manual](#))

1. Enter 2015-07-28 as both the start date and end date
 1. these dates may change – precise date information will be on the EV webpage
2. Click “Request” The report will be added to the queue
3. Click “Refresh list” The report will move from the queue to the processed list
4. Click “Download”, save the file locally & import into your system
5. This may require configuring your system to receive cases from the sender MLMSERVICE



New process: XML testing 3

Import the cases into your database

Change the receive & receipt dates for all cases to the day you downloaded them

Change the safety report ID

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 & then send follow-up versions



New process: production

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 registration 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

New process for those using an accepted database

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 the EMA](#)
2. Obtain Eudravigilance Gateway certification (for internet communication)
3. Communication test (to assure successful Gateway to Gateway communication)
4. Single case test
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



New process: single case test

- Send a single case to EV
- Receive ACK
- Email gattesting@ema.europa.eu informing them of the single case test & your sender identifier
- EMA will validate the case was transmitted successfully with correct sender ID & case numbers
- Process should normally take 1 business day



Steps you can take right now



Steps you can take right now 1

Register for test

- If you are not an MAH, email gattesting@ema.Europa.eu to register your interest in testing so that we can create the correct profiles
- If you are already registered in test, then it is not necessary to re-register

Configure database to accept cases from MLMSERVICE

Obtain gateway certification & perform communication test

- If you already have an active profile & will not be changing your gateway, then this is not necessary



Steps you can take right now 2

Download the current test cases and import into your database

- If you are not an MAH, email gattesting@ema.europa.eu to ask for a copy of the cases & we will send them to you

Subscribe to the EMA [RSS](#)/[Twitter](#) feeds

- When the method for booking a testing slot is published, we will publish this information in our news section and all subscribers will be immediately notified