



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 November 2019
EMA/571561/2019
Information Management

EudraVigilance Release Notes v.1.22

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Summary of changes

Date	Version	Summary of change
01/08/2019	1.20	Updated version
08/10/2019	1.20 Corr.	Corrected version (SD-223387 status changed from Closed to Open)
30/10/2019	1.21	Updated version following release of EV registration improvements
04/11/2019	1.22	Updated version following latest MedDRA version 22.1 upgrade

About this document

This document lists and briefly describes the following areas for the releases of the EudraVigilance system. This includes the EudraVigilance messaging system, the EVWEB interface and the EV post function, and the EudraVigilance registration system:

- **What's New:** The enhancements and other changes released (new feature).
- **Known Issues:** The issues that exist (open issue).
- **Fixed Issues:** The issues that are fixed (fixed issue).
- **Points to Note:** The important aspects to keep in mind (point to note).

Release date: 04 November 2019

What is New?

Id	Description
1	The new MedDRA version 22.1 has been implemented in the EudraVigilance system on 4 th November 2019 (12:00:00 CET)
2	<p>The EudraVigilance Registration system has been improved to include:</p> <ul style="list-style-type: none">• a feature to provide users with the ability to update in EV their contact details, under a new tab called "Manage my profile" in the EV restricted area. This feature can be used by the QPPV to change the address information for QPPV codes used in the XEVMPD• a feature to provide users with the ability to update their organization address in EV• a feature to warn users in EV for OMS LOC-ID that have been marked as inactive (disabled): <i>The organization address has been marked as obsolete in OMS. Please inform your Responsible Person to update the organization address under the Manage my organization tab in the EV restricted area.</i> <p>Please refer to the EudraVigilance registration manual published on EMA website</p>

Fixed Issues

Id	Description	Status	PHV/SD issue
1	Business rule 631 "Batch lot number mandatory for all suspected or interacting drugs. Field should be completed with a value or an appropriate null flag" not working as expected in all situations.	Closed	SD-201907
2	New business rule added 831 "Since the element Age at Time of Onset of Reaction / Event (unit) - D.2.2b has a value, the element Age at Time of Onset of Reaction / Event (number) - D.2.2a must contain a value."	Closed	SD-202056
3	Fix to EVWEB, when creating patient death sections that are including nullflavors can cause invalid messages to be created.	Closed	SD-226371
4	ICSR form fix, free text medical history fields D.7.2 not created on the form if no structured medical history information provided.	Closed	SD-245645
5	For invalid ICSR messages submitted in E2B (R2) format, negative ack messages may not be returned to the sender organisation by the EudraVigilance system	Closed	PHV-6643
6	EVWEB users cannot log in when they have used special characters such as '&' and '+' in their EV password	Closed	PHV-6948
7	Printing Bulk Export search criteria. The new print functionality might not complete quickly	Closed	PHV-7369
8	ICSR Download search, case sensitivity issue with worldwide case ID	Closed	SD-188466
9	Routes of administration updated to support ICH version 2.2. Both version 2.1 and 2.2 are supported for sending to EudraVigilance	Closed	SD-192701
10	EVWEB ICSR Sender type (C.3.1) not showing correct value associated with registered Organisation type	Closed	SD-193422
11	When the messaging system is processing many E2B(R2) messages at the same time, a messages can be wrongly classified as non-valid DTD/XSD.	Closed	SD-201882

Known Issues

Id	Description	Proposed workaround	Status	PHV issue
1	Sender organisation type is not displaying correctly in the EVWEB interface and ICSR form for some sponsor organisations of clinical trials	No action required. This is a display issue in EV, EMA confirm that the underlying data is correct.	Open	PHV-6930
2	EVWEB Create and send, users cannot fully remove data in the Test results section field "Result unstructured Data field". This can lead to a validation error message if data are entered in the other structured fields	Users should avoid changing lab test results from unstructured to structured. If information is entered in both fields the user will need to remove the test section affect from the treeview and then re-create it	Open	PHV-7387

Id	Description	Proposed workaround	Status	PHV issue																				
3	<p>Due to the change of the time zone on the EV system on the 29 March 2019, the following data fields will show for data submitted to EV before this date, a 1 hour time difference when viewed in the EVWEB interface or the ICSR form, as compared to the original data submitted to the EV system. This applies to ICSR sent by an organisation (L3 access) or when viewed by a NCA EV user (L3 access).</p> <table border="1" data-bbox="268 748 699 1350"> <thead> <tr> <th>DATA ELEMENT</th> <th>FIELD NAME</th> </tr> </thead> <tbody> <tr> <td>ICH E2B(R3) N.1.5</td> <td>Date of Batch Transmission</td> </tr> <tr> <td>ICH E2B(R3) N.2.r.4</td> <td>Date of Message Creation</td> </tr> <tr> <td>ICH E2B(R3) C.1.2</td> <td>Date of Creation</td> </tr> <tr> <td>ICH E2B(R3) D.2.1</td> <td>Date of Birth</td> </tr> <tr> <td>ICH E2B(R3) D.6</td> <td>Last Menstrual Period Date</td> </tr> <tr> <td>ICH E2B(R3) D.10.2.1</td> <td>Date of Birth of Parent</td> </tr> </tbody> </table> <table border="1" data-bbox="268 1406 699 1648"> <thead> <tr> <th>DATA ELEMENT</th> <th>FIELD NAME</th> </tr> </thead> <tbody> <tr> <td>ICH E2B(R3) ACK.M.4</td> <td>Acknowledgement Date of Batch Transmission</td> </tr> <tr> <td>ICH E2B(R3) ACK.A.3</td> <td>Date of ICSR Batch Transmission</td> </tr> </tbody> </table> <p>L2A/B access will not be impacted as these data fields are not made available to the users in accordance with the EudraVigilance Access Policy.</p>	DATA ELEMENT	FIELD NAME	ICH E2B(R3) N.1.5	Date of Batch Transmission	ICH E2B(R3) N.2.r.4	Date of Message Creation	ICH E2B(R3) C.1.2	Date of Creation	ICH E2B(R3) D.2.1	Date of Birth	ICH E2B(R3) D.6	Last Menstrual Period Date	ICH E2B(R3) D.10.2.1	Date of Birth of Parent	DATA ELEMENT	FIELD NAME	ICH E2B(R3) ACK.M.4	Acknowledgement Date of Batch Transmission	ICH E2B(R3) ACK.A.3	Date of ICSR Batch Transmission	User should be aware of how the data is displayed in EVWEB while EMA is working on the long term changes to make the whole EV system compliant with Time zone use.	Open	SD-247721
DATA ELEMENT	FIELD NAME																							
ICH E2B(R3) N.1.5	Date of Batch Transmission																							
ICH E2B(R3) N.2.r.4	Date of Message Creation																							
ICH E2B(R3) C.1.2	Date of Creation																							
ICH E2B(R3) D.2.1	Date of Birth																							
ICH E2B(R3) D.6	Last Menstrual Period Date																							
ICH E2B(R3) D.10.2.1	Date of Birth of Parent																							
DATA ELEMENT	FIELD NAME																							
ICH E2B(R3) ACK.M.4	Acknowledgement Date of Batch Transmission																							
ICH E2B(R3) ACK.A.3	Date of ICSR Batch Transmission																							

Id	Description	Proposed workaround	Status	PHV issue
4	When searching for a MedDRA term in EVWEB, please note that the search is case sensitive, e.g. in MedDRA 22.0 the term "Lumbar syndrome" has been replaced by "LUMBAR syndrome", the later should now be used.		Open	EVHUM-1566
5	Business rule correction if the patient onset age unit (D.2.2b) is populated and but patient onset age value (D.2.2a) is null the error message that D.2.2b has to be populated should be triggered		Open	SD-223387

EudraVigilance Registration changes

Since the implementation of the new registration process using the EMA's Identity and access management tool a number of issues concerning user access has occurred. The majority of these issues are related to the migration of historic organisation and user data into the new system. The cleaning of the historic data has required significant effort and is now mostly complete.

The main types of issues can be characterised as follows:

1	<p>Users with more than one registered Identity:</p> <p>Individuals that work for multiple organisations may have registered with EudraVigilance with different e-mail addresses. This leads to the user having more than one set of user login credentials.</p>	To resolve this, the user can request for their multiple accounts to be merged into one identity that has one e-mail contact details.	Open	
2	<p>EudraVigilance organisation identifiers linked to the same OMS Organisation Identifier:</p> <p>The EudraVigilance system previously allowed the same organisation to have more than one registration for the same organisation name and address. However, the OMS system only allows one organisation identifier per legal entity per country. During the migration and linkage of EudraVigilance Organisation Identifiers to the OMS organisation identifiers in</p>	In EudraVigilance this issue is resolved through the change of one or more of the organisations into virtual affiliates, in these situations one organisation will remain as an affiliate or headquarter and the other organisations are changed into virtual affiliates of the headquarter.	Open	

	<p>some instances this has led to several EudraVigilance Organisations sharing the same OMS organisation ID.</p> <p>This causes an issue as the EMA's Identity and access management tool provides access based on the OMS organisation ID and not the EudraVigilance Organisation ID, therefore granting access is not possible when there is such one to many linkages in the system.</p>			
3	<p>Disabled organisation message:</p> <p>Each organisation registered in EudraVigilance is required to have one user identified as responsible for that organisation. If this user revokes their access all other users will be unable to access that organisation until the new responsible user has been registered.</p>	<p>It is recommended that organisations plan the transfer of the role in advance and become familiar with the EV registration manual.</p>	Open	

Points to Note

1. It is recommended to use recent version of Google Chrome, Mozilla Firefox or Internet Explorer 11 as preferred internet browsers.
2. ICH regional data elements are not supported. Therefore ICSRs containing these non-EU regional data elements may not receive acknowledgements.
Proposed workaround: Do not include non-EU regional data elements.
3. ICSR download requests pending for more than 2 days will be cancelled by EMA. Users are advised to re-run the ICSR down-load requests.
4. MAHs should **not** send acknowledgements for any ICSRs downloaded from EudraVigilance.
5. The EVWEB application is available during EMA office hours 08:30 – 18:00 (UK time), Monday to Friday. EVWEB is also available outside of these hours apart from scheduled maintenance and routine data management tasks.

The following tasks are performed outside of EMA office hours in order to support the operation of EudraVigilance:

- classification of ICSRs against the xEVMPD/Art.57 database;
- detection and management of duplicate ICSRs;
- assignment of the substance based access (Level 2) for MAHs.

These scheduled activities run every day Monday to Sunday between 11:59 p.m. and 04:00 a.m. (UK time). EVWEB services resume as soon as these automated tasks have completed. Access to EVWEB is not possible whilst these activities are being performed and during which a maintenance page is displayed.

If a larger than normal number of ICSRs is received within a day, the system may become available again later than 04:00 a.m. UK time. However, in such situations EVWEB should still be accessible from 08:30 a.m. (UK time) (EMA office hours).

- ICSR download requests launched by MAHs that have not completed before the scheduled maintenance and data management activities start, are made available as soon as the EVWEB interface is available again.
 - Submissions made via the EudraVigilance gateway are not affected by the scheduled maintenance and data management activities, however acknowledgements will be returned after these processes have finished. The same applies to the L2A/B download requests.
6. All service issues/outages are reported on the EMA service desk homepage at <https://servicedesk.ema.europa.eu>. Please consult this page to check on the EudraVigilance service availability
 7. E2B(R3) messages containing corrupted attachments do not receive negative acknowledgements. Sender organisations should ensure that they implement the RFC1951 deflate algorithm correctly. If no ACK message is received after 48h, please contact EMA service desk.

Users should be remembered that electronic submissions of ICSRs can only be considered as valid if a MDN and valid ACK message is received from the EudraVigilance system. If not received, it is the responsibility of MAHs to contact EMA service desk to investigate the potential issue.

8. Please note EMA routine maintenance windows as follows:

- Mondays 16:30 to 18:00 (UK time)
- Tuesdays 16:30 to 18:00 (UK time)
- Wednesdays 16:30 to 18:00 (UK time)
- Thursdays 16:30 to 18:00 (UK time)

Please be aware that during these time windows, the maintenance activities may lead to a partial or full unavailability of the EudraVigilance system (EVWEB interface for the submission of ICSRs, including the 'Post' functions), depending on the activity to be performed.

If you experience any technical issues during the above time windows i.e. where EudraVigilance is partially available, you are kindly requested to retry the same operations outside the maintenance window before contacting the EMA Service Desk.

Please note that these maintenance activities do not impact the electronic transmission of ICSRs and acknowledgements to EudraVigilance; i.e. **messages can be sent to the system as usual.**