26 July 2018
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Information Management

EudraVigilance Release Notes v.1.17

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:

- **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: 26 July 2018

What is New?

The new release of EudraVigilance includes a number of improvements that increase the performance and usability of the system by all stakeholders. Some of these improvements will also enhance aspects of the functionality of the system, which are highlighted below.

Id	Description
1	The EudraVigilance production environment is integrated EMA's [Account Management](#) portal and [Organisation Management Service (OMS)](#).

Fixed Issues

Id	Description	Status	PHV issue
1	Processing time out of ICSR messages that contain over 100 ICSRs or ICSRs that contain many reactions, drugs and drug-reaction assessments	Closed	PHV-6612 PHV-7112
2	The conditions provided for ICSR search filters should work as "AND" and not as "OR"	Closed	PHV-7267
3	Headquarter user cannot see SUSARs sent by its affiliates	Closed	PHV-7374
4	Line breaks in Base64 string in XML is throwing error	Closed	PHV-7262
5	CT masters are included in the NCA rerouting	Closed	PHV-7327
6	Performance issues in ICSR search caused by implementation of PHV-7001	Closed	PHV-7232
7	XML parsing fails when dtd/xsd not available	Closed	PHV-7212

Known Issues

Id	Description	Proposed workaround	Status	PHV issue
1	For invalid ICSR messages submitted in E2B (R2) format, negative ack messages may not be returned to the sender organisation by the EudraVigilance system	If no ACK message is received after 48h, please contact EMA service desk.	Open	PHV-6643
2	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
3	EVWEB users cannot log in when they have used special characters such as '&' and "+" in their EV password	EV password setting page will be updated to prevent this. Latin standard characters [a-z][A-Z][0-9] should be used instead of the listed special characters; accented characters should also not be used.	Open	PHV-6948

Id	Description	Proposed workaround	Status	PHV issue
4	Printing Bulk Export search criteria. The new print functionality might not complete quickly	Users of this functionality will need to wait until the print function has completed	Open	PHV-7369
5	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

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.

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.