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Information Management

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD) training

Frequently asked questions

¹ New Q&As added.



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1. Mandatory participation

Question: Is it mandatory for every user to receive training on submission of medicinal product report messages in the XEVMPD?

Answer: At least **one user from each organisation** should follow the training and obtain a '*Notification of successful completion of the XEVMPD knowledge evaluation*'. This is to ensure the quality of data submitted to the database. Also, '*Notification of successful completion of the XEVMPD knowledge evaluation*' is required from at least **one user** from each organisation during the organisation's registration process with EudraVigilance before the data submission can begin:

- If your organisation will be registering for the submission of **authorised** medicinal product data, at least one participant from your organisation should perform the XEVMPD knowledge evaluation for the submission of authorised medicinal product data in the XEVMPD.
- If your organisation will be registering for the submission of **un-authorised** (referred to in the XEVMPD as 'development') medicinal product data, at least one participant from your organisation should perform the XEVMPD knowledge evaluation for the submission of development medicinal product data in the XEVMPD.

1.1. **NEW:** Mandatory training for QPPV/Responsible Person (RP)

Question: Is it mandatory for the organisation's QPPV/RP to undergo the XEVMPD training and obtain the knowledge evaluation?

Answer: No, it is not mandatory for an organisation's QPPV or RP to undergo the XEVMPD training and obtain the knowledge evaluation. Any suitable individual from the organisation may complete the training/evaluation and obtain the '*Notification of successful completion of the XEVMPD knowledge evaluation*'. The organisation's QPPV/RP may provide the '*Notification of successful completion of the XEVMPD knowledge evaluation*' of that individual as a supporting document during the organisation's initial registration with EudraVigilance.

1.2. **Participation from 3rd party service provider organisation users**

Question: We are using a 3rd party service provider organisation to submit extended EudraVigilance product report messages (XEVPRMs). Do they need to be trained on how to use the XEVMPD?

Answer: If you arranged with a 3rd party service provider to submit electronically, via an XEVPRM, information on authorised or development medicinal products on your behalf, it is sufficient that a member of staff from the 3rd party service provider organisation has successfully completed the XEVMPD training and obtained the knowledge evaluation. The organisation's QPPV/RP may provide the '*Notification of successful completion of the XEVMPD knowledge evaluation*' of that individual from the 3rd party service provider as a supporting document during the organisation's initial registration with EudraVigilance.

2. **NEW:** Format of e-learning training

Question: Can the e-learning be completed online?

Answer: The e-learning training is not performed online. The e-learning training consists of the users self-studying the available training materials. To receive access to the XEVMPD XCOMP environment and to request a knowledge evaluation by the EMA, the user must [register via the EMA Service Desk Portal](#).

3. **NEW:** Process to register for XEVMPD e-learning training and knowledge evaluation

Question 1: What is the complete process to register for the XEVMPD knowledge evaluation via e-learning?

Answer: Before registering, users should review the available XEVMPD-related documentation:

- XEVMPD e-learning presentations and User manual for the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) user interface (XEVMPDweb) published on the [XEVMPD training webpage](#);
- Depending on which type of products the organisation will be submitting (authorised medicinal product data or un-authorised medicinal product data), the relevant Guidance document should be reviewed:
 - [Chapter 3.II: Extended EudraVigilance product report message \(XEVRPM\) user guidance](#), providing detailed guidance on the submission of AMPs
 - [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#), providing detailed guidance on the submission of DMPs.

Once prepared, users should submit an EMA Service desk ticket via the [Request \(for\) XEVMPD/Art.57 Services](#) form, specifying in the subject of the form that the request is related to XEVMPD e-learning registration request.

In the request, users must provide their **full name, company name** and **business email**, and **specify if the knowledge evaluation is requested for the submission of authorised medicinal products (AMPs), development medicinal products (DMPs) or both (AMPs & DMPs)**.

The training team will check how many users from the same organisation already registered for the e-learning and, if the user limit has not been reached, the user will be registered and provided with documents required for the knowledge test along with instructions on how to request access to the XEVMPD XCOMP environment for training purposes. After successfully completing the evaluation, a '*Notification of successful completion of the XEVMPD knowledge evaluation*' will be provided to the participant via the same ticket.

Note: XEVMPD tickets may be automatically closed by the system if no response is provided for an extended period. If a ticket is closed in this way, the user registered for the XEVMPD knowledge evaluation can either reopen the ticket or submit a new one via the [EMA Service Desk](#).

3.1. **NEW:** Limit of 5 participants per organisation for XEVMPD e-learning

Question: Why can we register only up to 5 users from our organisation for the e-learning training?

Answer: The XEVMPD e-learning training evaluation is a free of charge service, which is aimed at providing support to companies developing their in-house expertise and training courses for new staff and not to train users on an individual basis. The '*Notification of successful completion of the XEVMPD knowledge evaluation*' is required from one user during the **initial registration of the organisation** with EudraVigilance. Users that obtained the '*Notification of successful completion of the XEVMPD knowledge evaluation*' can train others to ensure internal knowledge transfer.

There is no limit on how many participants can register from one organisation for the virtual online training course organised on behalf of the EMA by the Drug Information Association (DIA).

3.2. NEW: Request for knowledge evaluation on behalf of other users

Question: Can I request the XEVMPD knowledge evaluation on behalf of other users in my organisation by raising a Service Desk ticket for them?

Answer: No. Users who wish to register for the XEVMPD knowledge evaluation via e-learning must raise the ticket themselves through the EMA Service Desk using their own EMA account. They must also complete the XEVMPD knowledge evaluation using their own individual account. Tickets submitted by one user requesting the evaluation on behalf of another will be rejected due to confidentiality concerns.

3.3. NEW: Provision of personal email during the e-learning training registration request

Question: Can I provide a personal e-mail address for XEVMPD knowledge evaluation registration via e-learning instead of my business e-mail?

Answer: No. Users wishing to undergo the XEVMPD knowledge evaluation via e-learning must not provide personal e-mail addresses such as those ending in gmail.com, yahoo.com, rediff.com, etc.

Users must ensure they have a valid business e-mail address associated with the organisation to which they are currently affiliated, and they must also have an EMA account linked to that same business e-mail. The same business e-mail address must be provided during the registration process.

3.4. NEW: Processing timeframes related to XEVMPD e-learning training

Question: What are the timeframes involved when registering for XEVMPD knowledge evaluation via e-learning?

Answer:

- **Response to initial registration:** Once users submit a request for the XEVMPD knowledge evaluation through the EMA Service Desk, the ticket is assigned to the XEVMPD Training Team, who have 5 working days to process the registration.
- **Approval of access to the XEVMPD XCOMP environment:** After registering for the knowledge evaluation, the user must request access to the XEVMPD XCOMP environment **for training purposes** via the EMA Account Management Portal using the instructions received from the XEVMPD Training Team. The training team will then review and approve/deny the access request within 5 working days.
- **Access to the XEVMPD XCOMP environment for training purposes:** Once the access is approved, access to the XEVMPD XCOMP environment will be limited to 8 weeks from the date the access was approved. Users are expected to complete their knowledge evaluation within this period. After the 8-week period, the access will be revoked.
- **Evaluation of submitted documents:** Once all the required test documents are provided by the registered user for evaluation, the XEVMPD Training Team will evaluate them within 5 working days.

4. XEVMPD knowledge evaluation

Question 1: How many attempts do I have to pass the knowledge evaluation? And what happens if I do not pass during the allowed attempts?

Answer: The EMA allows a maximum of three attempts to pass the XEVMPD knowledge evaluation for both parts i.e. Part 1: Multiple-Choice Questionnaire and Part 2: XEVMPD Product Message Report.

If a registered user is unable to pass the evaluation within these three attempts via e-learning, they are advised to register for the XEVMPD knowledge evaluation via the virtual online training course organised on behalf of the EMA by the Drug Information Association (DIA).

Question 2: As a user from sponsor organisation, do I have to participate in the knowledge evaluation on the submission of authorised medicinal product data?

Answer: If your organisation will be registering as a 'sponsor' organisation, and your organisation will submit only development product data in the XEVMPD, you should review the materials relevant for the submission of development medicinal products in the XEVMPD. You can then perform the knowledge evaluation on the submission of development medicinal products only.

4.1. Validity of the 'Notification of successful completion of the XEVMPD knowledge evaluation'

Question: I followed the XEVMPD training and received the '*Notification of successful completion of the XEVMPD knowledge evaluation*'. I will be leaving my current organisation and would like to know if this notification will be valid in my new organisation, or if I'll have to repeat the knowledge evaluation?

Answer: The notification will be valid even if you move to a new organisation. The knowledge evaluation is assigned to the person who performed it, not the organisation for which the person works. You will not need to repeat the knowledge evaluation.

4.2. Training certificates

Question: Following the training and completion of the XEVMPD training course will I receive a certificate, or is the 'Notification of successful completion of the XEVMPD knowledge evaluation' sufficient as a proof that I have been trained?

Answer: Training 'Certificates' used to be issued in the past and were later replaced by 'Notifications'. Users, who successfully complete the XEVMPD knowledge evaluation, will receive a '*Notification of successful completion of the XEVMPD knowledge evaluation*' via email (in case the participant attended the virtual online training course organised by EMA's training organiser the Drug Information Association) or via the EMA Service Desk ticket (in case the participant attended the e-learning training and registered for this e-learning training via the EMA Service Desk). The Notification is the proof that user attended the training and passed the knowledge evaluation.

4.3. Timeline for performing the XEVMPD knowledge evaluation

Question: Is there a timeline during which I am required to perform the XEVMPD e-learning knowledge evaluation?

Answer: As part of your knowledge evaluation, you are required to enter product information in the XEVMPD XCOMP environment using the XEVMPD XCOMP user interface and provide the training team with an RTF file of your XEVPRM for assessment. Access to the XEVMPD XCOMP environment for training purposes is limited to maximum of 8 weeks. You are therefore strongly advised to perform the

knowledge evaluation within this period. Should you need to repeat the second part of the knowledge evaluation (i.e., the product report exam case submission), this should also be done within the 8-week period.

4.4. *NEW: How and where to retrieve the 'Notification of successful completion for XEVMPD' from previously passed trainings*

Question: Some years ago, I attended the XEVMPD training and since I passed the knowledge evaluation, I received the notification of successful completion. However, due to changing companies, my notification has been misplaced. Is it possible to obtain it again?

Answer: It is the responsibility of the registered user to keep their notification of successful completion safely stored. However, if the user cannot retrieve it, to obtain a copy of the notification, the user should contact the training provider (DIA or EMA), depending on the format in which training was attended:

- If the user followed the **e-learning training**: The user should submit [Request \(for\) XEVMPD/Art.57 Services](#) via the EMA Service Desk, specifying the participants name, company name and email address provided during the registration, year or date of registration and clarification if the knowledge evaluation was performed for the submission of AMPs, DMPs or both.
- If the user attended the **DIA organised virtual online training course**, the user should contact DIA colleagues directly by sending an email with the above referenced information to emaevents@diaglobal.org.

The respective training team will review their internal records and once the notification is retrieved, it will be provided to the requestor.

5. Knowledge update

Question: Years ago, I attended the EVMPD training and received a training certificate after the completion of the course. Is this certificate still valid or do I need to refresh my training?

Answer: If you already attended an EVMPD training course in the period of May 2004 to March 2012, your previously issued training certificate is still valid. However, users previously trained on EVMPD are strongly advised to review the updated XEVMPD user manual and relevant guidance document(s).

6. Access to the XEVMPD test environment (XCOMP) for training purposes

6.1. How/where to request XCOMP access for training purposes

Question: How/where can I request access to the XEVMPD XCOMP environment to practice and perform the test submission for the knowledge evaluation?

Answer: After you successfully register for the knowledge evaluation (e-learning training or virtual online training organised by the DIA), the respective training team will provide you with instructions on how and where to request the access.

6.2. NEW: Error message when accessing XCOMP

Question: As part of my registration for the XEVMPD knowledge evaluation I requested access for the XEVMPD test environment (XCOMP). However, when I try to log in, I receive an error message that I cannot access this page. What should I do?

Answer: The access was granted for maximum of 8 weeks; if this period passed, and your access was revoked, please reopen your existing training registration related ticket (if this is still possible) or submit a new [request for new XEVMPD credentials](#) via the [EMA Service Desk portal](#).

If you are still within the 8-week period, this might be a technical issue. You should therefore report this as an access issue using the ['Report an Issue with XEVMPD/Art.57' EMA Service Desk form](#).

6.3. NEW: Access to XCOMP rejected

Question: I have requested access to the XEVMPD XCOMP environment via the EMA Account Management portal. However, my access request was rejected by the EMA. Could you explain why?

Answer: XCOMP access with the user role 'XEVMPD e-learning training participant' is granted solely for the purpose of completing the XEVMPD knowledge evaluation via the e-learning training. Users must not request this access for any other purpose. If your request was rejected, this may be due to one of the following reasons:

- You have not registered for the XEVMPD e-learning knowledge evaluation.
- The details submitted in the e-learning training registration request submitted via the EMA Service Desk ticket do not match the details used when requesting access. Please ensure that the information provided in your access request aligns with the information in your EMA Service Desk ticket.
- The user, who registered for the XEVMPD knowledge evaluation and the user who submitted the access request via the EMA Account Management portal are not the same person. Access must be requested only by the individual who registered for the knowledge evaluation. Other users from the same organisation, who wish to take the knowledge evaluation, must follow the entire registration process separately using their own accounts.
- The access request was submitted before raising a ticket to register for the XEVMPD knowledge evaluation via the EMA Service Desk. Access should only be requested after successful registration and after receiving the instruction document from the XEVMPD Training team.
- Access was requested using a personal email address such as yahoo.com, gmail.com, or rediff.com. instead of business email address provided during the knowledge evaluation registration process.

7. Cost of XEVMPD e-learning knowledge evaluation

Question: What is the fee for participation in the XEVMPD e-learning knowledge evaluation?

Answer: The XEVMPD e-learning training materials are available cost-free; the e-learning XEVMPD knowledge evaluation is also free of charge.

8. NEW: Upgraded XEVMPD User interface (XEVMPDweb)

Question: New XEVMPD user interface (XEVMPDweb) was made available to industry from January 2026. Since when can we expect XEVMPD trainings to be performed in this new environment?

Answer: XEVMPD trainings are performed in the upgraded user interface (XEVMPDweb) of the XCOMP environment) from 29 January 2026.

8.1. Re-training of existing XEVMPD users

Question: Are existing users required to re-train in the new user interface (XEVMPDweb)?

Answer: No. The upgraded user interface (XEVMPDweb) is very similar to the previously used UI (XEVMPD EVWEB), with the same functionalities. It is recommended that existing users review the user manual for the upgraded user interface [i.e. the 'User manual for the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) user interface (XEVMPDweb)'] for awareness.