EudraVigilance training quiz EV-M5b – EudraVigilance Data Analysis System (EVDAS) training for Marketing Authorisation Holders

Fields marked with * are mandatory.

Introduction

The intent of this quiz is to enhance your understanding of the content covered in EudraVigilance training module EV-M5b. Please note that the objective of the quizzes is to allow users to verify their understanding of the key takeaways from the E-learning modules. They are not a part of a formal examination and should NOT be confused with the 'Competency assessment', which represents a formal evaluation of the submission of ICSRs for new users and which will be developed in Q4 2016.

If you have not yet completed the E-learning module for Module EV-M5b - it is recommended that you do so before attempting this quiz.

10 multiple choice questions will follow. After submitting your answer to a given question you will be immediately informed of the outcome of your answer. It is suggested that you repeat the quiz until you are able to succesfully answer all of the included questions.

Question 1

*Where can I get guidance on the periodicity of monitoring of EudraVigilance data?

- In the Directive 2001/83/EC
- In the GVP Module IX on Signal Management
- In the Commission Implementing Regulation (EU) 520/2012
- In the GVP Module IX on Signal Management and the Commission Implementing Regulation (EU) 520/2012

Question 1 - Results

Congratulations, that was the correct answer.

The Commission implementing regulation states that MAHs, NCAs and the Agency shall ensure the

continuous monitoring of EudraVigilance with a frequency proportionate to the risks and the need for additional information. Moreover, the GVP Module IX on signal management provides us with specific guidance on the frequency of monitoring: A two weeks' interval is recommended for active substances contained in medicinal products included in the additional monitoring list, and the interval between reviews of EV data should not exceed 6 months.

Unfortunately the answer you provided was incorrect.

It is suggested that you refer back to the E-learning material for this module to refresh your understanding, before re-attempting this quiz.

Question 2

*What is the level of access provided to MAHs in EVDAS according to the EudraVigilance access policy?

- ○ Level 1 and 2a
- ○ Level 1
- ○ Level 2a
- ○ Level 2b

Question 2 - Results

Congratulations, that was the correct answer.

EVDAS access for MAHs is implemented according to Level 1 access for Stakeholders Group III.

Unfortunately the answer you provided was incorrect.

It is suggested that you refer back to the E-learning material for this module to refresh your understanding, before re-attempting this quiz.

Question 3

*Which one of the statements is correct with regards the level of EudraVigilance access provided to MAHs in EVDAS?

a) access is provided at the level of the brand name of the product for the cases where the product name is provided.

b) access is provided for spontaneous cases.

c) access is provided for the cases where the drug of interest is coded as suspect, interacting, concomitant

or not administered.

d) access is provided once there is at least one post-authorisation ICSR within the EEA.

- ⊙ c
- ⊙ d
- ⊙ a, b
- ⊙ b

Question 3 - Results

Congratulations, that was the correct answer.

The correct answer is b. Access is provided for cases in the EV post-authorisation module and that includes spontaneous.

Unfortunately the answer you provided was incorrect.

It is suggested that you refer back to the E-learning material for this module to refresh your understanding, before re-attempting this quiz.

Question 4

* Which one of the following statements is correct regarding the active substance grouping.

a) Grouping is a manual activity performed by the Agency to facilitate the analysis of aggregated data.

b) The active substance high level is formed by different names of an active substance (e.g. different salts).

c) amlodipine besilate and amlodipine maleate are grouped to the active substance high level 'amlodipine'

d) You can change the grouping of your products in the MAH pharmacovigilance queries dashboard

- ⊙ a, c
- ⊙ a, b, c
- ⊙ All the statements are correct
- ⊙ b, c

Question 4 - Results

Congratulations, that was the correct answer.

The correct answer is a, b and c.

Grouping is a manual activity performed by the Agency to facilitate the analysis of aggregated data. The active substance high level is formed by different names of an active substance (e.g. different salts). As an example of the active substance grouping, we have seen in the module that amlodipine besilate and amlodipine maleate are grouped to the active substance high level 'amlodipine'

Unfortunately the answer you provided was incorrect.

It is suggested that you refer back to the E-learning material for this module to refresh your understanding, before re-attempting this quiz.

Question 5

*How can I get an eRMR in EVDAS with a reference period of 4 months?**

- ○ Using the eRMR fixed reference period report
- ○ Using the eRMR ad-hoc reference period report
- ○ I can only be retrieve eRMRs from EVWEB
- ○ An eRMR with a reference period of 4 months cannot be retrieved from EVDAS

Question 5 - Results

Congratulations, that was the correct answer.

An eRMR with a reference period of 4 months cannot be retrieved from EVDAS. The reference period in the ad hoc eRMR is limited to 3 months and 2 weeks in the past.

Unfortunately the answer you provided was incorrect.

It is suggested that you refer back to the E-learning material for this module to refresh your understanding, before re-attempting this quiz.

Question 6

*Which cases will be counted and included in the columns new in the eRMR?**

- ○ Cases received for the first time in EudraVigilance, Follow-ups And de-duplicated cases
- ○ Cases received for the first time in EudraVigilance, plus follow-ups
- ○ Cases containing a new MedDRA PT for the specific active substance
- ○ Cases received for the first time in EudraVigilance

Question 6 - Results

Congratulations, that was the correct answer.

The cases counted in the 'new' columns in the eRMR are cases received for the first time in EudraVigilance, Follow-ups and de-duplicated cases

Unfortunately the answer you provided was incorrect.

It is suggested that you refer back to the E-learning material for this module to refresh your understanding, before re-attempting this quiz.

Question 7

*****How can I save my prompts selections in the EVDAS reports so that I can use the same criteria in the future?**

- ⦾ By saving your current customisation
- ⦾ By printing the prompts page
- ⦾ You cannot save your prompt selection
- ⦾ Requesting that functionality to the EMA helpdesk

Question 7 - Results

Congratulations, that was the correct answer.

You can apply the same prompts' selections from previous reports by saving your customisation. This is a EVDAS functionality provided in the prompt page options.

Unfortunately the answer you provided was incorrect.

It is suggested that you refer back to the E-learning material for this module to refresh your understanding, before re-attempting this quiz.

Question 8

*****What is the threshold for the number of cases of a Drug Event Combination to meet the Signal of Disproportionate Reporting criteria in EudraVigilance for the general population?**

- 3 or more cases for active substances included in the additional monitoring list and 5 or more cases for the other active substances.
- 2 or more cases for active substances included in the additional monitoring list and 5 or more cases for the other active substances.
- As determined by the MAH.
- 3 or more cases.

Question 8 - Results

Congratulations, that was the correct answer.

The threshold for the Definition of an SDR in EV for the General population is 3 or more cases for active substances contained in medicinal products included in the additional monitoring list in accordance with REG Art 23 (see GVP Module X), unless the sole reason for inclusion on the list is the request of a post-authorisation safety study (PASS); 5 or more cases for the other active substances.

Unfortunately the answer you provided was incorrect.

It is suggested that you refer back to the E-learning material for this module to refresh your understanding, before re-attempting this quiz.

Question 9

*How can I get information in EVDAS about cases related to medication errors?

- Only when reported in the field G.k.10.r additional information on drug for E2B(R3) cases.
- In the eRMR output and in the line listing report by using MedDRA.
- Medication errors are not submitted to EudraVigilance.
- Medication errors are only provided under level 2a.

Question 9 - Results

Congratulations, that was the correct answer.

The eRMR provides the number of cases per drug even combination related to medication errors, also MedDRA can be used in the EVDAS reports to filter the data according to the relevant terms (e.g. Medication errors SMQ).

Unfortunately the answer you provided was incorrect.

It is suggested that you refer back to the E-learning material for this module to refresh your understanding, before re-attempting this quiz.

Question 10

*Regarding the ICSR form, which one of the statements is correct?**

- ○ It can be accessed directly from the action links in the eRMR.
- ○ For the cases submitted under ICH-E2B(R2) the system will provide me with the CIOMS I form and for the cases submitted under the new ICH-E2B(R3) the system will provide me with the new ICSR form.
- ○ Some sections are not populated in the form if no data has been submitted.
- ○ Provides the seriousness criteria only for cases submitted under ICH-E2B(R2).

Question 10 - Results

Congratulations, that was the correct answer.

The ICSR forms follows a special dynamism for some sections and that means that if no data has been provided for the entire section, that section is not populated in the form. Be aware that all the ICSR forms follow the same format regardless of cases submitted under ICH E2B(R2) or (R3).

Unfortunately the answer you provided was incorrect.

It is suggested that you refer back to the E-learning material for this module to refresh your understanding, before re-attempting this quiz.

Conclusion

Thank you for completing this quiz - we hope you have found it useful in cementing your understanding of this module. If you have any queries regarding the content in this quiz, please feel free to re-examine the training material for this course on the EudraVigilance training page.

A PDF version of your quiz results can be sent to a specified email address by clicking on the "Submit" button below.