EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EV Reporting process for users: Creating and sending ICSRs using EVWEB part II

Training Module EV-M3e

Content Summary

- Introduction
- Nullifications and Amendments
- Creating patient death reports
- Creating Parent Child reports
- Creating Observational Studies reports
- Creating Clinical Trial SUSARs
- Summary

Content Summary

Introduction: Target audience

- Target audience for this training module:
  - National Competent Authorities (NCAs) in the European Economic Area (EEA)
  - Marketing authorisation holders (MAHs)
  - Sponsors of clinical trials (Sponsors)
  - Research institutions/Academia

Introduction: Learning objectives

Following the completion of EV-M3e training module you should be able to understand how to create the following types of report using EVWEB:

- Nullifications and Amendments
- Creating patient death reports
- Parent Child report
- Observational Studies
- Clinical Trial SUSARs

Nullifications and Amendments

Amendment or Follow-up

- The sender should report follow-up information on an expedited basis if significant new medical information has been received.
  - Significant new information relates e.g. to new adverse reaction(s), a change in the causality assessment and any new or updated information on the case that impacts on the medical interpretation of the case. Therefore, the identification of significant new information requiring expedited reporting always requires medical judgement

Nullifications and Amendments

Examples of when to use Amendments

- When, after internal review or expert opinion some items have been corrected without receipt of new information, e.g., amendment MedDRA coding due to change in interpretation of the ADR
- To submit case translations or articles in attachment (in C.4.r.2) [only upon request]
- C.1.5 ‘Date of Most Recent Information for this Report’: Unchanged

Nullifications and Amendments

Nullifications

- In line with the ICH E2B(R3) guideline, the nullification of individual cases should be used to indicate that a previously transmitted report should be considered completely void (nullified), for example when the whole case was found to be erroneous or in case of duplicate reports.
    - In the case of duplicate reports where one report needs to be nullified the remaining case should be updated by submitting a follow-up report.

Nullifications and Amendments

Nullifications

- Individual versions of ICSRs cannot be nullified, only the whole case (all versions of an ICSR).
- Once an individual case has been nullified, the case cannot be reactivated.
  - If it becomes necessary to resubmit the case that has been previously nullified, a new ICH E2B(R3) C.1.1 ‘Sender’s (case) safety report unique identifier’ and ICH E2B(R3) C.1.8.1 ‘Worldwide unique case identification’ should be assigned.

Nullifications and Amendments

- When an organisation submits a nullification report, EudraVigilance will automatically mark an ICSR as nullified if the pre-existing case has been submitted by the same organisation or one of its affiliates. These nullification reports will have the report classification “Nullified report”.
- If the pre-existing case was sent by a different organisation the report classification will be either “EEA nullification request” or “Nullification request”
  - EEA Nullification requests will be forwarded to National Competent Authorities to assess.

Creating patient death reports

- In the situation where a patient has died the patient death section of the ICSR should be completed. This is for both the situations where the death is linked to a suspected drug reaction and for when the death is not associated with a suspected drug reaction
- The reported death cause and autopsy section (if autopsy information is known) should be completed

Parent Child report

- Additional data elements need to be completed for reports affecting a child or foetus where the mother or father took the drug
- The patient section is complete with the details of the child or foetus
- The drug information is entered with the details of the parent taking the drug (exception for route of administration)
- Parent’s information is captured in the parents section of the ICSR

Observational Studies

- Non-interventional studies should be reported to EudraVigilance post-authorisation module as:
  - Report type: Report from studies
  - Study type: Other studies or Individual patient use

Clinical Trial SUSARs

- SUSARs should be reported to the EudraVigilance Clinical Trials Module only
- EU causality assessments are required for all suspect drugs in a SUSAR submission
- The study section must be completed for all submissions
- EudraCT numbers or Clinical Trial Portal numbers must be provided for EEA SUSARs

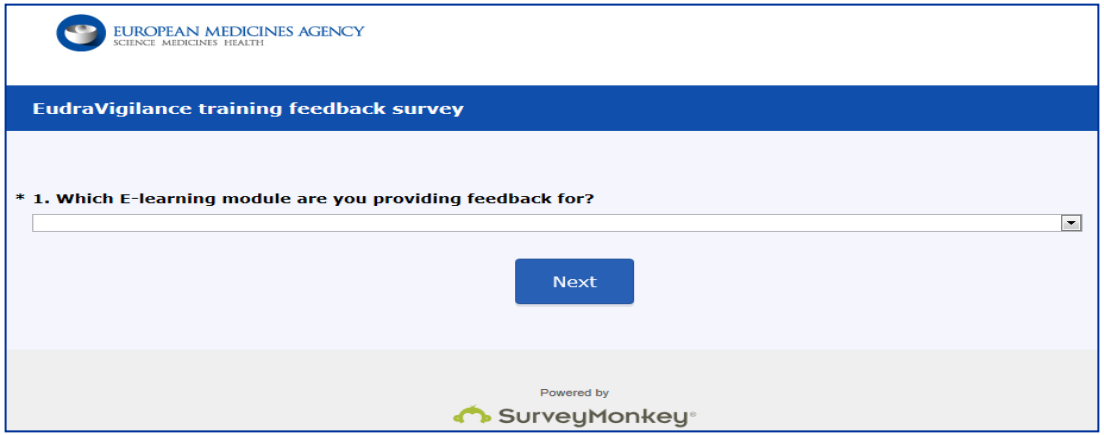
Summary

- Nullifications and Amendments
- Creating patient death reports
- Parent Child report
- Observational Studies
- Clinical Trial SUSARs

Feedback

- Please provide us with feedback on this E-learning module and any attendant guidance documents you have viewed by taking the EMA training survey.

- The survey is accessible via this link.



Thank you for your attention

Further information

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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