EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New ADRs reporting requirements for non-interventional post-authorisation studies

Good Vigilance Practices Module VI Rev. 1

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An agency of the European Union

GVP VI Rev.1 : New requirements on post-authorisation studies

Studies with primary data collection

- Information on all adverse events should be collected in the course of the study unless the protocol provides differently with a due justification for not collecting certain adverse events. GVP VIII to be updated to provide guidance on protocol.
- For all collected adverse events,
  - Comprehensive and high quality information should be sought.
  - Perform causality assessment.
  - Report cases of adverse reactions, which are suspected to be related to the studied medicinal product by the primary source or the receiver of the case. Valid ICSRs should be classified as solicited reports.
  - All collected adverse events should be summarised as part of any interim safety analysis and in the final study report.

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- All fatal outcomes should be considered as adverse events which should be collected.
  - ➢ In certain circumstances, suspected adverse reactions with fatal outcome may not be subject to expedited reporting as ICSRs.
    - ✓ Rational for not reporting should be clearly described in the protocol. E.g.,
      - Suspected adverse reactions with fatal outcome refer to study outcomes (efficacy end points),
      - Patients included in the study have a disease with high mortality,
      - Fatal outcomes have no relation to the objective of the study.

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- For adverse events for which protocol provides differently and does not require their systematic collection

➢ Inform healthcare professionals and consumers in protocol or other study documents of possibility to report cases of suspected adverse reactions to marketing authorisation holder of suspected medicinal product or to concerned competent authorities via national spontaneous reporting system.

➢ When made aware of them, these reports should also be summarised in the relevant study reports.

- New requirements mandatory for any new study started after 1 Jan 2015.

➢ Optional implementation for new or ongoing studies started before.

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- Requirements do not apply to studies conducted by organisations such as academia, medical research charities or research organisations in the public sector.
  - ➢ These organisations should follow local requirements as applicable.
  - ➢ However, where study is directly initiated, managed, financed, or where its design is controlled by a marketing authorisation holder, new requirements are applicable.
    - ✓ Contractual agreements should be in place to clearly define role and responsibilities for implementing these requirements.
    - ✓ This does not concern donation of a medicinal product for research purpose if the marketing authorisation holder has no control on the study.