EC Implementing Measure

The format of protocols, abstracts and final study reports for the non-interventional post-authorisation safety studies

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SCOPE

• Post-authorisation safety study

Any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

• Non-interventional post-authorisation safety study

• Studies which involve collection of data from patients and health care professionals, including those that make secondary use, for a post-authorisation safety study, of data previously collected for another purpose and stored in medical charts or electronic records.
SCOPE

Non-interventional post-authorisation safety studies which are initiated, managed or financed by a marketing authorisation holder pursuant to obligations imposed by a national competent authority or the Agency

OR

All non-interventional post-authorisation safety studies initiated by a marketing authorisation holder for an authorised medicinal product

→ Clarification requested to EMA legal sector
FORMAT

Format of study protocols, abstract of study results and final study report to be compatible with international standards:

• **Study protocol**: ISPE Guideline + ENCePP Checklist for study protocols

• **Abstract**: recommendations from leading biomedical journals (e.g. BMJ)

• **Final Study report**: STROBE statement and PRISMA statement
Exchange of information on protocols and results of studies

• The study protocol and the abstract of the final study report shall be made public to ensure transparency.

• In order to facilitate consultation and tracking of the progress of studies, information on studies, including the study protocol and the abstract of the final study report, shall be entered in a publicly-accessible electronic register of studies.

  • study protocol to be entered prior to the start of data collection; updated study protocol to be uploaded when substantial amendments are made after start of data collection

  • abstract of study results to be entered in study register within 12 months of the end of data collection, when the final study report is sent to the competent authority (unless written waiver has been granted).
Exchange of information on protocols and results of studies

- Proposal to establish a searchable central EU register of observational studies administered by the Agency.

- When study protocol and abstract of study results are provided in a language that is not English (e.g. study requested by only one MS and carried out in that MS only), an **English translation of at least the title of study, abstract of study protocol, abstract of final study report** will be provided and entered in the study register.
Quality

- Information of main investigator, co-investigators and study sites to be included in study protocol.

- Each individual involved in conducting a study shall be qualified by education, training, and experience to perform his tasks.

- The study shall be scientifically sound and guided by ethical principles in all its aspects.

- The marketing authorisation holder shall consider all relevant EMA guidance with respect to designing, conducting and analysing a study (e.g. ENCePP Guide on methodological standards, specialised guidance for certain medicinal products).
Audit

• The marketing authorisation holder shall ensure that all study information shall be handled and stored in such a way that it can be accurately reported, interpreted and verified, while protection of personal data of study subjects shall be ensured.

• When the study makes secondary use of data from electronic records, verification of records shall refer to the analytical dataset.

• The marketing authorisation holder shall ensure that the analytical dataset and statistical programmes used for generating the data included in the final study report are kept in electronic format and are available for auditing and inspection. Any change to the data shall be documented.

• Studies may be subject to inspection by the competent authority.
Questions ?