Adverse Event Management

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Why is safety management important?

Documenting and reporting Adverse Events (AEs) during the course of a clinical study helps identify **Adverse Drug Reactions (ADRs)** associated with a pharmaceutical product.

Sponsors are required to notify Investigators of all adverse drug reactions that are both serious and unexpected.

Investigators are expected to be familiar with all Adverse Events reported in their current studies.

One of the most common and consistent findings from an audit or inspection is the failure to identify and report all Adverse Events during a clinical study.

What is an Adverse Event?

- ✓ An **AE** is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which occurrence does not necessarily have a causal relationship with the treatment.

- ✓ An **AE** can therefore be any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

Identifying an Adverse Event

DO questions like:

- ✓ How are you feeling today?
- ✓ How have you been feeling since the last visit?
- ✓ How do you feel now, compared to before you started the study?

AVOID questions like:

- ✓ Have you had any Adverse Events since your last visit?
- ✓ Leading questions, e.g.: Have you had headaches since the last vis

Documenting Adverse Events

Documentation by Study Staff:

✓ Adverse Events occurring during the course of a study must be reported to the Sponsor. Therefore, **AEs must be fully documented in source documents and as per study protocol**. In addition to the signs/ symptoms/ diagnoses, the following information should also be documented for each AE:

- ➪ Start date
- ➪ Stop date
- ➪ Treatment (if any)
- ➪ IP (Investigational Product) adjustments
- ➪ Causality
- ➪ Severity
- ➪ Any other information required by the study protocol and the Sponsor

Documenting Adverse Events

Points to Remember:

- ✓ **Causality** (relationship to study drug) and **severity** (mild, moderate, severe) must be assessed by a medically qualified and trained member of the study team.

- ✓ Always refer to the study protocol for information on what should be documented, collected, and reported regarding adverse events.

- ✓ AE reporting period may vary among Sponsors and study protocols. It may begin on the first day the subject takes the Investigational Product (IP). In other cases, it might start when the subject signs the informed consent form.

- ✓ Some AEs may continue for several visits. Keep track and follow up at every visit until they are resolved or deemed to be permanent.

What is a Serious Adverse Event (SAE)?

✓ A **Serious Adverse Event** (SAE) is any untoward medical occurrence that:

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- ➪ Results in death
- ➪ Is life-threatening
- ➪ Requires in patient hospitalization or prolongation of existing
- ➪ Results in persistent or significant disability/incapacity
- ➪ is a congenital anomaly/birth defect.

✓ SAEs require expedited/rapid reporting to the Sponsor within **24 hours** after the knowledge of these events.

AESI (Adverse Event of Special Interest)

A

- An adverse event of special interest can be an event **Serious or Non-serious.**

E

- An adverse event of scientific and medical concern specific to the sponsor's product or program.

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- Investigators must report to the Sponsor within **24 hours** after the knowledge.

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- Always refer to the **study protocol** to ensure that you are in compliance with this requirement.

Pregnancy

➪While not an Adverse Event by definition, Sponsors require reporting of pregnancy: **24 hours**

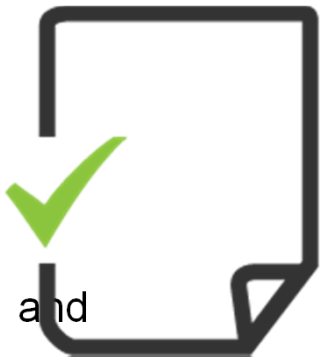
➪Some studies may require that a special pregnancy reporting be used for such reporting

➪As part of the study, the pregnancy **must be followed** to regardless of whether the subject continues in the study or not.

➪Some studies also require that the subject's partner's pregnancy be reported.

Safety Information

✓ The Sponsor is responsible for providing the Investigator with **safety information** for the Investigational Product(s):



➪ **Investigator's Brochure:** compilation of the clinical and nonclinical data on the Investigational Product(s)

➪ **SUSAR:** the Sponsor will report to Investigators all serious, unexpected and related events for the Investigational product being studied in their study:

➪ **Important:** The Investigator must ensure that the IRB/IEC is notified about these events in accordance with the IRB/IEC requirements.

Q&A

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References

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