Chicken Soup
for the Busy Coordinator

NHG Health

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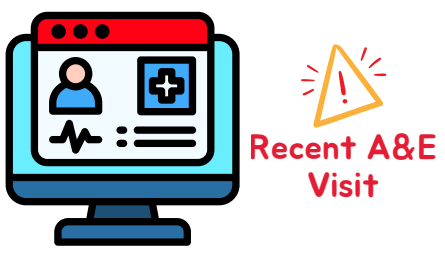
Management & Documentation of Adverse Events (AE): Best Practices

SCENARIO

Marcus, a clinical research participant, visited the A&E one evening with severe headaches and blurred vision. He mentioned his research participation to the Emergency Department (ED) nurse.

The ED nurse did not inform the study team. Marcus was treated and discharged the same night without the investigator's knowledge.



Weeks later, a study monitor discovers the A&E visit during a routine medical records review.

There were no AE management and assessment documentation by Investigator in the source record (e.g. medical records)

Why Timely & Proper AE Management & Documentation Matters

Unreported and undocumented AEs can have serious consequences:

- Obscures the true safety profile of the investigational product, since critical signals like Marcus's headache and blurred vision may be **lost entirely.**
- **Compromises participant protection** since without formal assessment of causality or severity, potential risks go unaddressed.

What Should Have Been Done?

- Before Study Initiation:
  - Principal Investigator (PI) should describe what would be regarded as AE and serious adverse events (SAE) in the study protocol.
  - Ensure all study team members are trained to identify AE.
- Specifically ask participants about any adverse events at every study visit.
- Regularly review electronic medical records (EMR) to identify AEs.
- PI should ensure that **adequate medical care** is provided to the participant for treatment of adverse events.
- PI should have reviewed the ED records, **document the assessment and management of the AE in the source records timely, e.g. medical records.**
- Documentation should include:
  - ✅ Details of the event
  - ✅ Expectedness, causality and severity of event
  - ✅ Date of onset and end date
  - ✅ Actions taken including treatment provided to subject and medication prescribed
  - ✅ Outcome of event

Prevention Going Forward

- Consider providing participants with a study contact card they can present at any healthcare facility, so that clinical staff know who to contact

- Consider to establish a protocol for clinical team to alert the research team.

- Explore the use of hospital EMR system for notifications. E.g. EPIC "in-basket" function.

Reminder

Assess and report AEs per applicable regulatory, IRB & Institutional requirements (e.g. Events that meet Expected SAE (for HBR regulated studies) or UPIRTSO criteria must be reported to DSRB)*

**For more details on SAE, UPIRTSO, reporting timeline and requirements, refer to PCR SOP 501-C05 UPIRTSO and Expected SAE and ICH E6(R3) Good Clinical Practice Guidelines, Section 2.7 (Participant Medical Care and Safety Reporting).*

Other Best Practices for AE Management & Documentation

Establish a clear internal process for capturing AEs that occur outside of scheduled study visits, including ED visits, hospitalisations, and consultations with other specialists.

Remind subjects at every visit to inform the study team of any new medical events or healthcare encounters between visits.

Conduct regular reconciliation between the AE log and medical records to catch any discrepancies early.

Promptly document any AE entries as soon as the investigator becomes aware of the event and not retrospectively document months later.

Reference: NHG Health PCR Standard Operating Procedures 501-C05 Unanticipated Problems Involving Risks to Subjects or Others and Expected Serious Adverse Event

ICH E6(R3) Good Clinical Practice Guidelines, Section 2.7 (Participant Medical Care and Safety Reporting)

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