

## Good Clinical Practice Q&A: Focus on AEs/SAEs

### What data elements are important to document when reporting AEs/SAEs?

Study sponsors generally instruct investigators to assess the occurrence of protocol-defined AEs and SAEs at all subject evaluation time points during the study. All AEs and SAEs, whether volunteered by the subject, discovered by study personnel during questioning, or detected through physical examination, laboratory test, or other means, must be recorded in the subject's medical record and in the CRF.

Generally, investigators are asked, in recording any AE/SAEs, to document an accurate characterization/description of the event; date of the onset and cessation of the event; severity/intensity of the event; whether treatment was required and, if so, what treatment or action was taken; outcome (e.g., did the subject recover from the AE?); and the investigator's assessment of the relationship between the AE/SAE and the investigational medical product (IMP).

Sponsors should pursue complete case details for real-time evaluation of SAEs that are considered possibly related to the IMP. If known, a complete report should contain all of the following elements:

- Description of the event, including time to onset
- Suspected and concomitant medication details (e.g., dose, lot number, schedule, dates, duration)
- Patient demography (e.g., age, race, sex), baseline medical conditions before IMP exposure, co-morbid conditions, relevant medical/family history, and risk factors
- Documentation of the diagnosis and procedures done regarding the SAE
- Clinical course of the event and outcome (e.g., hospitalization or death)
- Relevant therapeutic measures and laboratory data at baseline, during and after therapy
- Information about response to de-challenge and re-challenge<sup>1</sup>

### Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2009, #9.14 p. 325

### Source

"Good Clinical Practice: A Question & Answer Reference Guide 2009," is available for \$45.95 at <http://www.barnettinternational.com/>.