

Good Clinical Practice Q&A: Focus on Safety Reporting

For the purposes of safety reporting, are the terms "severe" and "serious" considered synonymous?

The terms "severe" and "serious" are not synonymous. Severity (or intensity) refers to the grade of a specific adverse event (AE), as in a mild (Grade 1), moderate (Grade 2), or severe (Grade 3) myocardial infarction. "Serious" is a regulatory definition and is based on subject or event outcome or action criteria usually associated with events that pose a threat to a subject's life or functioning. Seriousness (not severity) serves as the guide for defining the Sponsor's regulatory reporting obligations (i.e., to the applicable regulatory authorities). AE severity and seriousness should be assessed independently by investigators.¹

If a subject enrolled in a study comes to an emergency room (ER) with chest pain and is hospitalized overnight for observation, must site staff report this as a SAE?

Yes. For the seriousness criterion of "inpatient hospitalization" to apply, an overnight stay in the hospital is required. Admission to an ER and release without an overnight stay would not satisfy the "inpatient hospitalization" seriousness criterion. However, there could be other reasons that this event might be classified as serious – for example, the chest pain might be considered "medically important" as defined in the protocol.²

What would an SAE's onset date be if a patient on study develops symptoms of congestive heart failure (CHF) on Monday and is admitted to the hospital the following Friday?

If known, the complete onset date (month-day-year) of the first signs and/or symptoms of the most recent CHF episode should be recorded. In this case, it would be Monday. If the onset date of the first signs and/or symptoms is unknown, the date of hospitalization or diagnosis should be recorded.³

References

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2006, pg. 186
2. Ibid, pg. 186-187
3. Ibid, pg. 187

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2005," is available for \$39.95 at <http://www.barnettinternational.com/>