



GCP Quiz

Case Study on Protocol Compliance

Answers

This month's GCP quiz features a case study on protocol compliance. Consider the following scenario and answer the questions below the case.

Case Study

A protocol comparing a novel anti-inflammatory compound to naproxen sodium for long-term maintenance therapy in patients with osteoarthritis of the knee or hip requires subjects to have a five-year history of documented arthritis. Subjects first enter a pre-treatment screening phase during which the subject must be removed from any current treatments for a period of not less than one week, and have joint pain on movement present at least three hours each day for at least one week immediately prior to enrollment in the study and randomization to treatment.

A nurse handling routine office visits in the investigator's rheumatology clinic refers patient R. King, a 66 year-old female to the clinical research coordinator for consideration for a clinical study.

Questions

1. GCP requires the investigator to comply with the protocol. Describe specifically the documentation that the coordinator should locate in this potential subject's chart to ensure the subject is protocol-eligible for the screening phase.
 - Dated medical record entries of at least five years duration indication osteoarthritis of the knee or hip should be present.
2. What type of source documentation should be prepared to demonstrate the subject's eligibility for randomization to treatment?
 - Source documentation should include a medical record entry stating the date the potentially eligible subject was removed from any current treatment(s), including the name(s) of the current treatment. If the subject is not currently receiving any treatment, a dated entry should state as such. This dated entry must occur at least one week prior to the date of randomization.
 - In addition to the above, written documentation should be present, either in a medical record, or on another document, that provides evidence that the subject experienced joint pain on movement for at least three hours each day for at least one week immediately prior to enrollment in the study and randomization to treatment. GCP does not prescribe any specific method for this documentation. Therefore, it should be clear from inspection of the data that the subject met these entry criteria.



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2. To be in compliance with GCP, when should this subject sign an informed consent form?

- The subject should sign the informed consent form, prior to being removed from any current treatment, because the removal from treatment is a component of the proposed study.

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