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ACRP Certified Professional Exam Sample Questions (Q109-Q114):

NEW QUESTION # 109

A study to determine the effective dose and regimen of a new IP for the treatment of hypothyroidism is considered to be:

- A. Phase IV
- B. Phase I
- C. Phase III
- D. Phase II

Answer: D

Explanation:

A Phase II clinical trial is typically conducted to evaluate the efficacy of a drug, determine the optimal dosing regimen, and further assess its safety profile. Since the objective is to establish the effective dose and regimen for hypothyroidism treatment, this clearly falls under Phase II.

GCP guidelines categorize Phase II trials as those aimed at determining efficacy and optimal dosing of investigational products. "Phase II trials focus on determining the therapeutic efficacy, optimal dosage, and further evaluating the safety of the investigational product." Objectives:

- * Identify effective dosing regimens.
- * Evaluate therapeutic efficacy for targeted conditions.

NEW QUESTION # 110

Access to study documentation for auditors and inspectors during an audit or inspection at a clinical trial site is the responsibility of the:

- A. Sponsor
- B. CRC
- C. CRA
- D. PI

Answer: D

Explanation:

The Principal Investigator (PI) is responsible for providing access to study documentation during an audit or inspection. This includes regulatory files, participant records, and study logs. The PI ensures that auditors and inspectors have appropriate access while maintaining the confidentiality of subject data.

GCP guidelines clearly assign the responsibility for maintaining and granting access to trial documentation to the PI at the study site. "The PI is responsible for ensuring that study-related documents are available for review during audits or inspections." Objectives:

- * Maintain transparency during inspections.
- * Ensure compliance with documentation requirements.

NEW QUESTION # 111

A serious unexpected ADR is one:

- A. Severity and nature of the reaction is consistent with protocol.
- B. That does not need to be reported to the IRB/IEC.
- C. Where the severity of the reaction is not consistent with IB.
- D. That results in the death of the subject.

Answer: C

Explanation:

A serious unexpected adverse drug reaction (ADR) is characterized by an event that is not consistent with the information provided in the Investigator's Brochure (IB). Such reactions may indicate new risks associated with the investigational product and warrant immediate reporting to the sponsor and regulatory authorities.

This answer follows the ICH E6(R2) GCP guidelines, which specify the criteria for reporting serious and unexpected adverse events. "An unexpected adverse drug reaction is one whose nature or severity is not consistent with the applicable product information (e.g., IB)." Objectives:

- * Understanding classification of ADRs
- * Ensuring timely and accurate reporting of unexpected events

NEW QUESTION # 112

The inclusion and exclusion criteria are in place so all subjects are:

- A. Medically appropriate and protected from ethical vulnerability.
- B. Healthy and willing to complete the clinical trial.
- C. Patients with the disease under study and will not have any adverse events.
- D. Ethically vulnerable and patients with the disease under study.

Answer: A

Explanation:

Inclusion and exclusion criteria are designed to ensure that participants are medically appropriate for the study and are not ethically vulnerable. This reduces risks to subjects and ensures that the collected data accurately reflects the target population.

The answer follows GCP principles that emphasize participant safety and data validity through well-defined inclusion/exclusion criteria.

"Inclusion and exclusion criteria are crucial for ensuring the safety of participants and the scientific validity of study results."

Objectives:

- * Ensuring participant safety.
- * Maintaining ethical standards in clinical research.

NEW QUESTION # 113

A PI is reviewing the CRF for a recent subject visit and notices the participant's heart rate and temperature are not recorded. Which of the following study documentation practices was neglected?

- A. Original
- B. Attributable
- C. Contemporaneous
- D. Complete

Answer: D

Explanation:

The missing data indicates a lack of completeness in the study documentation. Completeness is a fundamental requirement in clinical trials, as all necessary information must be recorded accurately and in full. Missing vital signs such as heart rate and temperature can compromise the validity of the data and affect the study's outcomes.

GCP guidelines state that all data collected during the study must be complete, accurate, and consistent with source documents.

"Clinical trial documentation must be complete, containing all data as required by the protocol to ensure data integrity." Objectives:

- * Ensure comprehensive data recording.
- * Maintain accuracy and completeness in study records.

NEW QUESTION # 114

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