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ACRP Certified Professional Exam Sample Questions (Q85-Q90):

NEW QUESTION # 85
Who is responsible for outlining written procedures in a study to assure that changes or corrections in CRFs are documented, are necessary, and are endorsed by the investigator?

- A. Sponsor
- B. Data Manager

- C. CRA
- D. CRO

Answer: A

Explanation:
The sponsor is responsible for establishing written procedures to ensure that all changes or corrections in Case Report Forms (CRFs) are properly documented and justified. These procedures must include who is authorized to make changes, how corrections are documented, and how they are endorsed by the investigator.
This practice ensures data accuracy and traceability.
GCP guidelines indicate that sponsors must establish and maintain procedures for data handling and documentation to ensure accuracy and reliability.
"The sponsor should develop written procedures to ensure that CRF changes are justified, documented, and endorsed by the investigator." Objectives:
* Maintain data accuracy and consistency.
* Ensure transparent documentation practices.

NEW QUESTION # 86
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 III
- C. Phase II
- D. Phase I

Answer: C

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 # 87
The site submitted all start-up documents for a study to the sponsor and the IRB/IEC. The site also has subjects identified for screening. What should happen FIRST?

- A. Obtain IRB/IEC approval
- B. Schedule a site initiation visit
- C. Ship/receive IP
- D. Verify subject eligibility

Answer: A

Explanation:
Before proceeding with any trial-related activities, including subject screening, the site must first obtain IRB /IEC approval. This approval ensures that the study has been reviewed for ethical considerations, risk assessment, and adherence to regulatory requirements. Without IRB/IEC approval, initiating the study would violate ethical guidelines and regulatory standards.
GCP guidelines mandate that no clinical trial procedures, including screening, commence without prior IRB /IEC approval.
"IRB/IEC approval must be obtained before initiating any study-related activities, including screening and subject recruitment." Objectives:
* Ensure ethical compliance before study initiation.
* Protect participant rights and safety.

NEW QUESTION # 88
An investigator participating in a multicenter clinical trial has had 2 of the 4 subjects admitted to the emergency room for life-threatening infections. The investigator made the decision to stop treatment with IP and test for infections in the remaining subjects. What are the NEXT steps the investigator should take?

- A. Update the IB to add the risk of infection and submit to the sponsor for approval.
- B. Notify the sponsor of the change in study plan and submit the deviation to the IRB/IEC for review.
- C. Add the risk of infection to the ICF and submit to the IRB/IEC for review.
- D. Discontinue current subjects from the study and monitor subjects for any anticipated safety events.

Answer: B

Explanation:
The investigator must promptly notify the sponsor about the observed safety concerns and the decision to stop the IP administration. This constitutes a protocol deviation that must be reported tothe IRB/IEC for ethical oversight. It is essential to document the deviation accurately and seek guidance on whether to continue or modify the study procedures.
GCP guidelines require that significant deviations impacting participant safety be reported to both the sponsor and the IRB/IEC for appropriate review and action.
"Significant safety-related deviations must be reported promptly to the sponsor and IRB/IEC to ensure proper oversight and participant protection." Objectives:
Ensure prompt reporting of safety concerns.
Maintain compliance with ethical oversight requirements.

NEW QUESTION # 89
A new device trial is being considered. Before committing to participate in the trial, what is the MOST important item the PI needs to evaluate?

- A. Information to be included in the advertising flyer
- B. Availability of qualified staff to conduct the trial
- C. Length of time to receive the approved trial device
- D. Location of stored trial records

Answer: B

Explanation:
The availability of qualified staff to conduct the trial is essential for maintaining compliance with protocol requirements and ensuring patient safety. Without adequately trained and available staff, the trial's integrity and data quality are compromised.
This answer is based on GCP guidelines emphasizing the importance of having trained and qualified personnel before initiating a trial. "The PI must ensure that sufficient qualified staff is available to conduct the trial as per the protocol and regulatory requirements." Objectives:
* Assessing resource availability
* Ensuring readiness to initiate a clinical trial

NEW QUESTION # 90
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