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ACRP Certified Professional Exam Sample Questions (Q81-Q86):

NEW QUESTION # 81

After the site qualification visit report has been finalized, it must be:

- A. Stored in the sponsor's budgets and contracts file.
- B. Sent to the IRB/IEC for review and approval.
- **C. Kept in the CRO/sponsor's trial master file.**
- D. Included in the PI's regulatory file.

Answer: C

Explanation:

The finalized site qualification visit report must be maintained in the sponsor's trial master file (TMF) as part of the essential documents. The TMF serves as the repository for all documents that demonstrate compliance with the protocol and regulatory requirements. Storing the report in the TMF ensures traceability and documentation of the site's suitability for conducting the trial. GCP guidelines require that site qualification visit reports be included in the trial master file to maintain comprehensive documentation of site assessments.

"Finalized site qualification visit reports must be stored in the sponsor's trial master file to ensure proper documentation and compliance." Objectives:

- * Maintain documentation of site qualifications.
- * Ensure compliance through comprehensive record-keeping.

NEW QUESTION # 82

A sponsor writes a protocol comparing an IP XYZ to a marketed drug ABC to determine if XYZ is more efficacious in the target population than ABC. Both drugs are prepared in identically masked IV bags and distributed according to the randomization scheme outlined in the protocol such that the study team is unaware of the treatment assignment.

Which of the following is an appropriate title for this study?

- A. A randomized, double-blind, superiority study comparing the efficacy of XYZ to ABC in the target population
- B. A randomized, double-blind, double-dummy, superiority study comparing the efficacy of XYZ to ABC in the target population
- C. A randomized, single-blind, placebo-controlled study comparing the efficacy of XYZ to ABC in the target population
- D. A randomized, open-label, comparator study comparing the efficacy of XYZ to ABC in the target population

Answer: A

Explanation:

Since both the investigator and the participant are unaware of the treatment assignment, the study is classified as double-blind. The study aims to establish the superiority of XYZ over ABC, making it a superiority study.

The use of masked IV bags confirms the double-blind design.

The answer is verified from GCP guidelines on blinding and superiority study designs.

"In double-blind studies, neither the participant nor the investigator knows the treatment assignment, which prevents bias."

Objectives:

- * Understanding blinding methods in clinical trials
- * Ensuring unbiased efficacy comparisons

NEW QUESTION # 83

SAEs must be reported immediately by the site to the:

- A. DSMB/IDMC.
- B. Sponsor.
- C. Regulatory agency.
- D. IRB/IEC.

Answer: B

Explanation:

Serious Adverse Events (SAEs) must be reported immediately to the sponsor. The sponsor then assesses the severity, causality, and potential impact on the study and decides whether further reporting to regulatory authorities and IRB/IEC is required. Immediate reporting ensures that appropriate actions are taken to safeguard participant safety.

GCP guidelines specify that the site must notify the sponsor immediately about any SAE to ensure timely safety assessment and reporting.

"Sites must report all serious adverse events immediately to the sponsor, who will then determine the appropriate regulatory and ethical reporting requirements." Objectives:

- * Ensure rapid reporting of serious adverse events.
- * Maintain safety monitoring during the trial.

NEW QUESTION # 84

IP is dispensed to all subjects who:

- A. Consented for the trial.
- B. Need IP for their medical condition.
- C. Are eligible to receive it in the trial.
- D. Screened for the trial.

Answer: C

Explanation:

The investigational product (IP) is only dispensed to subjects who meet the eligibility criteria as defined in the study protocol. Eligibility is confirmed during screening and baseline assessments. Simply consenting to the trial does not guarantee receipt of IP. According to GCP guidelines, IP dispensing must strictly follow eligibility criteria to maintain protocol compliance and subject safety. "IP should only be dispensed to subjects who have been deemed eligible according to the protocol's inclusion and exclusion criteria."

Objectives:

- * Maintain adherence to protocol criteria.
- * Protect participant safety by ensuring proper eligibility.

NEW QUESTION # 85

Which one of the following is a primary objective of a Phase III study of a new IP?

- **A. To demonstrate or confirm therapeutic benefit**
- B. To establish the safety profile
- C. To show superiority over another treatment
- D. To establish dose information

Answer: A

Explanation:

Phase III clinical trials primarily aim to demonstrate or confirm the therapeutic benefit of a new investigational product (IP) compared to standard treatments or placebo. These trials are typically larger and are designed to provide robust evidence of efficacy and further evaluate safety.

According to GCP guidelines, Phase III trials focus on confirming the therapeutic efficacy of the IP in a larger population.

"Phase III trials aim to confirm the therapeutic benefit and safety of the investigational product compared to existing treatments."

Objectives:

- * Confirm therapeutic efficacy.
- * Provide comprehensive safety data.

NEW QUESTION # 86

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