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ACRP CP PRACTICE EXAM QUESTIONS WITH LATEST SOLUTIONS 2024

What would be the first priority for an investigator when a subject wishes to withdraw prematurely from the trial? - answer✓✓Try to obtain the subject's reason for withdrawal.

CRO recently switched from paper CRF to an EDC system. The EDC system must conform to the established requirements for:- answer✓✓Validation, accuracy, reliability, completeness

Part of a sponsor's responsibility pertaining to electronic trial data handling is to - answer✓✓maintain an audit trail, data trail, and edit trail.

A research subject's responsibilities for study participation should be described in the:- answer✓✓ICF

What document would an investigator reference to learn more about the previous clinical and nonclinical results of studies of the IP? - answer✓✓Investigators brochure

During a multi site clinical study, whose responsibility is it to report subject recruitment rate? - answer✓✓The CRA

An unconscious adult subject was enrolled in a study after obtaining consent from an LAR, and protocol therapy was initiated. The subject showed significant improvement in his clinical condition, and regained consciousness. The Investigator should inform the subject about the study and - answer✓✓Obtain consent from the subject for the study

A site is in the start up phase of an industry sponsored phase 3 trial, and has received IRB approval. The site can begin enrolling subjects after.... - answer✓✓A signed clinical trial agreement between the site and sponsor is in place

A site is screening potential subjects for a study looking at mild cognitive impairment. One of the inclusion criteria is a score of 25 or less on a psychometric test, a research specific tool which measures cognitive ability. Which of the following individuals can administer the psychometric test to the potential subjects? - answer✓✓A research assistant who is certified to administer the psychometric test

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ACRP Certified Professional Exam Sample Questions (Q28-Q33):

NEW QUESTION # 28

While reviewing reports of data completion, the sponsor notices low retention rates at many participating sites. What is an appropriate FIRST action for the sponsor to take?

- A. Require participants to provide documented reason for withdrawal.
- B. Interview participants who have dropped out.
- C. Submit revised ICFs to the IRB/IEC with increased compensation for participants.
- D. Meet with the site staff to understand their workflows and to review retention strategies.

Answer: D

Explanation:

Meeting with site staff to understand workflows and retention strategies is the most practical first step. By engaging with the team, the sponsor can identify potential issues affecting retention, such as site-related factors, participant burden, or protocol complexities. Addressing these issues collaboratively can improve retention without needing major protocol changes.

GCP guidelines recommend assessing and understanding site-specific challenges before making procedural changes or protocol amendments.

"Engaging with site staff to discuss retention issues helps identify root causes and develop practical solutions." Objectives:

* Improve participant retention through collaboration.

* Identify and address site-specific challenges.

NEW QUESTION # 29

During a mid-study sponsor audit of a clinical trial, the auditor notices that all of the protocol-required subject drug dosing diaries were incomplete. The effect of this will be the inability to:

- A. Verify compliance with IP regimen.
- B. Evaluate study data.
- C. Validate protocol endpoints.
- D. Conduct safety analysis.

Answer: A

Explanation:

Subject drug dosing diaries are essential for documenting adherence to the investigational product (IP) regimen. Incomplete or missing diaries compromise the ability to verify whether subjects followed the dosing schedule, which directly affects the trial's data integrity and the reliability of efficacy and safety assessments.

GCP guidelines stress the importance of maintaining accurate and complete dosing records to verify subject compliance with the protocol.

"Accurate documentation of dosing is essential to verify compliance with the investigational product regimen and ensure data accuracy." Objectives:

* Maintain accurate IP administration records.

* Ensure compliance monitoring throughout the study.

NEW QUESTION # 30

All of the following are steps to assure an effective risk management approach while conducting a clinical study EXCEPT:

- A. Assessing risk based on study impact.
- B. Identifying potential study risks.
- C. Documenting all possible risk scenarios.

- D. Controlling risk by setting thresholds of risk acceptability.

Answer: C

Explanation:

While identifying potential risks, assessing them based on their impact, and setting risk acceptability thresholds are integral parts of a risk management approach, documenting every possible risk scenario is impractical and unnecessary. Instead, focus should be on identifying and managing the most significant and likely risks that could affect the study's quality and safety.

GCP guidelines emphasize identifying, assessing, and controlling critical risks rather than exhaustively documenting all hypothetical scenarios.

"Effective risk management involves identifying key risks, evaluating their impact, and setting control measures, rather than documenting every possible risk." Objectives:

- * Implement practical and targeted risk management strategies.
- * Focus on significant and likely risks rather than hypothetical ones.

NEW QUESTION # 31

In order to conduct open-label, parallel group clinical trials according to sound scientific principles, which of the following design elements should be included?

- A. Randomization
- B. Blinding
- C. Placebo-controlled
- D. Privacy controls

Answer: A

Explanation:

Randomization is a key element in open-label, parallel group clinical trials to reduce selection bias and ensure that participant allocation is not influenced by investigators. Despite the absence of blinding in open-label studies, randomization maintains the validity and reliability of the results by evenly distributing confounding factors between groups.

GCP guidelines recommend randomization as a core element in clinical trial design to ensure unbiased allocation of participants.

"Randomization in parallel group trials helps minimize selection bias and ensures the comparability of intervention groups."

Objectives:

- * Maintain scientific rigor through randomization.
- * Minimize selection bias in clinical studies.

NEW QUESTION # 32

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

Answer: B

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.

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