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ACRP CP PRACTICE Question with complete solution 2023

What would be the first priority for an investigator when a subject wishes to withdraw prematurely from the trial? - correct 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: - correct answer Validation, accuracy, reliability, completeness

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

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

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

During a multi site clinical study, whose responsibility is it to report subject recruitment rate? - correct 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 - correct 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... - correct 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? - correct answer A research assistant who is certified to administer the psychometric test

A research study, in which there is no intended clinical benefit to the subject, is being submitted to the IRB. What benefit information should be included in the ICF? - correct answer Wording indicating that there is no expected benefit should be included

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ACRP Certified Professional Exam Sample Questions (Q99-Q104):

NEW QUESTION # 99

A root cause analysis should be:

- A. Validated before use in a CAPA.
- B. Written by the investigator.
- **C. Focused on issues of non-compliance.**
- D. Specific to a clinical trial.

Answer: C

Explanation:

Root cause analysis (RCA) is a systematic process aimed at identifying the underlying reasons for non-compliance or errors in clinical trials. The purpose of RCA is to understand why a problem occurred so that corrective and preventive actions (CAPA) can be implemented effectively. Focusing on issues of non-compliance ensures that the study adheres to GCP and regulatory requirements.

GCP guidelines recommend performing a root cause analysis when deviations or non-compliance are identified to develop effective CAPA plans.

"Root cause analysis focuses on identifying non-compliance issues to implement corrective and preventive measures effectively."

Objectives:

- * Address non-compliance systematically.
- * Develop effective CAPA plans.

NEW QUESTION # 100

A hospital site is being considered for a trial that requires the IP refrigerator to be continuously monitored using the sponsor-provided Wi-Fi-enabled thermometer. The hospital's Wi-Fi connectivity is inconsistent.

During site selection, how should the CRA proceed?

- A. Accept this site and plan to undertake routine safety evaluations of the IP.
- B. Accept this site and implement and maintain QA and QC systems with written SOPs.
- **C. Before accepting this site, report the risk to the trial sponsor and await their decision.**
- D. Before accepting this site, ensure the refrigerator is calibrated and functioning properly.

Answer: C

Explanation:

Since the Wi-Fi connectivity is inconsistent, the CRA must assess the risk and report it to the trial sponsor for a decision. Accepting the site without proper risk evaluation may compromise the monitoring of the investigational product (IP) storage conditions, affecting trial integrity.

The answer follows GCP guidelines that emphasize assessing potential risks during site selection and involving the sponsor when critical issues arise.

"When faced with site-specific issues that may affect data integrity or product safety, the CRA should consult with the sponsor before making a final decision." Objectives:

- * Ensuring proper site selection
- * Managing potential risks proactively

NEW QUESTION # 101

Source data/documentation should be:

- A. Attributable, legible, correct, original, accurate, and complete.
- **B. Attributable, legible, contemporaneous, original, accurate, and complete.**
- C. Attributable, legible, contemporaneous, original, accurate, and clear.
- D. Attributable, legible, correct, original, accurate, and clear.

Answer: B

Explanation:

Source data/documentation in clinical trials must meet the ALCOA-C standard: Attributable, Legible, Contemporaneous, Original, Accurate, and Complete. This ensures that data is credible, traceable to the source, and maintains integrity throughout the study. These attributes are essential for maintaining high-quality, reliable, and verifiable clinical trial records.

GCP guidelines mandate that source documentation should adhere to the ALCOA-C principles to maintain data integrity and reliability.

"Source data must be attributable, legible, contemporaneous, original, accurate, and complete to meet quality and compliance standards." Objectives:

- * Maintain data integrity and reliability.
- * Adhere to best practices in clinical documentation.

NEW QUESTION # 102

Who is responsible for defining, establishing, and allocating all trial-related duties and functions prior to initiating a trial?

- **A. Sponsor**
- B. Investigator
- C. CRO
- D. IRB/IEC

Answer: A

Explanation:

The sponsor is responsible for defining, establishing, and allocating all trial-related duties and functions before the trial begins. This includes outlining roles and responsibilities in collaboration with investigators, CROs, and other stakeholders. Proper delegation ensures the trial is conducted according to protocol and regulatory requirements.

This answer is verified based on GCP guidelines, which clearly state that sponsors are responsible for the organization and management of trial-related tasks.

"The sponsor is responsible for allocating duties and functions related to the conduct of the trial, ensuring compliance with regulatory and ethical standards." Objectives:

- * Clarify the sponsor's role in clinical trial management
- * Define responsibilities in trial planning

NEW QUESTION # 103

Which of the following would the sponsor need to do FIRST to set up an effective clinical trial quality management system (QMS)?

- **A. Identify critical processes and data during protocol development.**
- B. Determine the quality tolerance limits for data transcription errors.
- C. Train the research coordinator on the required study assessments schedule.
- D. Perform a periodic review to see if the quality methods are effective and relevant.

Answer: A

Explanation:

The first step in establishing a robust quality management system (QMS) is to identify critical processes and data during protocol development. This step ensures that quality objectives are clear and that monitoring and quality control efforts are focused on the most significant aspects of the study. By understanding critical data points and processes early, the sponsor can design a more effective QMS to manage risks.

GCP guidelines emphasize identifying critical data and processes at the earliest stages to develop a risk-based quality management approach.

"Identification of critical data and processes at the protocol development stage is essential for designing an effective quality management system." Objectives:

- * Establish quality oversight from the start.
- * Implement a risk-based monitoring approach.

NEW QUESTION # 104

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