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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 (Q93-Q98):

NEW QUESTION # 93

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

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

Answer: C

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 # 94

An interim analysis is conducted during a clinical trial. To review the results, the sponsor assigns:

- A. Executive board members.
- B. Independent qualified individuals.
- C. Investigators participating in the trial.
- D. Regulatory authority expert advisors.

Answer: B

Explanation:

Interim analysis should be reviewed by independent qualified individuals, such as members of a Data Safety Monitoring Board (DSMB) or Independent Data Monitoring Committee (IDMC). This ensures that the analysis is unbiased and that decisions regarding continuation, modification, or termination of the trial are made objectively.

GCP guidelines emphasize that interim data should be reviewed by an independent committee to prevent bias and ensure participant safety.

"Interim analyses should be conducted by independent experts to maintain objectivity and safeguard trial integrity." Objectives:

- * Maintain impartiality during interim analysis.
- * Ensure unbiased decision-making regarding trial continuation.

NEW QUESTION # 95

Which entity has ultimate responsibility over the conduct of the multi-center clinical trial?

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

Answer: D

Explanation:

In a multi-center clinical trial, the Sponsor-Investigator holds ultimate responsibility for the overall conduct of the study. This includes ensuring compliance with the protocol, maintaining data integrity, and overseeing all participating sites. The Sponsor-Investigator must ensure that each site follows the same procedures and standards to maintain consistency across the trial.

According to GCP guidelines, the Sponsor-Investigator must take responsibility for all aspects of a multi-center trial, including site coordination and data management.

"The Sponsor-Investigator assumes ultimate responsibility for the conduct of a multi-center clinical trial, ensuring protocol compliance and data consistency." Objectives:

- * Maintain accountability across multi-center sites.
- * Ensure uniformity in trial conduct.

NEW QUESTION # 96

During a monitoring visit, a CRA notices that a piece of equipment required for the study needs to be serviced. Who is responsible for addressing this problem?

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

Answer: B

Explanation:

The Principal Investigator (PI) is responsible for ensuring that all equipment used in the clinical trial is properly maintained and serviced. If a monitor (CRA) identifies equipment that needs servicing, the PI must take immediate action to ensure the equipment is in working order to maintain the quality and integrity of the study data.

GCP guidelines emphasize the PI's responsibility to ensure that all equipment used in the study is functional, properly calibrated, and serviced as needed.

"The PI is responsible for maintaining the functionality and calibration of study-related equipment to ensure accurate data collection."

Objectives:

Maintain equipment functionality to ensure data accuracy.

Ensure proper maintenance as part of site management.

NEW QUESTION # 97

When assessing the monitoring needs for a study, sponsors should:

- **A. Ensure monitors have the scientific and/or clinical knowledge needed to monitor the trial adequately.**
- B. Ensure monitoring visits are conducted at periodic intervals with a minimum of monthly monitoring visits.
- C. Permit PIs to select a monitor for their site as long as they are independent of the PI.
- D. Use central monitoring instead of conducting physical monitoring visits at sites.

Answer: A

Explanation:

Sponsors must ensure that monitors are adequately qualified, possessing the necessary scientific and clinical knowledge to effectively oversee the trial. This ensures that monitors can accurately assess protocol compliance, data integrity, and participant safety. The quality of monitoring directly impacts the credibility of the trial outcomes.

GCP guidelines specify that monitors must be adequately trained and knowledgeable about the trial protocol, investigational product (IP), and clinical research standards.

"The sponsor must ensure that monitors have appropriate qualifications and training to conduct effective trial monitoring." Objectives:

- * Maintain data integrity through skilled monitoring.
- * Ensure patient safety and protocol compliance.

NEW QUESTION # 98

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