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ACRP Practice Exam Questions and Answers

A subject is issued 120 tablets and is instructed to take 2 tablets 4 times a day. He returns 88 tablets on the morning of day 9 fasting for laboratory tests. What percent compliant is he? -

ANSWER 50%

To be eligible for a trial, the subjects must have liver function tests no greater than two times the upper limit normal and renal function tests no greater than three times the upper limit normal. All of the following are normal ranges for the trial:

AST 5-65

ALT 5-35

BUN 4-25

Creat 0.5-1.2

Amylase 56-190

Lipase 4-24

ALK Phos 0-110 - ANSWER AST 130; ALT 70; BUN 50; Creat 2.4

A subject presents at a site with her husband after pre-qualifying on a phone screen. She states that she is legally blind and cannot read the ICF. A Braille ICF is not available. This subject is able to sign her name if her hand is guided to the signature line. Which of the following is the BEST course of action to obtain legal consent from the subject? - **ANSWER The subject and an impartial witness can sign the ICF after it is read to them and she verbally states her understanding.**

Which of the following is MOST useful for scheduling trial procedures? - **ANSWER trial schedule of events**

A subject is participating in a clinical trial where only the pharmacist and sponsor knows the identity of the IP. The pharmacist has no contact with the trial subject and the clinical team.

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ACRP Certified Professional Exam Sample Questions (Q47-Q52):

NEW QUESTION # 47

A study drug will be shipped, stored, and mixed at the hospital pharmacy and will be transferred to the study site for infusion. Which document describes how the transfer will occur?

- A. Clinical Monitoring Plan
- **B. Standard Operating Procedure**
- C. Data & Safety Monitoring Plan
- D. Investigator's Brochure

Answer: B

Explanation:

The Standard Operating Procedure (SOP) outlines the process for shipping, storing, mixing, and transferring the investigational product (IP) between locations. SOPs ensure that all steps are consistently followed and documented, maintaining the integrity and quality of the IP throughout the handling process. This is critical for maintaining compliance with Good Clinical Practice (GCP) and ensuring patient safety.

GCP guidelines specify that SOPs should cover the handling, transfer, and storage of investigational products to ensure quality control.

"SOPs provide detailed guidance on the handling and transfer of investigational products to ensure consistency and compliance."

Objectives:

- * Maintain the integrity of IP during transport and handling.
- * Ensure compliance through standardized procedures.

NEW QUESTION # 48

Which of the following statements is TRUE about an EDC system?

- A. IRB/IEC approval is required before the use of the computerized system.
- B. A separate workstation should be made available for the monitor.
- **C. There should be an audit trail to track data entries, deletions, and changes.**
- D. The eCRF should be an exact page-by-page replica of the paper CRF.

Answer: C

Explanation:

An Electronic Data Capture (EDC) system must include an audit trail to ensure data integrity. This audit trail records every data entry, modification, and deletion along with timestamps and user identification. It is a critical feature for maintaining traceability and accountability in clinical research, allowing for the reconstruction of data changes and ensuring compliance with Good Clinical Practice (GCP).

GCP guidelines mandate that electronic data systems used in clinical trials must maintain an audit trail to ensure data integrity and traceability.

"An audit trail is essential in an EDC system to document all data entries, changes, and deletions to maintain data integrity."

Objectives:

- * Ensure data integrity through traceable record-keeping.
- * Maintain compliance with regulatory standards.

NEW QUESTION # 49

Which of the following activities is the MOST efficient way of overseeing a CRO's management during a clinical trial?

- A. Central monitoring of data fields by sponsor

- B. Co-monitoring of CRO site visits
- **C. Risk-based audits of CRO activities as delegated**
- D. Pre-qualification assessment of CRO

Answer: C

Explanation:

Risk-based audits of CRO activities as delegated are considered the most efficient way of overseeing a CRO's management. This approach focuses on evaluating the critical risks that might impact data integrity and participant safety. It allows sponsors to allocate resources to areas with the highest potential for error or deviation, rather than performing exhaustive monitoring of all activities. The answer is verified as per guidelines on risk-based monitoring strategies, emphasizing targeted and efficient oversight of CRO functions.

"Risk-based monitoring emphasizes focusing on critical study parameters and the risks that have the potential to affect data quality and subject safety." Objectives:

- * Efficient management of outsourced clinical trial tasks.
- * Ensuring data integrity through targeted audits.

NEW QUESTION # 50

All site financial matters pertaining to a trial are listed in what document?

- A. Protocol
- **B. Signed contract**
- C. Informed consent form
- D. Financial disclosure

Answer: B

Explanation:

All financial agreements, including compensation, budgeting, and payment terms related to the conduct of a clinical trial, are documented in the signed contract between the sponsor and the site. This contract outlines the financial responsibilities and ensures transparency and compliance.

GCP guidelines stipulate that financial matters related to the conduct of a trial are to be formally documented in contractual agreements.

"The financial aspects of a clinical trial must be outlined in the signed agreement between the sponsor and the site, ensuring clear understanding of compensation and obligations." Objectives:

- * Ensure financial transparency and accountability.
- * Maintain compliance with contractual obligations.

NEW QUESTION # 51

A quality assurance audit of the EDC system SOP revealed a deficiency. Which of the following is the MOST likely reason?

- A. The number of unique eCRF templates was not specified.
- B. The number of users with access was not defined.
- C. The list of comparable technology solutions was not included.
- **D. The frequency of data backup was not defined.**

Answer: D

Explanation:

The frequency of data backup is a critical element of an Electronic Data Capture (EDC) system's Standard Operating Procedure (SOP). Ensuring regular and systematic data backup is essential for protecting trial data against loss or corruption. Failure to specify backup frequency indicates a gap in data security management.

GCP guidelines stress that data protection, including regular backups, is essential to maintaining data integrity in clinical trials.

"EDC system SOPs must include clear guidelines on data backup frequency to safeguard the integrity and availability of study data."

Objectives:

- * Ensure data security through regular backups.
- * Maintain data integrity in clinical research.

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