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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 (Q52-Q57):

NEW QUESTION # 52

Who is responsible to ensure training for key staff members unable to attend the site initiation visit?

- A. Investigator
- B. Monitor
- C. Sponsor
- D. Coordinator

Answer: A

Explanation:

The Principal Investigator (PI) is responsible for ensuring that all site staff involved in the study are adequately trained, even if they were unable to attend the Site Initiation Visit (SIV). This responsibility includes organizing training sessions or providing relevant training materials to maintain consistency and compliance with study protocols.

According to GCP guidelines, the PI must ensure that all staff members involved in the trial are adequately informed and trained on their specific responsibilities.

"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions." Objectives:

- * Maintain consistent training for all clinical staff.
- * Ensure compliance with study procedures.

NEW QUESTION # 53

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

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

Answer: A

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 # 54

Per the protocol, participants' blood creatinine level must be no greater than 2.5 times the upper limit of normal (0.7-1.2 mg/dL).

What is the maximum creatinine level the participant can have and be eligible for the trial?

- A. 1.8 mg/dL
- B. 3.0 mg/dL
- C. 2.6 mg/dL
- D. 3.6 mg/dL

Answer: B

Explanation:

To calculate the maximum allowable creatinine level, multiply the upper limit of normal (1.2 mg/dL) by 2.5.

$$1.2 \times 2.5 = 3.0 \text{ mg/dL}$$

Therefore, the maximum creatinine level that a participant can have to remain eligible for the trial is 3.0 mg/dL.

GCP guidelines specify that eligibility criteria, including lab values, must be strictly followed to maintain protocol compliance.

"The protocol specifies that laboratory values must not exceed the defined limits to ensure participant safety and data integrity."

Objectives:

- * Maintain accurate interpretation of laboratory criteria.
- * Ensure compliance with protocol-defined inclusion/exclusion criteria.

NEW QUESTION # 55

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

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

Answer: C

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 # 56

Which of the following should be reviewed and evaluated by qualified experts to assess implications for the safety of the trial subjects?

- A. PI roles and responsibilities
- B. Project feasibility considerations
- C. Sample collection storage, disposal, and shipment requirements
- **D. Emerging animal toxicological and clinical data**

Answer: D

Explanation:

Qualified experts should evaluate emerging animal toxicological and clinical data to assess potential safety implications for trial subjects. These data are critical in identifying potential risks, adverse effects, or safety concerns before exposing human subjects to the investigational product. Early detection of safety issues through expert evaluation helps protect participant well-being.

GCP guidelines stress the importance of expert assessment of preclinical and clinical data to identify risks and ensure participant safety.

"Emerging toxicological and clinical data should be carefully reviewed by qualified experts to identify safety concerns before clinical use." Objectives:

- * Ensure participant safety through expert data analysis.
- * Identify potential safety risks early in the trial process.

NEW QUESTION # 57

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