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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 twotimes 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 trialschedule 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 (Q91-Q96):

NEW QUESTION # 91

Which of the following documents is maintained by a PI to ensure compliance with sponsor requirements?

- A. Training records of site personnel on study protocol, and their study-related duties and functions.
- B. A monitoring report that identifies deviation from the approved protocol.
- C. A monitoring plan that is tailored to the specific human subject protection and data integrity risks of the trial.
- D. Regulatory submission of protocol and accompanying documents to relevant regulatory authority.

Answer: A

NEW QUESTION # 92

After enrolling and treating a few subjects on an investigator-initiated trial, the PI would like to include a subject diary for each trial subject to capture their activities and experiences on the trial regimen. After the PI has generated a diary, what should the PI do next?

- A. Submit the diary to the regulatory authority for approval.
- B. **Submit the diary to the IRB/IEC for approval.**
- C. Submit the diary to the sponsor for approval.
- D. No approval is necessary: give the diary to each subject.

Answer: B

Explanation:

Any new data collection tool introduced during a clinical trial, including subject diaries, must be reviewed and approved by the IRB/IEC before implementation. This ensures that the new tool is ethically appropriate, respects subject privacy, and aligns with the approved protocol.

This answer aligns with ICH E6(R2) GCP guidelines, which mandate IRB/IEC approval for any new or modified subject-related documents introduced during a trial.

"All changes in study documents, including subject diaries, must be submitted for IRB/IEC review to ensure compliance with ethical standards." Objectives:

- * Maintain compliance with IRB/IEC requirements.
- * Ensure ethical handling of subject data.

NEW QUESTION # 93

The process of ensuring and documenting that an electronic data processing system conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance is called:

- A. Quality Control
- B. **Validation**
- C. Programming
- D. Quality Assurance

Answer: B

Explanation:

Validation is the process of ensuring that an electronic data processing system meets the sponsor's specifications for completeness, accuracy, reliability, and consistent performance. It involves systematic testing and documentation to demonstrate that the system functions as intended, especially in the context of capturing, processing, and managing clinical trial data.

GCP guidelines specify that validation of electronic systems is crucial to maintain data integrity and compliance with regulatory standards.

"Validation ensures that electronic data systems function according to the sponsor's requirements, maintaining data accuracy and reliability." Objectives:

Maintain data integrity and reliability.

Demonstrate system compliance with regulatory requirements.

NEW QUESTION # 94

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

- A. Train the research coordinator on the required study assessments schedule.
- B. Perform a periodic review to see if the quality methods are effective and relevant.
- **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 # 95

While reviewing a new protocol, a PI realizes a specialized laboratory test is required that the local hospital does not perform. The PI locates a laboratory that performs the specialized test and retains their services.

Responsibility for ensuring the laboratory retained is qualified for this trial-related task lies with the:

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

Answer: C

Explanation:

The Principal Investigator (PI) is responsible for ensuring that any laboratory used for trial-related testing is appropriately qualified and certified. This includes verifying the laboratory's accreditation, quality control procedures, and ability to perform the required tests accurately. The PI must document the qualification process to ensure compliance with GCP and protocol requirements.

GCP guidelines state that the investigator is responsible for selecting and verifying the qualification of laboratories used in the study.

"The PI must ensure that any laboratory involved in the trial is properly qualified and capable of performing the specified tests according to protocol requirements." Objectives:

- * Maintain quality control in laboratory testing.
- * Ensure the accuracy and reliability of test results.

NEW QUESTION # 96

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