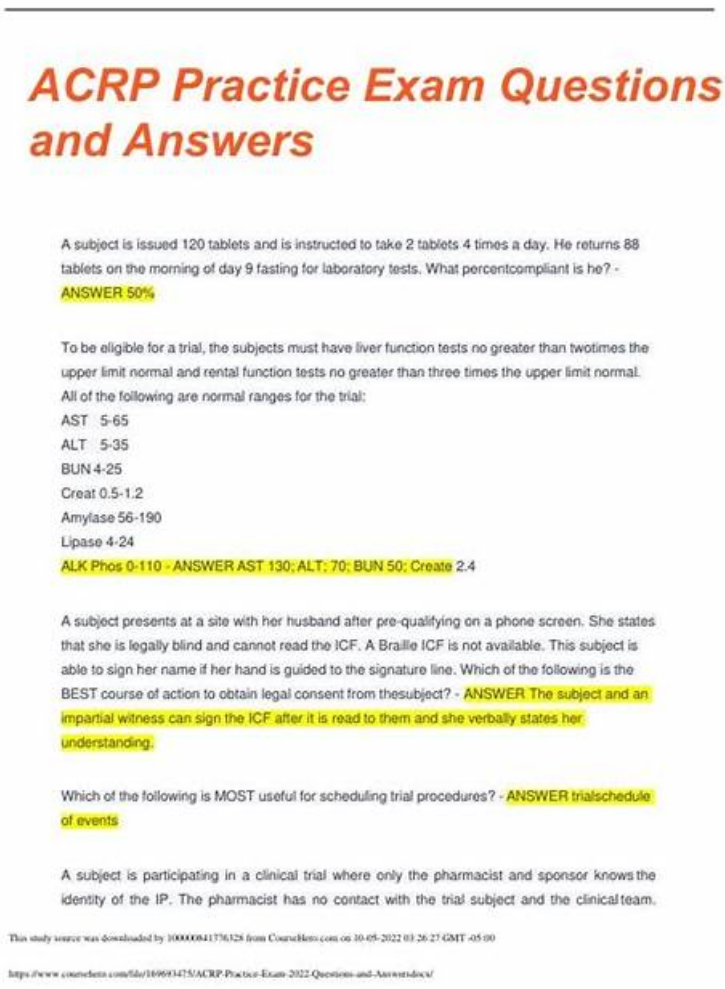
ACRP-CP Reliable Study Notes - ACRP-CP Valid Test Questions



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 percentcompliant 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 rental 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; Create 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 thesubject? - 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 clinicalteam.

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ACRP Certified Professional Exam Sample Questions (Q101-Q106):

NEW QUESTION # 101
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 sponsor for approval.
- B. Submit the diary to the IRB/IEC for approval.
- C. Submit the diary to the regulatory authority 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 # 102
A double-blind randomized Phase III trial seeks to recruit 500 subjects in 2 years. At the end of the first year,
150 subjects have been enrolled. Monitoring reports from the first year note 50% of subjects screened were screen failures due to exclusionary lab values. What action should the sponsor take?

- A. Re-train investigators on recruitment obligations.
- B. Reduce the target sample size based on feedback from the sites.
- C. Evaluate the screen failures to determine if the protocol needs revision.
- D. Allocate additional monitoring resources to the trial.

Answer: C

Explanation:
The high rate of screen failures indicates that the inclusion/exclusion criteria may be too stringent or not appropriately defined. The sponsor should evaluate the reasons for these failures and determine whether the protocol needs adjustment. Revising the criteria may increase recruitment efficiency without compromising the scientific validity of the study.
GCP guidelines advise reviewing and possibly revising protocols when screen failure rates are significantly high to ensure feasible recruitment.
"If a high number of screen failures occurs, the sponsor should evaluate the inclusion/exclusion criteria and consider protocol revisions." Objectives:
* Improve recruitment efficiency.
* Adapt protocol criteria to real-world conditions.

NEW QUESTION # 103
A PI is reviewing the CRF for a recent subject visit and notices the participant's heart rate and temperature are not recorded. Which of the following study documentation practices was neglected?

- A. Contemporaneous
- B. Complete
- C. Attributable

- D. Original

Answer: B

Explanation:
The missing data indicates a lack of completeness in the study documentation. Completeness is a fundamental requirement in clinical trials, as all necessary information must be recorded accurately and in full. Missing vital signs such as heart rate and temperature can compromise the validity of the data and affect the study's outcomes.
GCP guidelines state that all data collected during the study must be complete, accurate, and consistent with source documents. "Clinical trial documentation must be complete, containing all data as required by the protocol toensure data integrity." Objectives:
* Ensure comprehensive data recording.
* Maintain accuracy and completeness in study records.

NEW QUESTION # 104
Who is responsible for submitting a protocol amendment to the IRB/IEC?

- A. CRC
- B. CRA
- C. Sponsor
- D. Investigator

Answer: D

Explanation:
The investigator holds the responsibility for submitting any protocol amendments to the IRB/IEC for review and approval. This step ensures that all changes are ethically evaluated before being implemented, maintaining compliance with regulatory requirements.
According to GCP guidelines, the investigator must submit protocol changes to the IRB/IEC to secure approval before making any modifications to the study.
"The investigator must inform the IRB/IEC of any proposed protocol changes and secure approval prior to implementation."
Objectives:
* Maintain ethical oversight in study modifications.
* Adhere to regulatory submission requirements.

NEW QUESTION # 105
A new device trial is being considered. Before committing to participate in the trial, what is the MOST important item the PI needs to evaluate?

- A. Length of time to receive the approved trial device
- B. Availability of qualified staff to conduct the trial
- C. Information to be included in the advertising flyer
- D. Location of stored trial records

Answer: B

Explanation:
The availability of qualified staff to conduct the trial is essential for maintaining compliance with protocol requirements and ensuring patient safety. Without adequately trained and available staff, the trial's integrity and data quality are compromised.
This answer is based on GCP guidelines emphasizing the importance of having trained and qualified personnel before initiating a trial.
"The PI must ensure that sufficient qualified staff is available to conduct the trial as per the protocol and regulatory requirements."
Objectives:
* Assessing resource availability
* Ensuring readiness to initiate a clinical trial

NEW QUESTION # 106
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