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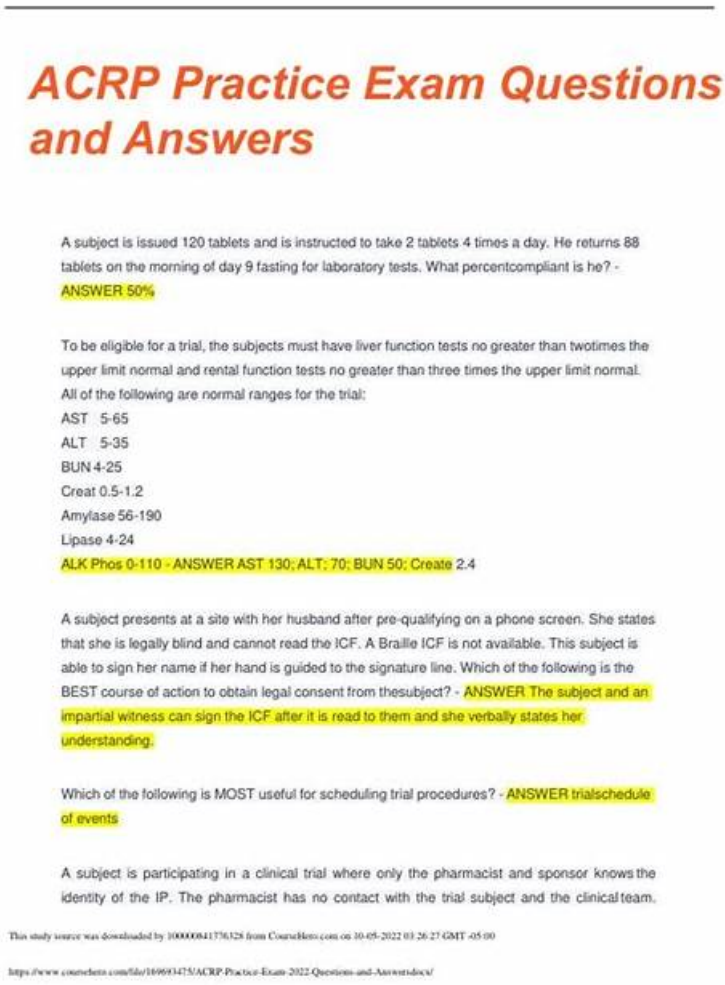

ACRP Practice Exam Questions and Answers

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 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 (Q36-Q41):

NEW QUESTION # 36
Centralized monitoring can:

- A. Enable appropriate stratification of subject enrollment.
- B. Identify IP accountability and storage issues.
- C. Confirm why sites are deviating from the protocol.
- D. Indicate the need to send monitors to perform onsite visits.

Answer: D

Explanation:
Centralized monitoring involves the remote evaluation of data trends, outliers, and inconsistencies across sites. If significant issues are identified through centralized monitoring, it may prompt the need for targeted on-site visits to investigate and resolve the identified issues. This approach optimizes resource utilization and focuses on potential problem areas.
GCP guidelines support the use of centralized monitoring to identify risks that warrant on-site monitoring, promoting efficient and targeted oversight.
"Centralized monitoring can identify data patterns or anomalies that indicate the need for an on-site visit to verify and address the issue." Objectives:
* Enhance monitoring efficiency through data-driven decisions.
* Prioritize on-site visits based on identified risks.

NEW QUESTION # 37
Which entity has ultimate responsibility over the conduct of the multi-center clinical trial?

- A. CRO
- B. IRB/IEC
- C. Regulatory authority
- 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 # 38
A hospital site is being considered for a trial that requires the IP refrigerator to be continuously monitored using the sponsor-provided Wi-Fi-enabled thermometer. The hospital's Wi-Fi connectivity is inconsistent.
During site selection, how should the CRA proceed?

- A. Accept this site and plan to undertake routine safety evaluations of the IP.
- B. Before accepting this site, report the risk to the trial sponsor and await their decision.
- C. Before accepting this site, ensure the refrigerator is calibrated and functioning properly.
- D. Accept this site and implement and maintain QA and QC systems with written SOPs.

Answer: B

Explanation:
Since the Wi-Fi connectivity is inconsistent, the CRA must assess the risk and report it to the trial sponsor for a decision. Accepting the site without proper risk evaluation may compromise the monitoring of the investigational product (IP) storage conditions, affecting trial integrity.
The answer follows GCP guidelines that emphasize assessing potential risks during site selection and involving the sponsor when critical issues arise.
"When faced with site-specific issues that may affect data integrity or product safety, the CRA should consult with the sponsor before making a final decision." Objectives:
* Ensuring proper site selection
* Managing potential risks proactively

NEW QUESTION # 39
In addition to members who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial, it is recommended that the IRB/IEC should include:

- A. One member of the site's QA group.
- B. A total of five members.
- C. One member who is independent of the institution/trial site.
- D. One member whose primary area of interest is in the same scientific area.

Answer: C

Explanation:
The IRB/IEC should include at least one member who is not affiliated with the institution or trial site to ensure impartiality and objectivity in the review process. This helps maintain ethical oversight without internal biases influencing the decisions.
This answer is based on ICH E6(R2) GCP guidelines, which mandate the inclusion of non-affiliatedmembers to uphold the integrity of the ethical review process.
"The IRB/IEC should include at least one member who is not associated with the institution to provide an unbiased perspective." Objectives:
* Maintain impartiality in ethical review.
* Ensure diverse representation within the IRB/IEC.

NEW QUESTION # 40
Which statement does NOT represent a study monitor's responsibilities?

- A. Verify that the PI has adequate qualifications and resources to conduct the study.
- B. Report serious adverse events to the IRB/IEC.
- C. Provide communication between the sponsor and the PI.
- D. Check the accuracy and completeness of case report forms with source documents.

Answer: B

Explanation:
It is not the monitor's responsibility to report serious adverse events (SAEs) to the IRB/IEC. This responsibility typically falls on the PI or the sponsor. Monitors focus on data accuracy, protocol compliance, and communication between the site and the sponsor.
The answer follows GCP standards where the monitor's role is clearly defined, excluding SAE reporting to IRB/IEC.
"Monitors are responsible for verifying data accuracy and communicating with the sponsor but not for direct reporting of SAEs to the IRB/IEC." Objectives:
* Distinguish between the responsibilities of monitors and investigators
* Clarify SAE reporting protocols

NEW QUESTION # 41
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