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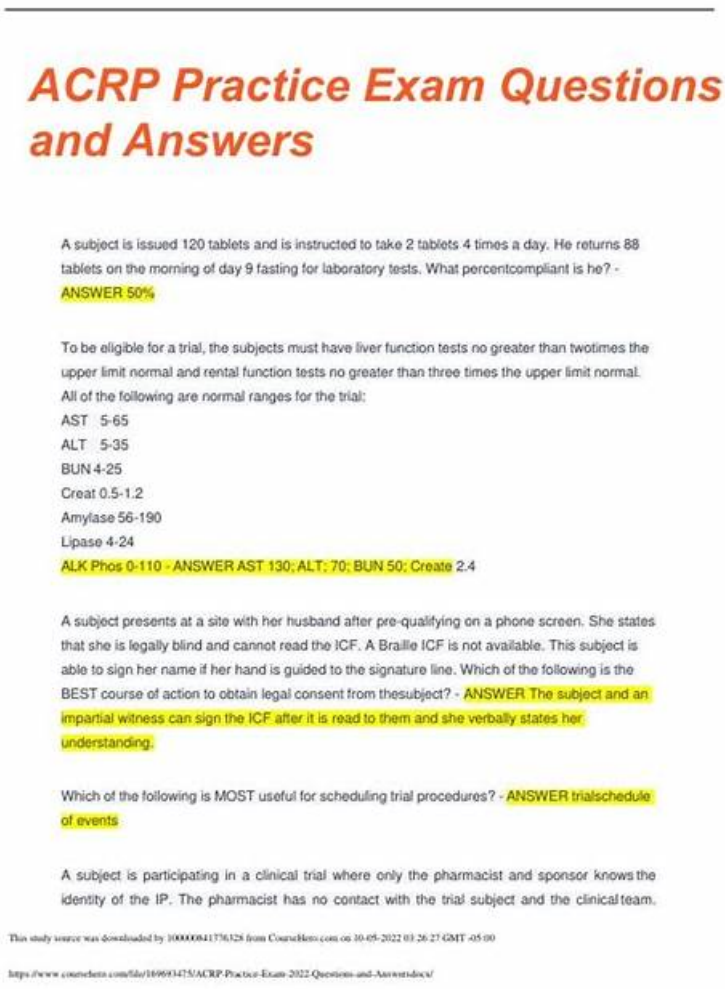

ACRP Practice Exam Questions and Answers

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 (Q89-Q94):

NEW QUESTION # 89
A protocol inclusion criterion requires the serum magnesium at screening to be within the normal range. After the subject received IP, the CRC discovers the subject's screening magnesium level was below the normal range and the sub-investigator marked the lab sheet as not clinically significant. Which of the following should be done FIRST?

- A. Notify the subject.
- B. Withdraw the subject.
- C. Notify the sponsor.
- D. Notify the regulatory authority.

Answer: C

Explanation:
When a protocol deviation is identified, especially one involving inclusion criteria, the sponsor must be notified immediately. The sponsor will assess the deviation and determine whether the subject can continue in the study. Early notification ensures appropriate action and compliance with protocol and regulatory guidelines.
This answer aligns with GCP principles that mandate sponsor notification in case of protocol deviations, especially when they may impact participant safety or data integrity.
"Any deviation from the protocol that affects subject eligibility must be reported to the sponsor immediately for evaluation and guidance." Objectives:
* Maintain adherence to protocol inclusion criteria.
* Report deviations promptly for safety assessment.

NEW QUESTION # 90
Upon receiving their first dose of study drug in the clinic, the subject exhibits an immediately life-threatening reaction. The protocol prohibits any concomitant medications. What should be the investigator's IMMEDIATE response?

- A. Call the medical monitor.
- B. Administer rescue medication.
- C. Report the AE to the sponsor.
- D. Consult the IB.

Answer: B

Explanation:
In a life-threatening situation, the investigator's first priority is the safety and well-being of the participant.
Administering rescue medication immediately is critical to stabilize the patient, regardless of protocol restrictions. Ethical considerations and patient safety always take precedence over protocol compliance.
GCP guidelines emphasize that subject safety is the primary concern, and appropriate medical care must be administered in emergencies.
"In cases of life-threatening events, the investigator should administer necessary medical interventions to safeguard the subject's health." Objectives:
* Prioritize patient safety in emergency situations.
* Make decisions based on medical necessity rather than protocol restrictions.

NEW QUESTION # 91
When determining whether a protocol deviation (PD) is reportable to the IRB/IEC, the PI should take into consideration whether the:

- A. PD affected participant recruitment.
- B. PD affected participant safety.

- C. Sponsor approved the PD.
- D. Participant verbally agreed to the PD.

Answer: B

Explanation:
The primary factor in determining whether a protocol deviation should be reported to the IRB/IEC is whether the deviation impacts participant safety or the integrity of the study data. Any deviation that could pose a risk to participants must be reported promptly to ensure ongoing ethical oversight.
GCP guidelines mandate reporting of any protocol deviations that affect safety or data integrity to the IRB /IEC.
"Protocol deviations that impact the safety of participants or the integrity of the study must be reported to the IRB/IEC." Objectives:
* Maintain participant safety.
* Ensure regulatory compliance through prompt reporting.

NEW QUESTION # 92
The CRC is prepared to consent a cognitively impaired participant to an Alzheimer's clinical trial. The CRC is required to utilize which of the following in the consent process?

- A. A witness
- B. A member of the research team
- C. A family member
- D. A legally acceptable representative

Answer: D

Explanation:
For cognitively impaired participants who may not fully understand the informed consent process, a legally acceptable representative (LAR) must be involved. This ensures that the participant's rights and interests are protected and that consent is obtained ethically and legally.
GCP guidelines mandate that, in cases where participants are unable to provide informed consent, an LAR must be involved to make decisions on their behalf.
"When a participant is cognitively impaired, informed consent must be obtained from a legally acceptable representative to ensure ethical participation." Objectives:
* Safeguard the rights of vulnerable populations.
* Maintain ethical standards in the consent process.

NEW QUESTION # 93
Which of the following would the sponsor need to do FIRST to set up an effective clinical trial quality management system (QMS)?

- A. Identify critical processes and data during protocol development.
- B. Perform a periodic review to see if the quality methods are effective and relevant.
- C. Train the research coordinator on the required study assessments schedule.
- D. Determine the quality tolerance limits for data transcription errors.

Answer: A

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 # 94
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