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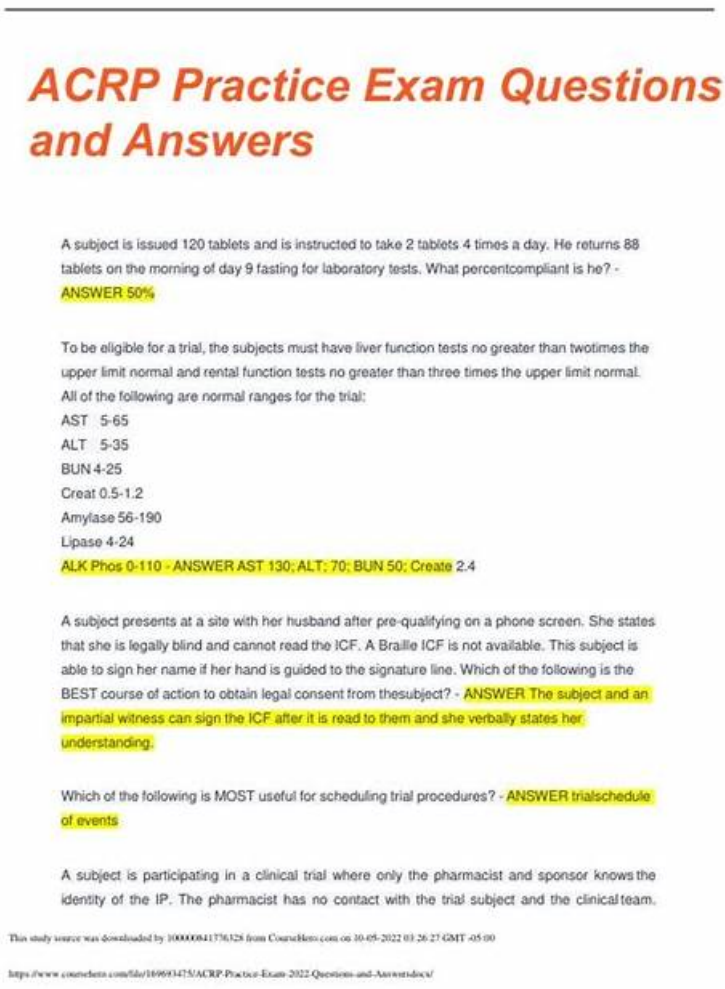

ACRP Practice Exam Questions and Answers

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 (Q79-Q84):

NEW QUESTION # 79
A trial subject was involved in a traffic accident. The emergency room (ER) doctor notifies the investigator that he wants to give the subject a blood transfusion. Blood transfusion is one of the prohibited treatments in the trial. How should the investigator respond?

- A. Advise the ER doctor to transfuse the blood, and the PI should report this incident to the sponsor.
- B. Ask the ER doctor not to transfuse blood and consider another treatment compliant with the protocol.
- C. Advise the ER doctor to transfuse blood, and the PI should withdraw the subject from the trial.
- D. Report this incident immediately to the sponsor and leave the treatment decision to them.

Answer: A

Explanation:
The investigator must prioritize the subject's immediate health and safety. In a medical emergency, the appropriate response is to advise the ER doctor to proceed with the necessary medical intervention (blood transfusion). Afterward, the PI must promptly report the incident to the sponsor as a protocol deviation.
GCP guidelines emphasize that patient safety takes precedence over protocol requirements in emergency situations.
"In situations where immediate medical intervention is necessary to prevent harm, the investigator should ensure that the appropriate care is given and subsequently report the event as a deviation." Objectives:
* Prioritize patient safety in emergencies.
* Report protocol deviations promptly.

NEW QUESTION # 80
SAEs must be reported immediately by the site to the:

- A. DSMB/IDMC.
- B. Sponsor.
- C. Regulatory agency.
- D. IRB/IEC.

Answer: B

Explanation:
Serious Adverse Events (SAEs) must be reported immediately to the sponsor. The sponsor then assesses the severity, causality, and potential impact on the study and decides whether further reporting to regulatory authorities and IRB/IEC is required. Immediate reporting ensures that appropriate actions are taken to safeguard participant safety.
GCP guidelines specify that the site must notify the sponsor immediately about any SAE to ensure timely safety assessment and reporting.
"Sites must report all serious adverse events immediately to the sponsor, who will then determine the appropriate regulatory and ethical reporting requirements." Objectives:
* Ensure rapid reporting of serious adverse events.
* Maintain safety monitoring during the trial.

NEW QUESTION # 81
The objective of a randomized clinical trial is to look at whether an IP is effective in preventing recurrence of a disease. What would be a possible primary endpoint of the trial?

- A. Impact of an approved vaccine against the disease
- B. Occurrence of known side effects of the IP
- C. Use of concomitant medications to treat the symptoms
- D. Time to occurrence of symptoms of the disease

Answer: D

Explanation:
In a clinical trial aimed at assessing whether an IP prevents disease recurrence, the primary endpoint would typically be the "time to occurrence of symptoms" indicating a relapse or recurrence. This endpoint directly measures the IP's effectiveness in prolonging the symptom-free period.
This answer follows the GCP guideline, which states that primary endpoints should directly reflect the trial's objectives, particularly when evaluating recurrence prevention.
"In trials evaluating recurrence prevention, the primary endpoint should measure the time until recurrence of the target symptoms or condition." Objectives:
* Assess the efficacy of IP in preventing disease recurrence.
* Accurately measure the time to recurrence as a primary endpoint.

NEW QUESTION # 82
An investigator in a multicenter trial reports multiple occurrences of an SAE to the sponsor. Who is responsible for reporting the SAEs to the remaining sites' IRB/IECs?

- A. Investigator at each site
- B. Regulatory authority
- C. Original reporting investigator
- D. Study sponsor

Answer: D

Explanation:
The study sponsor is responsible for disseminating information about SAEs to all participating sites. This ensures consistent and timely communication of safety concerns, allowing each site to take appropriate actions in line with local regulations and IRB/IEC requirements.
The answer aligns with ICH E6(R2) GCP guidelines which mandate the sponsor to communicatesafety information to all investigators and sites involved in a multicenter trial.
"The sponsor must inform all investigators of safety information that could affect the conduct of the trial or the safety of subjects." Objectives:
* Maintain consistent safety reporting across all trial sites.
* Ensure regulatory compliance in multicenter trials.

NEW QUESTION # 83
A Phase I drug trial has been completed and preparations are being made to proceed to a Phase II trial. Who is responsible for revising the IB with this updated information?

- A. Health authority
- B. Sponsor
- C. DSMB/IDMC
- D. Investigator

Answer: B

Explanation:
The sponsor is responsible for updating the Investigator's Brochure (IB) with new information obtained from the completed Phase I trial. The IB must reflect the most current data on the drug's safety, efficacy, and dosing to support Phase II planning and execution.
According to GCP guidelines, the sponsor must ensure that the IB is updated regularly with relevant findings from ongoing and completed trials.
"The sponsor is responsible for ensuring that the Investigator's Brochure is updated with the latest safety and efficacy data before advancing to the next phase of the trial." Objectives:
* Keep the IB current and accurate.
* Inform investigators of the latest safety and efficacy data.

NEW QUESTION # 84

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