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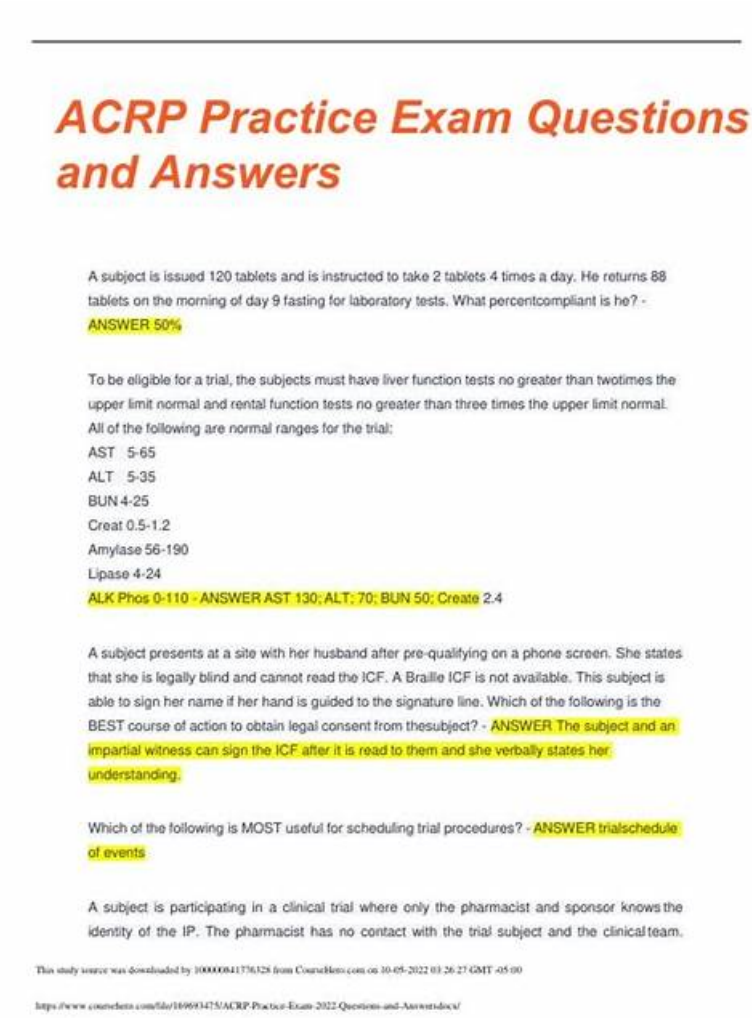

ACRP Practice Exam Questions and Answers

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 (Q56-Q61):

NEW QUESTION # 56
A quality assurance audit of the EDC system SOP revealed a deficiency. Which of the following is the MOST likely reason?

- A. The number of unique eCRF templates was not specified.
- B. The frequency of data backup was not defined.
- C. The number of users with access was not defined.
- D. The list of comparable technology solutions was not included.

Answer: B

Explanation:
The frequency of data backup is a critical element of an Electronic Data Capture (EDC) system's Standard Operating Procedure (SOP). Ensuring regular and systematic data backup is essential for protecting trial data against loss or corruption. Failure to specify backup frequency indicates a gap in data security management.
GCP guidelines stress that data protection, including regular backups, is essential to maintaining data integrity in clinical trials.
"EDC system SOPs must include clear guidelines on data backup frequency to safeguard the integrity and availability of study data."
Objectives:
* Ensure data security through regular backups.
* Maintain data integrity in clinical research.

NEW QUESTION # 57
Which of the following elements of the Informed Consent are NOT required?

- A. Statement that study involves research
- B. A description of any reasonably foreseeable risks or discomforts
- C. Subject legal rights can be waived
- D. A description of potential benefits

Answer: C

Explanation:
Informed consent must not include any language that implies a waiver of the participant's legal rights or releases the investigator, sponsor, or institution from liability for negligence. Such language violates ethical standards and the principles of voluntary participation.
According to GCP guidelines and ethical principles, the informed consent document must not include any clause that waives a participant's legal rights.
"An informed consent form must not include language that waives the participant's legal rights or releases the sponsor or investigator from liability." Objectives:
* Protect participant rights in clinical trials.
* Ensure that consent is given voluntarily and ethically.

NEW QUESTION # 58
Which one of the following is a primary objective of a Phase III study of a new IP?

- A. To demonstrate or confirm therapeutic benefit
- B. To show superiority over another treatment
- C. To establish dose information
- D. To establish the safety profile

Answer: A

Explanation:
Phase III clinical trials primarily aim to demonstrate or confirm the therapeutic benefit of a new investigational product (IP) compared to standard treatments or placebo. These trials are typically larger and are designed to provide robust evidence of efficacy and

further evaluate safety.
According to GCP guidelines, Phase III trials focus on confirming the therapeutic efficacy of the IP in a larger population.
"Phase III trials aim to confirm the therapeutic benefit and safety of the investigational product compared to existing treatments."
Objectives:
* Confirm therapeutic efficacy.
* Provide comprehensive safety data.

NEW QUESTION # 59
The coding system for a double-blind clinical trial is accessible by the:

- A. PI
- B. IRB/IEC
- C. Sponsor
- D. Regulatory authority

Answer: C

Explanation:
The sponsor is typically responsible for maintaining the code that links the treatment assignment to participants in a double-blind clinical trial. The code is securely maintained and is only accessible in cases where unblinding is necessary for safety reasons. This process helps to preserve the integrity of the study while allowing for emergency unblinding if needed.
GCP guidelines state that the sponsor should maintain the blind unless unblinding is necessary due to safety concerns or regulatory requirements.
"The sponsor maintains the randomization code and ensures that unblinding occurs only when necessary, to protect the study's integrity." Objectives:
* Maintain the integrity of double-blind trials.
* Allow controlled access to randomization codes.

NEW QUESTION # 60
The inclusion and exclusion criteria are in place so all subjects are:

- A. Healthy and willing to complete the clinical trial.
- B. Medically appropriate and protected from ethical vulnerability.
- C. Ethically vulnerable and patients with the disease under study.
- D. Patients with the disease under study and will not have any adverse events.

Answer: B

Explanation:
Inclusion and exclusion criteria are designed to ensure that participants are medically appropriate for the study and are not ethically vulnerable. This reduces risks to subjects and ensures that the collected data accurately reflects the target population.
The answer follows GCP principles that emphasize participant safety and data validity through well-defined inclusion/exclusion criteria.
"Inclusion and exclusion criteria are crucial for ensuring the safety of participants and the scientific validity of study results."
Objectives:
* Ensuring participant safety.
* Maintaining ethical standards in clinical research.

NEW QUESTION # 61
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