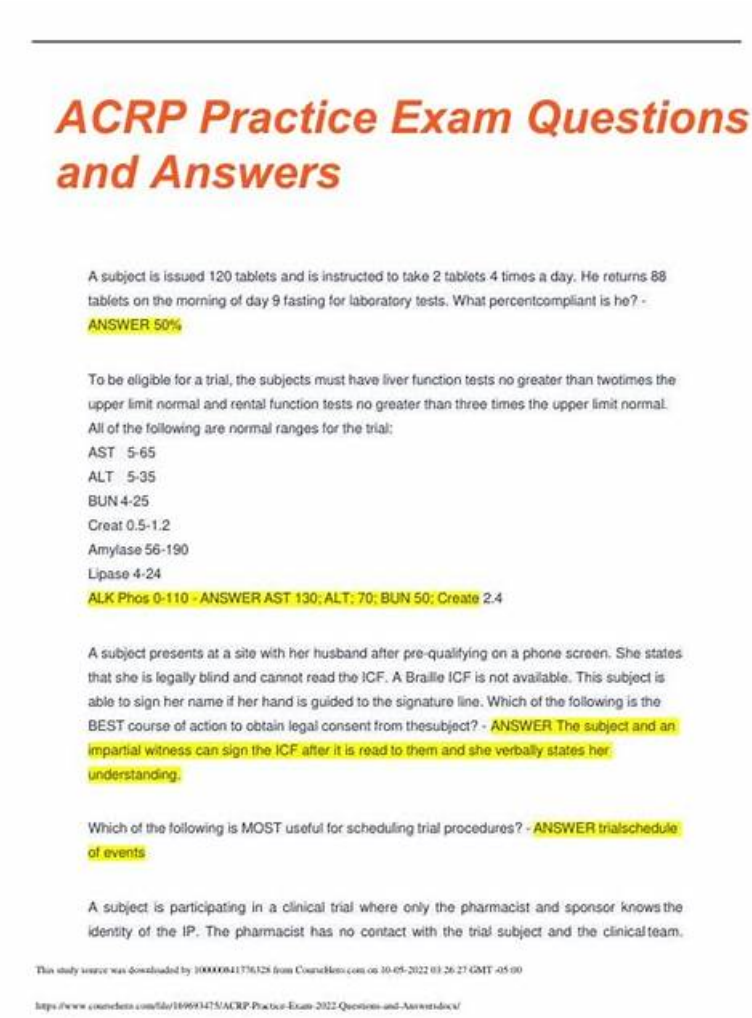
New ACRP ACRP-CP Exam Labs & Vce ACRP-CP File



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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also gives the total score and correct answer rate.

ACRP Certified Professional Exam Sample Questions (Q105-Q110):

NEW QUESTION # 105
After the completion or termination of a clinical trial, who should store the enrollment log?

- A. Regulatory authority
- B. CRO
- C. Sponsor
- D. PI

Answer: D

Explanation:
The Principal Investigator (PI) is responsible for maintaining and securely storing essential documents, including the enrollment log, after the completion or termination of a clinical trial. This ensures that all participant-related records are retained for audit or inspection as per regulatory requirements.
This answer is consistent with GCP guidelines, which specify that the PI is accountable for retaining essential trial documents at the study site.
"The investigator should maintain records of trial participants, including the enrollment log, as part of the essential documents for trial conduct." Objectives:
* Maintain data integrity and compliance with record-keeping requirements.
* Ensure secure and accessible storage of participant information.

NEW QUESTION # 106
The investigator/institution should permit:

- A. Monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).
- B. Monitoring and auditing by the appropriate regulatory authority(ies), and inspection by the sponsor.
- C. Monitoring and inspection by the appropriate regulatory authority(ies), and auditing by the sponsor.
- D. Monitoring and inspection by the sponsor, and auditing by the appropriate regulatory authority(ies).

Answer: C

Explanation:
The investigator and institution must allow both monitoring and inspection by the appropriate regulatory authorities and auditing by the sponsor. This dual oversight ensures that the trial complies with regulatory standards and sponsor requirements, thereby maintaining the integrity and validity of the data.
GCP guidelines specify that regulatory authorities have the right to inspect, while sponsors typically conduct audits to verify compliance and data quality.
"The institution should permit monitoring and inspection by regulatory authorities and auditing by the sponsor to ensure compliance with GCP and protocol adherence." Objectives:
* Facilitate monitoring and inspection for compliance.
* Ensure trial data integrity and quality assurance.

NEW QUESTION # 107
A quality assurance audit of the EDC system SOP revealed a deficiency. Which of the following is the MOST likely reason?

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

Answer: A

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 # 108
Which one of the following is a primary objective of a Phase III study of a new IP?

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

Answer: C

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 # 109
A study is using an EDC system. After the data is entered into EDC, who is the next to review and conduct SDV of this data?

- A. Monitor
- B. Data Manager
- C. Sponsor
- D. QA Department

Answer: A

Explanation:
After data entry into the Electronic Data Capture (EDC) system, the monitor (typically a Clinical Research Associate - CRA) conducts Source Data Verification (SDV). The monitor compares the data entered in the EDC system with the source documents to ensure accuracy, completeness, and consistency. This step is essential for maintaining data integrity and compliance with GCP standards.
GCP guidelines require that monitors verify data accuracy through SDV as part of routine monitoring responsibilities.
"The monitor is responsible for performing Source Data Verification (SDV) to ensure that the data recorded in the EDC system matches the source documents." Objectives:
* Verify data accuracy in clinical trials.
* Ensure compliance with data management protocols.

NEW QUESTION # 110
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