

ACRP ACRP-CP Lerntipps, ACRP-CP Probesfragen

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 percent compliant is he? -

ANSWER 50%

To be eligible for a trial, the subjects must have liver function tests no greater than two times the upper limit normal and renal 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; Creat 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 the subject? - 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 trial schedule 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 clinical team.

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ACRP Certified Professional Exam ACRP-CP Prüfungsfragen mit Lösungen (Q87-Q92):

87. Frage

In order to conduct open-label, parallel group clinical trials according to sound scientific principles, which of the following design elements should be included?

- A. Blinding
- B. Privacy controls
- C. Placebo-controlled
- **D. Randomization**

Antwort: D

Begründung:

Randomization is a key element in open-label, parallel group clinical trials to reduce selection bias and ensure that participant allocation is not influenced by investigators. Despite the absence of blinding in open-label studies, randomization maintains the validity and reliability of the results by evenly distributing confounding factors between groups.

GCP guidelines recommend randomization as a core element in clinical trial design to ensure unbiased allocation of participants.

"Randomization in parallel group trials helps minimize selection bias and ensures the comparability of intervention groups."

Objectives:

- * Maintain scientific rigor through randomization.
- * Minimize selection bias in clinical studies.

88. Frage

SAEs must be reported immediately by the site to the:

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

Antwort: D

Begründung:

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.

89. Frage

A PI is reviewing the CRF for a recent subject visit and notices the participant's heart rate and temperature are not recorded. Which of the following study documentation practices was neglected?

- A. Original
- B. Attributable
- **C. Complete**
- D. Contemporaneous

Antwort: C

Begründung:

The missing data indicates a lack of completeness in the study documentation. Completeness is a fundamental requirement in clinical trials, as all necessary information must be recorded accurately and in full. Missing vital signs such as heart rate and temperature can compromise the validity of the data and affect the study's outcomes.

GCP guidelines state that all data collected during the study must be complete, accurate, and consistent with source documents.

"Clinical trial documentation must be complete, containing all data as required by the protocol to ensure data integrity." Objectives:

- * Ensure comprehensive data recording.
- * Maintain accuracy and completeness in study records.

90. Frage

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

Antwort: C

Begründung:

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.

91. Frage

A sponsor wants to transfer duties to a CRO. Which of the following statements is the MOST correct?

- **A. All duties transferred to a CRO should be specified in writing.**
- B. Regulatory authorities must be notified promptly of the transfer of any duties to a CRO.
- C. The IRB/IEC must approve the transfer of duties to a CRO.
- D. Any trial-related duties can be documented as transferred by verbal agreement.

Antwort: A

Begründung:

When a sponsor transfers specific tasks to a Contract Research Organization (CRO), it must be documented in writing. This formal documentation clearly delineates responsibilities and ensures that both parties are aware of their roles and obligations. Verbal agreements are not sufficient for regulatory compliance.

ICH E6(R2) GCP guidelines mandate that all delegated tasks must be documented formally to ensure clarity and compliance.

"The sponsor should document in writing any responsibilities transferred to a CRO to ensure clear delineation of roles." Objectives:

- * Maintain clear documentation of delegated tasks.
- * Ensure compliance with regulatory standards.

92. Frage

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- [illegible]

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