

Right ACRP ACRP-CP Questions: Epic Ways to Pass Exam [2025]

ACRP CP Exam Actual Questions and Answers 100% Correct | Updated 2023-2024

1571 - Answer  IND application; Permit to do research on humans for the first time; has background info; and rationale; updated annually

1572 - Answer  Investigator statement; commitment, done nationally and internationally by sponsors intending to have marketing approval for IP

IB - Answer  Clinical and non-clinical data on the investigational product that is relevant to the study in human subjects; supplied prior to regulatory approval

Study type - Open Label - Answer  everyone knows the treatment

Study type - Single blind - Answer  one party knows Tx, usually the patient does not know but the monitoring team does

Study type - Double Blind - Answer  2 or more people are blinded, usually the patient and monitoring team do not know which drug is given.

A 3rd party unblinded pharmacist is used and an unblinded CRA is needed

Study Type - Double dummy - Answer  Use to blind similar Tx's; one is active and one is placebo. This occurs when the drug and placebo cannot be made identical (pill vs liquid)

Study Type - Parallel - Answer  Two groups of treatments. One group receives only treatment A and another group receives only treatment B

Study Type - Crossover - Answer  Usually Chronic disease; receives more than one Tx with a washout in between. A then B; could be randomized so the sequence changes

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ACRP Certified Professional Exam Sample Questions (Q66-Q71):

NEW QUESTION # 66

A serious unexpected ADR is one:

- A. Where the severity of the reaction is not consistent with IB.
- B. That does not need to be reported to the IRB/IEC.
- C. That results in the death of the subject.
- D. Severity and nature of the reaction is consistent with protocol.

Answer: A

Explanation:

A serious unexpected adverse drug reaction (ADR) is characterized by an event that is not consistent with the information provided in the Investigator's Brochure (IB). Such reactions may indicate new risks associated with the investigational product and warrant immediate reporting to the sponsor and regulatory authorities.

This answer follows the ICH E6(R2) GCP guidelines, which specify the criteria for reporting serious and unexpected adverse events.

"An unexpected adverse drug reaction is one whose nature or severity is not consistent with the applicable product information (e.g., IB)." Objectives:

- * Understanding classification of ADRs
- * Ensuring timely and accurate reporting of unexpected events

NEW QUESTION # 67

AEs that occur between study visits of a clinical trial should be evaluated by the:

- A. Principal Investigator
- B. Study pharmacovigilance physician
- C. Subject's primary care physician
- D. Medical monitor

Answer: A

Explanation:

The Principal Investigator (PI) is responsible for evaluating Adverse Events (AEs) that occur between study visits. The PI must assess the severity, causality, and potential relationship to the investigational product (IP).

Proper evaluation ensures that any necessary medical interventions are promptly administered and that relevant information is recorded and reported accurately.

GCP guidelines specify that the PI is accountable for the medical care of trial subjects, including evaluating AEs and ensuring their safety.

"The PI must evaluate any adverse events occurring between study visits to determine their relevance to the investigational product and manage patient care." Objectives:

- * Ensure prompt and accurate evaluation of AEs.
- * Maintain the safety and well-being of study participants.

NEW QUESTION # 68

A double-blind randomized Phase III trial seeks to recruit 500 subjects in 2 years. At the end of the first year, 150 subjects have been enrolled. Monitoring reports from the first year note 50% of subjects screened were screen failures due to exclusionary lab values. What action should the sponsor take?

- A. Reduce the target sample size based on feedback from the sites.
- B. Evaluate the screen failures to determine if the protocol needs revision.

- C. Allocate additional monitoring resources to the trial.
- D. Re-train investigators on recruitment obligations.

Answer: B

Explanation:

The high rate of screen failures indicates that the inclusion/exclusion criteria may be too stringent or not appropriately defined. The sponsor should evaluate the reasons for these failures and determine whether the protocol needs adjustment. Revising the criteria may increase recruitment efficiency without compromising the scientific validity of the study.

GCP guidelines advise reviewing and possibly revising protocols when screen failure rates are significantly high to ensure feasible recruitment.

"If a high number of screen failures occurs, the sponsor should evaluate the inclusion/exclusion criteria and consider protocol revisions." Objectives:

- * Improve recruitment efficiency.
- * Adapt protocol criteria to real-world conditions.

NEW QUESTION # 69

A study drug will be shipped, stored, and mixed at the hospital pharmacy and will be transferred to the study site for infusion. Which document describes how the transfer will occur?

- **A. Standard Operating Procedure**
- B. Clinical Monitoring Plan
- C. Data & Safety Monitoring Plan
- D. Investigator's Brochure

Answer: A

Explanation:

The Standard Operating Procedure (SOP) outlines the process for shipping, storing, mixing, and transferring the investigational product (IP) between locations. SOPs ensure that all steps are consistently followed and documented, maintaining the integrity and quality of the IP throughout the handling process. This is critical for maintaining compliance with Good Clinical Practice (GCP) and ensuring patient safety.

GCP guidelines specify that SOPs should cover the handling, transfer, and storage of investigational products to ensure quality control.

"SOPs provide detailed guidance on the handling and transfer of investigational products to ensure consistency and compliance."

Objectives:

- * Maintain the integrity of IP during transport and handling.
- * Ensure compliance through standardized procedures.

NEW QUESTION # 70

When designing a clinical trial, why is it important to define the study population?

- **A. To support the study objectives**
- B. To determine where to conduct the study
- C. To support subject recruitment to the study
- D. To determine the study objectives

Answer: A

Explanation:

Defining the study population is crucial because it ensures that the trial targets the appropriate group for evaluating the investigational product (IP). A well-defined population supports the study objectives by providing reliable and interpretable data that can address the research questions.

GCP guidelines emphasize the need for a clearly defined study population to ensure the generalizability and accuracy of trial results.

"The study population must be clearly defined to ensure that the trial data are relevant and applicable to the intended patient group."

Objectives:

- * Enhance the scientific validity of clinical trial outcomes.
- * Support the accurate interpretation of efficacy and safety data.

NEW QUESTION # 71

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