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ACRP-CP CERTIFICATION EXAM 2025/2026 LATEST STUDY QUESTIONS WITH CORRECT ANSWERS GUARANTEED PASS | RATED A4

A Clinical Research Coordinator (CRC) adjusted the dose of the Investigation Product (IP) for a subject as the subject was suffering from Adverse Events (AEs) like headaches and vomiting. When is a CRC allowed to do this task? - Answer>>> Only when the CRC is a qualified physician and has been delegated this responsibility by the PI

A CRA notices during an onsite visit that the date on IRB approval letter for a protocol is prior to the effective date indicated on the cover page of the protocol and the signatures of the investigator and sponsor. What should the CRA do FIRST? - Answer>>> Confirm dates of initial receipt of the sponsor protocol and the IRB submission dates.

You are helping your Investigator write a protocol for a new combination of drugs for treatment of Irritable Bowel Syndrome. Since this is an Investigator Initiated Study you know you will need to establish a/an - Answer>>> Independent Data Monitoring Committee

Your Investigator wants to participate in a Phase 3 Pharmacokinetics study. Pharmacokinetic studies are commonly conducted in later phases to answer what questions? - Answer>>> 1, Food effects on bioavailability

- 2. Information in sub-populations such as patients with impaired elimination
- 3. Drug to drug interactions

The pediatric population represents a vulnerable subgroup. Therefore: special measures are needed to protect the rights of pediatric study participants and to shield them from undue risk. Which of the following should be taken into consideration? - Auswer>>> 1. Recruitment

- 2. Consent and Assent
- 3. Minimize risk
- 4. Minimize distress

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questions.

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

NEW QUESTION # 105

Who determines what criteria and procedures should be followed if a subject discontinues/withdraws their consent?

- A. PI
- B. Sponsor
- C. Subject
- D. CRO

Answer: B

Explanation:

The sponsor is responsible for defining the criteria and procedures for subject withdrawal or discontinuation of consent. This includes specifying how data already collected will be handled and whether any follow-up is required. The procedures must be clearly outlined in the study protocol and communicated to the research team.

This answer follows GCP guidelines, which state that the sponsor must ensure that procedures for subject withdrawal are clearly defined and documented.

"The sponsor is responsible for defining procedures to be followed if a subject discontinues participation or withdraws consent, including handling of data collected prior to withdrawal." Objectives:

- * Ensure transparent procedures for participant withdrawal.
- * Maintain data integrity while respecting participant autonomy.

NEW QUESTION # 106

A clinical trial is conducted to test the effect of an investigational drug on cholesterol levels. Statistical analysis will be performed to:

- A. Reject the alternative hypothesis that the drug has no effect on cholesterol levels.
- B. Reject the null hypothesis that the drug has no effect on cholesterol levels.
- C. Fail to reject the null hypothesis that the drug has an effect on cholesterol levels.
- D. Fail to reject the alternative hypothesis that the drug has an effect on cholesterol levels.

Answer: B

Explanation:

The purpose of statistical analysis in a clinical trial is to evaluate whether the data supports rejecting the null hypothesis, which typically states that there is no effect or difference. If the analysis finds a statistically significant result, the null hypothesis is rejected, indicating that the investigational drug has an effect on cholesterol levels.

The answer follows statistical principles in clinical trials, where the null hypothesis is rejected if evidence shows a significant difference or effect.

"In hypothesis testing, rejecting the null hypothesis indicates that the treatment effect is statistically significant." Objectives:

- * Understand hypothesis testing in clinical research.
- * Interpret statistical outcomes accurately.

NEW QUESTION # 107

Upon receiving their first dose of study drug in the clinic, the subject exhibits an immediately life-threatening reaction. The protocol prohibits any concomitant medications. What should be the investigator's IMMEDIATE response?

- A. Call the medical monitor.
- B. Administer rescue medication.
- C. Report the AE to the sponsor.
- D. Consult the IB.

Answer: B

Explanation:

In a life-threatening situation, the investigator's first priority is the safety and well-being of the participant.

Administering rescue medication immediately is critical to stabilize the patient, regardless of protocol restrictions. Ethical

considerations and patient safety always take precedence over protocol compliance.

GCP guidelines emphasize that subject safety is the primary concern, and appropriate medical care must be administered in emergencies.

"In cases of life-threatening events, the investigator should administer necessary medical interventions to safeguard the subject's health." Objectives:

- * Prioritize patient safety in emergency situations.
- * Make decisions based on medical necessity rather than protocol restrictions.

NEW QUESTION # 108

IP is dispensed to all subjects who:

- A. Need IP for their medical condition.
- B. Consented for the trial.
- C. Screened for the trial.
- D. Are eligible to receive it in the trial.

Answer: D

Explanation:

The investigational product (IP) is only dispensed to subjects who meet the eligibility criteria as defined in the study protocol. Eligibility is confirmed during screening and baseline assessments. Simply consenting to the trial does not guarantee receipt of IP. According to GCP guidelines, IP dispensing must strictly follow eligibility criteria to maintain protocol compliance and subject safety. "IP should only be dispensed to subjects who have been deemed eligible according to the protocol's inclusion and exclusion criteria." Objectives:

- * Maintain adherence to protocol criteria.
- * Protect participant safety by ensuring proper eligibility.

NEW QUESTION # 109

In an investigator-initiated study, who is responsible for implementing appropriate corrective and preventive actions when significant non-compliance is discovered?

- A. CRA
- B. CRC
- C. PI
- D. IRB/IEC

Answer: C

Explanation:

In investigator-initiated studies, the PI holds primary responsibility for addressing non-compliance, including root cause analysis and implementation of CAPA plans. This ensures that any issues affecting the study's integrity are adequately addressed and prevented in the future.

The answer is verified based on ICH E6(R2) guidelines which emphasize the PI's responsibility for maintaining compliance at the study site.

"The PI must develop and implement corrective and preventive actions when non-compliance is identified during the study." Objectives:

- * Maintain compliance in investigator-initiated studies.
- * Address non-compliance through CAPA.

NEW QUESTION #110

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