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ACRP 141 Exam Study Guide Questions with Complete Solutions 100% Verified 2024/2025

What individual serves as the primary liaison between the sponsor and the investigator? - Correct Answer monitor

Who is responsible for verifying that the investigator follows the approved protocol and all approved amendments? - Correct Answer monitor

Who must be notified if a trial is suspended or terminated prematurely? - Correct Answer the sponsor should promptly inform the investigator/institutions and the regulatory authorities of the termination or suspension and the reasons for the termination or suspension

Who must the monitor inform of CRF entry errors, omissions, or illegibility? - Correct Answer investigator

factorial design - Correct Answer Used for the specific purpose of examining interaction of A and B; 2 or more treatments are evaluated simultaneously through the use of varying combinations of the treatments

1. A alone
2. B alone
3. both A & B (useful in determining joint effects of A & B)
4. neither A or B

*another important use of the design is to establish the dose-response characteristics of the simultaneous use of treatments C & D

What are the purposes of multi center trials? - Correct Answer 1. an accepted way of evaluating a new medication more efficiently; may present as the only practical means of accruing sufficient subjects to satisfy the trial objective within a reasonable time-frame

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ACRP Certified Professional Exam Sample Questions (Q78-Q83):

NEW QUESTION # 78

The PI did not record the relationship to IP in the medical chart when assessing an adverse event. The CRC noticed the omission and brought it to the PI's attention. How should this be addressed?

- A. The PI should amend the medical chart.
- B. The CRC should write a note to file.
- C. The CRC should amend the medical chart.
- D. The PI should notify the monitor.

Answer: A

Explanation:

The PI is responsible for ensuring accurate documentation of adverse events (AEs) in the medical chart, including their relationship to the investigational product (IP). If an omission is identified, the PI must correct it by making a dated and signed amendment to maintain data accuracy and completeness.

GCP guidelines state that the PI must maintain accurate and complete records, including the assessment of the relationship between AEs and the IP.

"The investigator must document the assessment of the relationship between the AE and the investigational product to ensure accurate clinical records." Objectives:

- * Maintain accuracy in adverse event documentation.
- * Ensure data integrity through appropriate corrections.

NEW QUESTION # 79

Who should vote during the IRB/IEC review and discussion process?

- A. All IRB/IEC members
- B. All members who were involved in the review and discussion
- C. All members who were involved in the review and discussion and non-member experts
- D. All IRB/IEC members and non-member experts

Answer: B

Explanation:

During the IRB/IEC review process, only members who actively participated in the review and discussion are eligible to vote. This ensures that votes are cast by those who are adequately informed about the study and can make an educated decision. Non-member experts may participate in discussions but do not have voting rights.

GCP guidelines state that voting rights in IRB/IEC meetings are limited to members who have thoroughly reviewed and discussed the study, maintaining unbiased and informed decision-making.

"Only IRB/IEC members who were involved in the review and discussion should participate in the voting process." Objectives:

- * Ensure informed voting in ethical review processes.
- * Maintain integrity and objectivity in IRB/IEC decisions.

NEW QUESTION # 80

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

Answer: A

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 # 81

A serious unexpected ADR is one:

- A. Where the severity of the reaction is not consistent with IB.
- B. That results in the death of the subject.
- C. That does not need to be reported to the IRB/IEC.
- 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 # 82

Source data/documentation should be:

- A. Attributable, legible, contemporaneous, original, accurate, and complete.
- B. Attributable, legible, correct, original, accurate, and complete.
- C. Attributable, legible, correct, original, accurate, and clear.
- D. Attributable, legible, contemporaneous, original, accurate, and clear.

Answer: A

Explanation:

Source data/documentation in clinical trials must meet the ALCOA-C standard: Attributable, Legible, Contemporaneous, Original, Accurate, and Complete. This ensures that data is credible, traceable to the source, and maintains integrity throughout the study.

These attributes are essential for maintaining high- quality, reliable, and verifiable clinical trial records.

GCP guidelines mandate that source documentation should adhere to the ALCOA-C principles to maintain data integrity and reliability.

"Source data must be attributable, legible, contemporaneous, original, accurate, and complete to meet quality and compliance standards." Objectives:

- * Maintain data integrity and reliability.
- * Adhere to best practices in clinical documentation.

NEW QUESTION # 83

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