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ACRP Certified Professional Exam Sample Questions (Q23-Q28):

NEW QUESTION # 23

A study protocol must contain which of the following elements?

- A. Participant reimbursement details
- B. Data management plan
- C. Description of statistical methods
- D. Chemical structure of the IP

Answer: C

Explanation:

A clinical study protocol must include a clear description of the statistical methods to be used in analyzing the collected data. This ensures that the analysis plan is predefined, unbiased, and statistically sound. The statistical methodology must address how the primary and secondary endpoints will be evaluated.

GCP guidelines require that the protocol clearly outlines statistical methods to ensure accurate and unbiased analysis of trial data. "The protocol should include a detailed description of the statistical methods employed to ensure the validity of the trial results."

Objectives:

- * Maintain transparency in data analysis.
- * Ensure scientific rigor in evaluating study outcomes.

NEW QUESTION # 24

A clinical trial is conducted to measure the effectiveness of music therapy to reduce anxiety in intensive care unit patients. Patients are randomly assigned to receive headphones with music of their choice or headphones with white noise. The group receiving the white noise headphones is considered which type of control group?

- A. Placebo
- B. Alternate dose
- C. No treatment
- D. Active control

Answer: A

Explanation:

In this trial, the white noise group acts as a placebo control. While they are receiving an intervention (white noise), it is not the active therapeutic intervention (music therapy) being tested. Placebo controls help in assessing the effect of the active intervention by comparing it to a neutral or non-therapeutic alternative.

GCP guidelines state that a placebo control is a neutral intervention used to compare the effects of an active treatment.

"A placebo group is one that receives a neutral intervention, used to measure the efficacy of the active intervention by comparison."

Objectives:

- * Differentiate between active and placebo control groups.
- * Evaluate therapeutic efficacy objectively.

NEW QUESTION # 25

What is a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed, and accurately reported according to the protocol, sponsors, SOPs, GCP, and the applicable regulatory requirements?

- A. Audit
- B. Inspection
- C. Site qualification
- D. Routine monitoring

Answer: A

Explanation:

An audit is a systematic and independent examination of trial-related activities and documents. Its purpose is to determine whether the study was conducted in compliance with the protocol, GCP, and regulatory requirements. Audits are usually performed by the sponsor or an independent auditor and focus on evaluating data integrity and trial conduct.

GCP guidelines define an audit as a thorough examination to ensure adherence to protocol and regulatory requirements.

"An audit is a systematic and independent examination of trial-related activities to verify compliance with the protocol and regulatory standards." Objectives:

Ensure compliance and data integrity.

Identify any gaps in trial conduct.

NEW QUESTION # 26

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 # 27

A serious unexpected ADR is one:

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

Answer: D

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 # 28

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