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Exam : **ACRP-CP**

Title : ACRP Certified Professional Exam

Version : DEMO

1.An investigator in a multicenter trial reports multiple occurrences of an SAE to the sponsor.
Who is responsible for reporting the SAEs to the remaining sites' IRB/IECs?
A. Study sponsor
B. Regulatory authority
C. Investigator at each site
D. Original reporting investigator
Answer: A
Explanation:
The study sponsor is responsible for disseminating information about SAEs to all participating sites. This ensures consistent and timely communication of safety concerns, allowing each site to take appropriate actions in line with local regulations and IRB/IEC requirements.
The answer aligns with ICH E6(R2) GCP guidelines which mandate the sponsor to communicate safety information to all investigators and sites involved in a multicenter trial.
"The sponsor must inform all investigators of safety information that could affect the conduct of the trial or the safety of subjects."

2.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."

3.While reviewing reports of data completion, the sponsor notices low retention rates at many participating sites.
What is an appropriate FIRST action for the sponsor to take?
A. Interview participants who have dropped out.
B. Require participants to provide documented reason for withdrawal.
C. Submit revised ICFs to the IRB/IEC with increased compensation for participants.
D. Meet with the site staff to understand their workflows and to review retention strategies.
Answer: D
Explanation:
Meeting with site staff to understand workflows and retention strategies is the most practical first step. By engaging with the team, the sponsor can identify potential issues affecting retention, such as site-related

factors, participant burden, or protocol complexities. Addressing these issues collaboratively can improve retention without needing major protocol changes.
GCP guidelines recommend assessing and understanding site-specific challenges before making procedural changes or protocol amendments.
"Engaging with site staff to discuss retention issues helps identify root causes and develop practical solutions."

4.The PI should ensure that source data is:
A. Kept on site for a minimum of 2 years.
B. Accurately reflected in the eCRFs.
C. Printed directly from the EMR.
D. On worksheets that are provided by the sponsor.
Answer: B
Explanation:
The PI is responsible for ensuring that the source data is accurately recorded in the electronic Case Report Forms (eCRFs). This accurate transposition of data is critical to maintaining data integrity and ensuring that the data collected at the site is consistent with the reported clinical outcomes.
GCP guidelines specify that source data should be accurate, legible, and directly reflected in the CRFs to maintain consistency and reliability.
"The PI must ensure that the source data are accurately and completely recorded in the eCRFs to maintain data integrity."

5.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. No treatment
C. Active control
D. Alternate dose
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."