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ACRP Certified Professional Exam Sample Questions (Q20-Q25):

NEW QUESTION # 20
Who is responsible for the ongoing safety evaluation of the IP?

- A. Regulatory agency
- B. PI
- C. Sponsor
- D. IRB/IEC

Answer: C

Explanation:
The sponsor is primarily responsible for the ongoing safety evaluation of the investigational product (IP) throughout the clinical trial. This responsibility includes monitoring adverse events, reporting serious adverse events (SAEs) to regulatory authorities, and updating the Investigator's Brochure (IB) with relevant safety data.
According to GCP guidelines, the sponsor must continuously evaluate safety data and report findings to regulatory bodies as necessary.

"The sponsor is responsible for the continuous safety monitoring of the investigational product and for ensuring that new safety information is communicated to investigators and regulators." Objectives:
* Ensure participant safety throughout the study.
* Maintain accurate and timely reporting of safety data.

NEW QUESTION # 21
A clinical trial is conducted to test the effect of an investigational drug on cholesterol levels. Statistical analysis will be performed to:

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

Answer: D

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 # 22
A protocol requires participants to take IP for 6 months. The protocol allows for any participants who are noncompliant to be replaced by enrolling additional participants, except if it is due to an AE. The investigator has enrolled 12 participants.
The status of the enrolled participants is as follows:
* 3 participants were withdrawn due to noncompliance
* 1 participant withdrew consent after experiencing severe nausea
* 1 participant had to discontinue IP for an unscheduled hospitalization
* 1 participant who is not returning for visits
* 2 participants completed the 6 months of treatment
* 4 participants currently on IP
How many participants should be replaced?

- A. 6 participants
- B. 3 participants
- C. 4 participants
- D. 5 participants

Answer: B

Explanation:
Since the protocol specifies that participants withdrawn due to an Adverse Event (AE) should not bereplaced, only the participants withdrawn for noncompliance (3 in total) should be replaced. The participant who withdrew consent due to severe nausea (an AE) and the one who discontinued IP due to hospitalization should not be replaced.
GCP guidelines specify that replacement of subjects should follow the protocol criteria, particularly when AEs are involved.
"Participants withdrawn due to AEs should not be replaced if the protocol stipulates this condition, while noncompliant participants may be replaced." Objectives:
* Follow protocol guidelines for participant replacement.
* Ensure compliance with study criteria.

NEW QUESTION # 23
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. Administer rescue medication.
- B. Consult the IB.
- C. Report the AE to the sponsor.
- D. Call the medical monitor.

Answer: A

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 # 24
Which of the following reports should be retained in participant charts?

- A. Lab reports
- B. IRB/IEC progress reports
- C. Safety reports
- D. DSMB/IDMC reports

Answer: A

Explanation:
Lab reports contain individual participant data relevant to their health status and the study's outcomes. These reports are essential for verifying subject safety and evaluating the effects of the investigational product (IP).
Therefore, they must be retained in the participant's medical records.
According to GCP guidelines, participant charts must include laboratory data as part of the essential documents to ensure accurate and complete clinical records.
"Lab reports must be maintained as part of the participant's chart for safety monitoring and data verification." Objectives:
* Maintain comprehensive medical records for each participant.
* Ensure availability of clinical data for audit and review.

NEW QUESTION # 25
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