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ACRP Certified Professional Exam Sample Questions (Q90-Q95):

NEW QUESTION # 90

A Phase I drug trial has been completed and preparations are being made to proceed to a Phase II trial. Who is responsible for revising the IB with this updated information?

- A. DSMB/IDMC
- B. Investigator
- C. Health authority
- D. Sponsor

Answer: D

Explanation:

The sponsor is responsible for updating the Investigator's Brochure (IB) with new information obtained from the completed Phase I trial. The IB must reflect the most current data on the drug's safety, efficacy, and dosing to support Phase II planning and execution. According to GCP guidelines, the sponsor must ensure that the IB is updated regularly with relevant findings from ongoing and completed trials.

"The sponsor is responsible for ensuring that the Investigator's Brochure is updated with the latest safety and efficacy data before advancing to the next phase of the trial." Objectives:

- * Keep the IB current and accurate.
- * Inform investigators of the latest safety and efficacy data.

NEW QUESTION # 91

An impartial witness should be present during the entire informed consent discussion when:

- A. An interpreter is translating the consent form for a subject.
- B. A subject has been determined to be vulnerable.
- C. A legally acceptable representative is unable to read.
- D. A parent/guardian is consenting for a minor subject.

Answer: C

Explanation:

An impartial witness is required when a legally acceptable representative (LAR) or the subject themselves cannot read. The witness ensures that the information is presented accurately and that the consent process is conducted ethically. The witness also signs the consent form to confirm that the subject or representative understands the study details.

GCP guidelines require an impartial witness to be present to confirm that the consent information is correctly conveyed and understood when the subject or LAR cannot read.

"An impartial witness is required when the subject or legally acceptable representative is unable to read, ensuring the consent process is transparent and ethically sound." Objectives:

- * Protect the rights of individuals with literacy challenges.
- * Maintain ethical standards in the consent process.

NEW QUESTION # 92

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 null 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 alternative 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 # 93

One key attribute for good study documentation is that the data are contemporaneous, which refers to the practice of:

- A. Comparing source document data to other data recorded in the same study time period.
- B. Allowing real-time access for data review in the eCRF.
- C. Recording data on source documents at the time the data are collected during the conduct of the study.
- D. Recording the date and time each data element is entered onto the source document.

Answer: C

Explanation:

Contemporaneous data means that data entries are made at the time of the event or as soon as possible after the event occurs. This practice ensures that the recorded data accurately reflect the participant's condition and study procedures, minimizing recall bias and errors. Maintaining contemporaneous records is a fundamental requirement for ensuring the accuracy and reliability of clinical trial data.

GCP guidelines specify that data should be recorded as close to the time of the event as possible to ensure accuracy and reliability.

"Data must be contemporaneously recorded, meaning they are documented at the time of the occurrence to accurately reflect the study conduct." Objectives:

- * Ensure accurate and real-time data capture.
- * Maintain data integrity by minimizing recall bias.

NEW QUESTION # 94

IP is dispensed to all subjects who:

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

Answer: C

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 # 95

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