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ACRP Certified Professional Exam Sample Questions (Q32-Q37):

NEW QUESTION # 32

A hospital site is being considered for a trial that requires the IP refrigerator to be continuously monitored using the sponsor-provided Wi-Fi-enabled thermometer. The hospital's Wi-Fi connectivity is inconsistent. During site selection, how should the CRA proceed?

- A. Accept this site and plan to undertake routine safety evaluations of the IP.
- B. Before accepting this site, report the risk to the trial sponsor and await their decision.
- C. Accept this site and implement and maintain QA and QC systems with written SOPs.
- D. Before accepting this site, ensure the refrigerator is calibrated and functioning properly.

Answer: B

Explanation:

Since the Wi-Fi connectivity is inconsistent, the CRA must assess the risk and report it to the trial sponsor for a decision. Accepting the site without proper risk evaluation may compromise the monitoring of the investigational product (IP) storage conditions, affecting trial integrity.

The answer follows GCP guidelines that emphasize assessing potential risks during site selection and involving the sponsor when critical issues arise.

"When faced with site-specific issues that may affect data integrity or product safety, the CRA should consult with the sponsor before making a final decision." Objectives:

- * Ensuring proper site selection
- * Managing potential risks proactively

NEW QUESTION # 33

A study to determine the effective dose and regimen of a new IP for the treatment of hypothyroidism is considered to be:

- A. Phase II
- B. Phase III
- C. Phase IV
- D. Phase I

Answer: A

Explanation:

A Phase II clinical trial is typically conducted to evaluate the efficacy of a drug, determine the optimal dosing regimen, and further assess its safety profile. Since the objective is to establish the effective dose and regimen for hypothyroidism treatment, this clearly falls under Phase II.

GCP guidelines categorize Phase II trials as those aimed at determining efficacy and optimal dosing of investigational products.

"Phase II trials focus on determining the therapeutic efficacy, optimal dosage, and further evaluating the safety of the investigational product." Objectives:

- * Identify effective dosing regimens.
- * Evaluate therapeutic efficacy for targeted conditions.

NEW QUESTION # 34

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. Fail to reject the null hypothesis that the drug has an 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 # 35

Prior to initiation of a clinical trial, review by an IRB/IEC is required for which of the following documents?

- A. Protocol, site coordinator CVs, and clinical trial agreement
- B. Protocol, informed consent, and clinical trial agreement
- **C. Protocol, IB, and information about payments and compensation available to subjects**
- D. IB, site coordinator CVs, and information about payments and compensation available to subjects

Answer: C

Explanation:

Before a clinical trial can begin, the IRB/IEC must review the protocol, Investigator's Brochure (IB), and any information related to payments and compensation. This review ensures that the study is ethically sound, scientifically valid, and that participants are informed about any financial considerations.

GCP guidelines specify that essential documents, including the protocol, IB, and compensation details, must be reviewed by the IRB/IEC to maintain ethical oversight.

"The IRB/IEC must evaluate the protocol, IB, and any financial disclosures to ensure ethical compliance and participant protection."

Objectives:

- * Guarantee ethical oversight in clinical trial conduct.
- * Protect participants through informed consent and transparency.

NEW QUESTION # 36

Which entity has ultimate responsibility over the conduct of the multi-center clinical trial?

- **A. Sponsor-Investigator**
- B. Regulatory authority
- C. CRO
- D. IRB/IEC

Answer: A

Explanation:

In a multi-center clinical trial, the Sponsor-Investigator holds ultimate responsibility for the overall conduct of the study. This includes ensuring compliance with the protocol, maintaining data integrity, and overseeing all participating sites. The Sponsor-Investigator must ensure that each site follows the same procedures and standards to maintain consistency across the trial.

According to GCP guidelines, the Sponsor-Investigator must take responsibility for all aspects of a multi-center trial, including site coordination and data management.

"The Sponsor-Investigator assumes ultimate responsibility for the conduct of a multi-center clinical trial, ensuring protocol compliance and data consistency." Objectives:

- * Maintain accountability across multi-center sites.
- * Ensure uniformity in trial conduct.

NEW QUESTION # 37

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