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The study subject asks you why the study is called a double blind study. You will explain double blind as

When the Investigator and sponsor staff who are involved in the treatment or clinical evaluation of the subjects and analysis of data are unaware of the treatment assignments

According to ICH E8 what type of study would have the following elements? Adequate and well controlled studies to establish efficacy

1. Randomized parallel dose response studies
2. Clinical safety studies
3. Studies of mortality/morbidity outcomes
4. Large simple trials

-Therapeutic Confirmatory

Your Investigator wants to participate in a Phase 3 Pharmacokinetics study. Pharmacokinetic studies are commonly conducted in later phases to answer what questions?

1. Food effects on bioavailability
2. Information in sub-populations such as patients with impaired elimination
3. Drug to drug interactions

A trial where the treatment assignment is not known by the study participant because of the use of placebo or other methods of masking the intervention; but the study team knows

Single blind

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ACRP Certified Professional Exam Sample Questions (Q101-Q106):

NEW QUESTION # 101

After enrolling and treating a few subjects on an investigator-initiated trial, the PI would like to include a subject diary for each trial subject to capture their activities and experiences on the trial regimen. After the PI has generated a diary, what should the PI do next?

- A. Submit the diary to the sponsor for approval.
- B. No approval is necessary: give the diary to each subject.
- **C. Submit the diary to the IRB/IEC for approval.**
- D. Submit the diary to the regulatory authority for approval.

Answer: C

Explanation:

Any new data collection tool introduced during a clinical trial, including subject diaries, must be reviewed and approved by the IRB/IEC before implementation. This ensures that the new tool is ethically appropriate, respects subject privacy, and aligns with the approved protocol.

This answer aligns with ICH E6(R2) GCP guidelines, which mandate IRB/IEC approval for any new or modified subject-related documents introduced during a trial.

"All changes in study documents, including subject diaries, must be submitted for IRB/IEC review to ensure compliance with ethical standards." Objectives:

- * Maintain compliance with IRB/IEC requirements.
- * Ensure ethical handling of subject data.

NEW QUESTION # 102

All site financial matters pertaining to a trial are listed in what document?

- A. Financial disclosure
- B. Informed consent form
- **C. Signed contract**
- D. Protocol

Answer: C

Explanation:

All financial agreements, including compensation, budgeting, and payment terms related to the conduct of a clinical trial, are documented in the signed contract between the sponsor and the site. This contract outlines the financial responsibilities and ensures transparency and compliance.

GCP guidelines stipulate that financial matters related to the conduct of a trial are to be formally documented in contractual agreements.

"The financial aspects of a clinical trial must be outlined in the signed agreement between the sponsor and the site, ensuring clear understanding of compensation and obligations." Objectives:

- * Ensure financial transparency and accountability.
- * Maintain compliance with contractual obligations.

NEW QUESTION # 103

An interim analysis is conducted during a clinical trial. To review the results, the sponsor assigns:

- A. Regulatory authority expert advisors.
- **B. Independent qualified individuals.**
- C. Investigators participating in the trial.
- D. Executive board members.

Answer: B

Explanation:

Interim analysis should be reviewed by independent qualified individuals, such as members of a Data Safety Monitoring Board (DSMB) or Independent Data Monitoring Committee (IDMC). This ensures that the analysis is unbiased and that decisions regarding continuation, modification, or termination of the trial are made objectively.

GCP guidelines emphasize that interim data should be reviewed by an independent committee to prevent bias and ensure participant safety.

"Interim analyses should be conducted by independent experts to maintain objectivity and safeguard trial integrity." Objectives:

- * Maintain impartiality during interim analysis.
- * Ensure unbiased decision-making regarding trial continuation.

NEW QUESTION # 104

A quality assurance audit of the EDC system SOP revealed a deficiency. Which of the following is the MOST likely reason?

- A. The list of comparable technology solutions was not included.
- B. The number of unique eCRF templates was not specified.
- C. The number of users with access was not defined.
- **D. The frequency of data backup was not defined.**

Answer: D

Explanation:

The frequency of data backup is a critical element of an Electronic Data Capture (EDC) system's Standard Operating Procedure (SOP). Ensuring regular and systematic data backup is essential for protecting trial data against loss or corruption. Failure to specify backup frequency indicates a gap in data security management.

GCP guidelines stress that data protection, including regular backups, is essential to maintaining data integrity in clinical trials.

"EDC system SOPs must include clear guidelines on data backup frequency to safeguard the integrity and availability of study data." Objectives:

- * Ensure data security through regular backups.
- * Maintain data integrity in clinical research.

NEW QUESTION # 105

All of the following are steps to assure an effective risk management approach while conducting a clinical study EXCEPT:

- **A. Documenting all possible risk scenarios.**
- B. Controlling risk by setting thresholds of risk acceptability.
- C. Identifying potential study risks.
- D. Assessing risk based on study impact.

Answer: A

Explanation:

While identifying potential risks, assessing them based on their impact, and setting risk acceptability thresholds are integral parts of a risk management approach, documenting every possible risk scenario is impractical and unnecessary. Instead, focus should be on identifying and managing the most significant and likely risks that could affect the study's quality and safety.

GCP guidelines emphasize identifying, assessing, and controlling critical risks rather than exhaustively documenting all hypothetical scenarios.

"Effective risk management involves identifying key risks, evaluating their impact, and setting control measures, rather than documenting every possible risk." Objectives:

- * Implement practical and targeted risk management strategies.
- * Focus on significant and likely risks rather than hypothetical ones.

NEW QUESTION # 106

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