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ACRP Certified Professional Exam Sample Questions (Q85-Q90):

NEW QUESTION # 85

A protocol requires participants to take 1 tablet of IP per day. At each visit, participants are supplied with enough IP for 35 days. They are asked to return any unused IP at the next visit. One participant returns at the 1-month visit at 30 days with 10 tablets of unused IP and at the 2-month visit at 60 days with 12 tablets of unused IP. What is the

participant's overall compliance?

- A. 71%
- B. 80%
- C. 66%
- **D. 77%**

Answer: D

Explanation:

Step 1: Calculate the total number of tablets dispensed:

- * Month 1: 35 tablets
- * Month 2: 35 tablets
- * Total: 70 tablets

Step 2: Calculate the number of tablets returned:

- * Month 1: 10 tablets
- * Month 2: 12 tablets
- * Total: 22 tablets

Step 3: Calculate the number of tablets taken:

- * $70 - 22 = 48$ tablets

Step 4: Calculate compliance:

- * Compliance = $(\text{Tablets Taken} / \text{Total Tablets}) \times 100$
- * Compliance = $(48 / 62) \times 100 \# 77\%$

GCP guidelines require accurate calculation of compliance based on returned IP counts, ensuring proper dose administration monitoring.

"Compliance rates are calculated by comparing the number of tablets taken to the total number of tablets dispensed, considering the returned count." Objectives:

- * Monitor compliance with IP administration.
- * Ensure accurate calculation of adherence rates.

NEW QUESTION # 86

Access to study documentation for auditors and inspectors during an audit or inspection at a clinical trial site is the responsibility of the:

- A. CRC
- B. CRA
- **C. PI**
- D. Sponsor

Answer: C

Explanation:

The Principal Investigator (PI) is responsible for providing access to study documentation during an audit or inspection. This includes regulatory files, participant records, and study logs. The PI ensures that auditors and inspectors have appropriate access while maintaining the confidentiality of subject data.

GCP guidelines clearly assign the responsibility for maintaining and granting access to trial documentation to the PI at the study site.

"The PI is responsible for ensuring that study-related documents are available for review during audits or inspections." Objectives:

- * Maintain transparency during inspections.
- * Ensure compliance with documentation requirements.

NEW QUESTION # 87

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."

Objectives:

- * Ensure accurate data transposition from source to CRF.
- * Maintain high standards of data quality and reliability.

NEW QUESTION # 88

Who is responsible for submitting a protocol amendment to the IRB/IEC?

- A. Investigator
- B. CRC
- C. CRA
- D. Sponsor

Answer: A

Explanation:

The investigator holds the responsibility for submitting any protocol amendments to the IRB/IEC for review and approval. This step ensures that all changes are ethically evaluated before being implemented, maintaining compliance with regulatory requirements. According to GCP guidelines, the investigator must submit protocol changes to the IRB/IEC to secure approval before making any modifications to the study.

"The investigator must inform the IRB/IEC of any proposed protocol changes and secure approval prior to implementation."

Objectives:

- * Maintain ethical oversight in study modifications.
- * Adhere to regulatory submission requirements.

NEW QUESTION # 89

Which of the following activities would be undertaken by the sponsor to BEST ensure overall quality of the study data?

- A. Conduct annual reviews of the protocol and accompanying study documents.
- B. Ensure there is an accompanying written record that describes the consent process.
- C. Ensure submission of a data management plan to the regulatory authorities.
- D. Develop a plan that describes the monitoring approach for a clinical study.

Answer: D

Explanation:

Developing a monitoring plan that outlines the approach to quality assurance is essential for maintaining data integrity throughout the clinical trial. This plan helps identify critical data points, risk-based monitoring strategies, and procedures for detecting and correcting data discrepancies. It ensures that the study data collected is accurate, complete, and verifiable.

GCP guidelines emphasize the importance of a monitoring plan to safeguard the quality and integrity of study data.

"The sponsor should develop a comprehensive monitoring plan to ensure the accuracy, completeness, and consistency of trial data."

Objectives:

- * Maintain high-quality data through structured monitoring.
- * Identify potential risks and address them proactively.

NEW QUESTION # 90

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