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ACRP Certified Professional Exam Sample Questions (Q18-Q23):

NEW QUESTION # 18
Which of the following statements accurately describes the responsibilities of stakeholders involved in the conduct of a clinical study?

- A. The CRC is responsible for identifying the relationship of an SAE to the IP.
- B. The regulatory authority is responsible for assessing and approving the clinical study protocol and accompanying CRF prior to implementation.
- C. The sponsor is responsible for overseeing any delegated activities to a CRO and ensuring that the delegation of these activities is documented.
- D. The IRB/IEC is responsible for obtaining consent from all subjects in the clinical study.

Answer: C

Explanation:
The sponsor holds the responsibility for overseeing any activities delegated to a Contract Research Organization (CRO). This includes ensuring that all delegated tasks are clearly documented and that the CRO performs them according to regulatory standards and the study protocol.
GCP guidelines state that while the sponsor may delegate tasks to a CRO, the ultimate responsibility for the trial's conduct remains with the sponsor.
"The sponsor retains responsibility for overseeing any delegated tasks to the CRO and must ensure that these responsibilities are appropriately documented." Objectives:
* Clarify delegation of duties in clinical trials.
* Maintain sponsor oversight for regulatory compliance.

NEW QUESTION # 19
Which of the following should be considered when implementing a risk-based monitoring plan?

- A. Monitoring schedule must be pre-defined in the monitoring plan.
- B. On-site monitoring frequency may change depending on the quality of the data.
- C. 100% source document review is mandatory.
- D. Centralized monitoring must be incorporated in any trials.

Answer: B

Explanation:
Risk-based monitoring focuses on adapting the frequency and intensity of on-site visits based on data quality and site performance. If the data is consistently accurate and reliable, the monitoring frequency may be reduced. Conversely, if issues are identified, more frequent monitoring may be necessary.
GCP guidelines emphasize a flexible approach to monitoring, allowing adjustments based on the risk profile and quality of data collected.
"Risk-based monitoring involves adapting the frequency of on-site visits according to the quality of the data and the site's compliance level." Objectives:
* Implement a dynamic monitoring strategy.
* Enhance efficiency while maintaining data integrity.

NEW QUESTION # 20
A quality assurance audit of the EDC system SOP revealed a deficiency. Which of the following is the MOST likely reason?

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

Answer: A

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 # 21
The composition of an IDMC/DSMB should include which one of the following?

- A. A sponsor representative who is knowledgeable about the study's unblinded information
- B. A lead PI for the study
- C. A member from the IRB/IEC
- D. A clinical scientist who is knowledgeable in the appropriate discipline

Answer: D

Explanation:
An Independent Data Monitoring Committee (IDMC) or Data and Safety Monitoring Board (DSMB) should include clinical scientists who are knowledgeable in the relevant medical and scientific areas. Their role is to objectively assess the ongoing safety data and efficacy of the investigational product, ensuring that participants' safety is not compromised.
GCP guidelines emphasize the need for experienced clinical scientists on IDMC/DSMBs to ensure that safety data is interpreted accurately and professionally.
"IDMC/DSMB should comprise independent experts, including clinical scientists, who have the expertise to evaluate safety and efficacy data objectively." Objectives:
* Ensure impartial evaluation of safety data.
* Maintain scientific integrity in monitoring clinical trials.

NEW QUESTION # 22
A representative from a regulatory authority shows up unannounced at a research site. After confirming their credentials, the representative requested to view the entire records, including identifiable information, from study XYZ that was closed out. Which of the following should the site personnel do next?

- A. Redact subject identification for privacy protection.
- B. Deny the request until the sponsor approves.
- C. Allow access to the entire records.
- D. Consult with the IRB/IEC first.

Answer: C

Explanation:
Regulatory authorities have the legal right to inspect clinical trial records, including identifiable information, even if the study has been closed out. After verifying the inspector's credentials, the site personnel must grant access to all requested documents to ensure compliance with regulations.
According to GCP guidelines, regulatory authorities have the right to access trial-related documents and data during inspections.
"Investigators must grant access to study records when requested by regulatory authorities as part of their inspection rights."
Objectives:
* Ensure compliance with inspection requirements.
* Maintain transparency with regulatory authorities.

NEW QUESTION # 23
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