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## **ACRP Certified Professional Exam Sample Questions (Q112-Q117):**

### **NEW QUESTION # 112**

The investigator/institution should permit:

- A. Monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).
- B. Monitoring and inspection by the sponsor, and auditing by the appropriate regulatory authority(ies).
- C. Monitoring and auditing by the appropriate regulatory authority(ies), and inspection by the sponsor.

- D. Monitoring and inspection by the appropriate regulatory authority(ies), and auditing by the sponsor.

**Answer: D**

Explanation:

The investigator and institution must allow both monitoring and inspection by the appropriate regulatory authorities and auditing by the sponsor. This dual oversight ensures that the trial complies with regulatory standards and sponsor requirements, thereby maintaining the integrity and validity of the data.

GCP guidelines specify that regulatory authorities have the right to inspect, while sponsors typically conduct audits to verify compliance and data quality.

"The institution should permit monitoring and inspection by regulatory authorities and auditing by the sponsor to ensure compliance with GCP and protocol adherence." Objectives:

- \* Facilitate monitoring and inspection for compliance.
- \* Ensure trial data integrity and quality assurance.

**NEW QUESTION # 113**

The sponsor must report a serious unexpected AE to the regulatory authorities within a maximum of

- A. 15 calendar days
- B. 7 calendar days
- C. 8 calendar days
- D. 30 calendar days

**Answer: A**

Explanation:

The sponsor is required to report serious unexpected adverse events (SAEs) to the regulatory authorities within 15 calendar days from the date of awareness. This reporting period is mandated to ensure that any new safety information that may affect the risk/benefit profile of the investigational product (IP) is promptly communicated, thereby protecting participant safety.

GCP guidelines specify that serious, unexpected, and related AEs must be reported to regulatory authorities within 15 days of being known to the sponsor.

"Serious unexpected adverse reactions that may affect the safety profile of the IP must be reported within 15 calendar days to the regulatory authorities." Objectives:

- \* Ensure timely reporting of safety information.
- \* Protect the safety of trial participants.

**NEW QUESTION # 114**

Which of the following documents is maintained by a PI to ensure compliance with sponsor requirements?

- A. A monitoring report that identifies deviation from the approved protocol.
- B. Training records of site personnel on study protocol, and their study-related duties and functions.
- C. A monitoring plan that is tailored to the specific human subject protection and data integrity risks of the trial.
- D. Regulatory submission of protocol and accompanying documents to relevant regulatory authority.

**Answer: B**

Explanation:

The PI is responsible for maintaining training records of site personnel, which demonstrate compliance with the sponsor's requirements for conducting the trial. Proper documentation of training ensures that all team members are knowledgeable about the protocol and study procedures.

GCP guidelines mandate that the PI maintains adequate records to demonstrate that all personnel involved in the study are properly trained and qualified.

"Training records of site personnel must be maintained to verify that the team is adequately trained on the protocol and their specific responsibilities." Objectives:

- \* Maintain training compliance.
- \* Document personnel qualifications for quality assurance.

**NEW QUESTION # 115**

The PI did not record the relationship to IP in the medical chart when assessing an adverse event. The CRC noticed the omission and brought it to the PI's attention. How should this be addressed?

- A. The CRC should amend the medical chart.
- **B. The PI should amend the medical chart.**
- C. The CRC should write a note to file.
- D. The PI should notify the monitor.

**Answer: B**

Explanation:

The PI is responsible for ensuring accurate documentation of adverse events (AEs) in the medical chart, including their relationship to the investigational product (IP). If an omission is identified, the PI must correct it by making a dated and signed amendment to maintain data accuracy and completeness.

GCP guidelines state that the PI must maintain accurate and complete records, including the assessment of the relationship between AEs and the IP.

"The investigator must document the assessment of the relationship between the AE and the investigational product to ensure accurate clinical records." Objectives:

- \* Maintain accuracy in adverse event documentation.
- \* Ensure data integrity through appropriate corrections.

#### **NEW QUESTION # 116**

The process of ensuring and documenting that an electronic data processing system conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance is called:

- A. Programming
- **B. Validation**
- C. Quality Control
- D. Quality Assurance

**Answer: B**

Explanation:

Validation is the process of ensuring that an electronic data processing system meets the sponsor's specifications for completeness, accuracy, reliability, and consistent performance. It involves systematic testing and documentation to demonstrate that the system functions as intended, especially in the context of capturing, processing, and managing clinical trial data.

GCP guidelines specify that validation of electronic systems is crucial to maintain data integrity and compliance with regulatory standards.

"Validation ensures that electronic data systems function according to the sponsor's requirements, maintaining data accuracy and reliability." Objectives:

Maintain data integrity and reliability.

Demonstrate system compliance with regulatory requirements.

#### **NEW QUESTION # 117**

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