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ACRP Certified Professional Exam Sample Questions (Q16-Q21):

NEW QUESTION # 16
A subject became pregnant 16 weeks into a clinical trial. She has been taking a daily dose of IP since enrollment. The baby was born missing two toes on each foot. How should this be reported by the site?

- A. This needs to be reported to the patient's primary care physician.
- B. This qualifies for prompt reporting to the IRB/IEC within 15 business days.
- C. This needs to be reported to the regulatory authorities within 10 business days.
- D. This qualifies for expedited reporting to the sponsor.

Answer: D

Explanation:
Any serious adverse event (SAE) that is unexpected, especially those involving congenital anomalies or birth defects, must be reported to the sponsor as an expedited safety report. The reporting should occur immediately to ensure prompt assessment and necessary action.
The answer aligns with ICH E6(R2) GCP guidelines, which require immediate reporting of SAEs related to IP use.
"Expedited reporting to the sponsor is required for unexpected serious adverse drug reactions, particularly those involving congenital anomalies." Objectives:
* Immediate safety reporting.
* Protecting the health of trial participants and their offspring.

NEW QUESTION # 17
Who must be blinded in a double-blind study in order to prevent bias?

- A. Data entry staff
- B. Subject
- C. IRB/IEC
- D. Pharmacist

Answer: B

Explanation:
In a double-blind study, both the participant (subject) and the investigator (or clinical staff administering the treatment) are blinded. This approach minimizes bias in treatment administration and outcome assessment.
Blinding the subject ensures that their responses are not influenced by their knowledge of the treatment they are receiving.
According to GCP guidelines, double-blinding is essential to eliminate both participant and investigator bias, ensuring objective trial results.
"Double-blind studies ensure that neither the participant nor the investigator knows which intervention is being administered, thereby minimizing bias." Objectives:
* Maintain the integrity of the study by preventing bias.
* Enhance the validity of trial outcomes.

NEW QUESTION # 18
Which of the following activities would be undertaken by the sponsor to BEST ensure overall quality of the study data?

- A. Develop a plan that describes the monitoring approach for a clinical study.
- 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. Conduct annual reviews of the protocol and accompanying study documents.

Answer: A

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 # 19
The sponsor should supply a PI with the IP after:

- A. Approval/favorable opinion from IRB/IEC and regulatory authority.
- B. Submission of documents to IRB/IEC and regulatory authority for review.
- C. Approval of protocol by the PI.
- D. Approval of protocol by the sponsor.

Answer: A

Explanation:
The sponsor may only provide the investigational product (IP) after the IRB/IEC and relevant regulatory authorities have approved the protocol. This ensures that the trial complies with ethical and legal standards before initiating IP administration.
According to GCP guidelines, sponsors must wait for all necessary approvals before distributing IP to the trial site.
"The investigational product may only be supplied after obtaining regulatory and IRB/IEC approval to ensure ethical conduct of the trial." Objectives:
* Ensure regulatory compliance before initiating IP distribution.
* Protect participant safety and ethical standards.

NEW QUESTION # 20
A sponsor wants a new clinical trial to be reviewed at regular intervals for progress, safety, and endpoint evaluation, and make recommendations to continue, modify, or stop the trial. How should they proceed?

- A. Develop a monitoring plan
- B. Establish a DSMB/IDMC
- C. Conduct routine investigators' meetings
- D. Draft a CAPA plan

Answer: B

Explanation:
A Data Safety Monitoring Board (DSMB) or Independent Data Monitoring Committee (IDMC) is established to review ongoing trial data at regular intervals. The DSMB evaluates safety, progress, and efficacy endpoints and makes recommendations to continue, modify, or terminate the study based on interim data. This independent oversight helps ensure participant safety and data integrity throughout the trial.
GCP guidelines recommend forming a DSMB for studies that involve high risks or long durations, ensuring continuous safety monitoring.
"The DSMB is responsible for the periodic review of accumulating data and providing recommendations regarding trial continuation, modification, or termination." Objectives:
* Ensure ongoing safety evaluation.
* Facilitate objective decisions on trial continuation.

NEW QUESTION # 21
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