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ACRP Certified Professional Exam Sample Questions (Q76-Q81):

NEW QUESTION # 76
The site submitted all start-up documents for a study to the sponsor and the IRB/IEC. The site also has subjects identified for screening. What should happen FIRST?

- A. Verify subject eligibility
- B. Ship/receive IP
- C. Obtain IRB/IEC approval
- D. Schedule a site initiation visit

Answer: C

Explanation:
Before proceeding with any trial-related activities, including subject screening, the site must first obtain IRB
/IEC approval. This approval ensures that the study has been reviewed for ethical considerations, risk assessment, and adherence to regulatory requirements. Without IRB/IEC approval, initiating the study would violate ethical guidelines and regulatory standards. GCP guidelines mandate that no clinical trial procedures, including screening, commence without prior IRB
/IEC approval.
"IRB/IEC approval must be obtained before initiating any study-related activities, including screening and subject recruitment."
Objectives:
* Ensure ethical compliance before study initiation.
* Protect participant rights and safety.

NEW QUESTION # 77
A written description of a trial in which the clinical and statistical description, presentations, and analyses are fully integrated into a single document is called a:

- A. Clinical Study Protocol
- B. IDMC/DSMB Report
- C. Clinical Study Report
- D. Investigator Brochure

Answer: C

Explanation:
A Clinical Study Report (CSR) is a comprehensive document that integrates clinical and statistical data from a clinical trial. It provides a complete and detailed account of the study's methods, results, and conclusions, including safety and efficacy analyses. The CSR is prepared at the end of the trial to summarize the data for regulatory submission and scientific publication. GCP guidelines state that the CSR should integrate both clinical and statistical information to provide a comprehensive overview of the trial's outcomes.
"The Clinical Study Report contains a complete and integrated presentation of clinical and statistical findings from a clinical trial."
Objectives:
* Document trial outcomes comprehensively.
* Facilitate regulatory review and scientific dissemination.

NEW QUESTION # 78
When designing a clinical trial, why is it important to define the study population?

- A. To determine where to conduct the study
- B. To support the study objectives
- C. To determine the study objectives
- D. To support subject recruitment to the study

Answer: B

Explanation:
Defining the study population is crucial because it ensures that the trial targets the appropriate group for evaluating the investigational product (IP). A well-defined population supports the study objectives by providing reliable and interpretable data that can address the research questions.
GCP guidelines emphasize the need for a clearly defined study population to ensure the generalizability and accuracy of trial results.
"The study population must be clearly defined to ensure that the trial data are relevant and applicable to the intended patient group."
Objectives:
* Enhance the scientific validity of clinical trial outcomes.
* Support the accurate interpretation of efficacy and safety data.

NEW QUESTION # 79
A study subject inadvertently disposed of IP medication bottles. The site should report this to the:

- A. IRB/IEC.
- B. Medical monitor.
- C. Regulatory authority.
- D. Sponsor.

Answer: D

Explanation:
The loss or disposal of investigational product (IP) must be reported to the sponsor. The sponsor will evaluate the situation and determine the next steps, including whether additional reporting to regulatory authorities or corrective actions are necessary.
Reporting to the sponsor ensures that the accountability of the IP is properly documented and managed.
GCP guidelines specify that any loss or disposal of IP should be immediately reported to the sponsor for appropriate action and documentation.
"Any incident involving the loss, mishandling, or disposal of IP should be reported to the sponsor to maintain accurate drug accountability." Objectives:
* Maintain accurate IP accountability.
* Comply with sponsor requirements for IP management.

NEW QUESTION # 80
A potential subject is interested in a new clinical trial and would like to learn more about the risks and benefits of participation. Where can they find this information?

- A. ICF
- B. Protocol
- C. Package insert
- D. IB

Answer: A

Explanation:
The Informed Consent Form (ICF) contains comprehensive information about the potential risks and benefits of participation in a clinical trial. It is a legally required document that ensures that subjects make an informed decision before enrollment.
The answer is consistent with GCP guidelines which mandate that the ICF clearly outlines the risks and benefits of participation to protect participant rights.
"The ICF should include a clear explanation of potential risks and benefits to ensure informed decision- making by the participant."
Objectives:
* Ensure informed decision-making by potential subjects.
* Provide transparent risk-benefit information.

NEW QUESTION # 81
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