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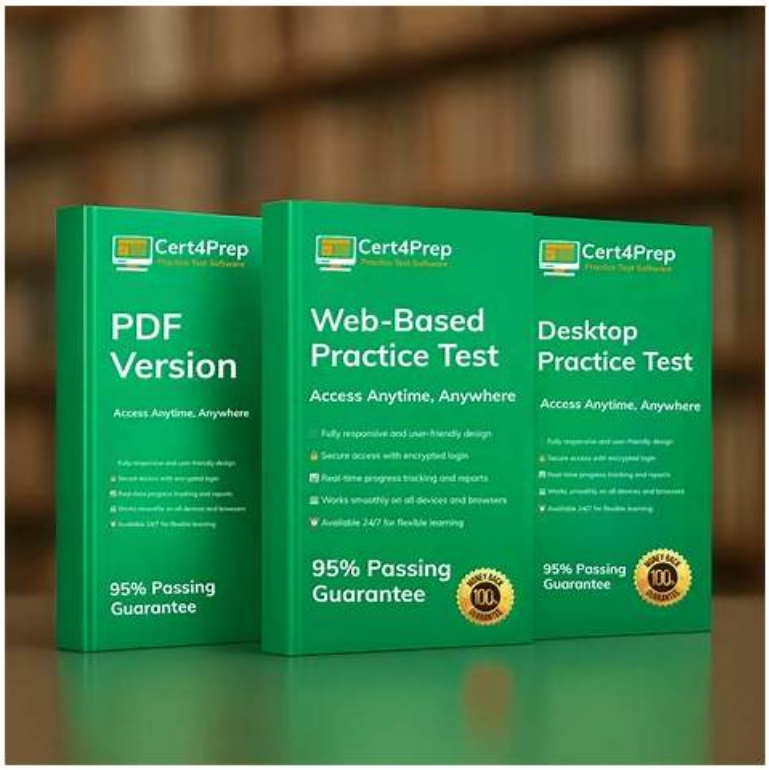

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ACRP Certified Professional Exam Sample Questions (Q88-Q93):

NEW QUESTION # 88
A double-blind randomized Phase III trial seeks to recruit 500 subjects in 2 years. At the end of the first year, 150 subjects have been enrolled. Monitoring reports from the first year note 50% of subjects screened were screen failures due to exclusionary lab values. What action should the sponsor take?

- A. Reduce the target sample size based on feedback from the sites.
- B. Allocate additional monitoring resources to the trial.
- C. Evaluate the screen failures to determine if the protocol needs revision.
- D. Re-train investigators on recruitment obligations.

Answer: C

Explanation:
The high rate of screen failures indicates that the inclusion/exclusion criteria may be too stringent or not appropriately defined. The sponsor should evaluate the reasons for these failures and determine whether the protocol needs adjustment. Revising the criteria may increase recruitment efficiency without compromising the scientific validity of the study.
GCP guidelines advise reviewing and possibly revising protocols when screen failure rates are significantly high to ensure feasible recruitment.
"If a high number of screen failures occurs, the sponsor should evaluate the inclusion/exclusion criteria and consider protocol revisions." Objectives:
* Improve recruitment efficiency.
* Adapt protocol criteria to real-world conditions.

NEW QUESTION # 89
Who should vote during the IRB/IEC review and discussion process?

- A. All IRB/IEC members
- B. All members who were involved in the review and discussion
- C. All members who were involved in the review and discussion and non-member experts
- D. All IRB/IEC members and non-member experts

Answer: B

Explanation:
During the IRB/IEC review process, only members who actively participated in the review and discussion are eligible to vote. This ensures that votes are cast by those who are adequately informed about the study and can make an educated decision. Non-member experts may participate in discussions but do not have voting rights.
GCP guidelines state that voting rights in IRB/IEC meetings are limited to members who have thoroughly reviewed and discussed the study, maintaining unbiased and informed decision-making.
"Only IRB/IEC members who were involved in the review and discussion should participate in the voting process." Objectives:
* Ensure informed voting in ethical review processes.
* Maintain integrity and objectivity in IRB/IEC decisions.

NEW QUESTION # 90
After the completion or termination of a clinical trial, who should store the enrollment log?

- A. CRO
- B. PI
- C. Regulatory authority
- D. Sponsor

Answer: B

Explanation:
The Principal Investigator (PI) is responsible for maintaining and securely storing essential documents, including the enrollment log, after the completion or termination of a clinical trial. This ensures that all participant-related records are retained for audit or inspection as per regulatory requirements.
This answer is consistent with GCP guidelines, which specify that the PI is accountable for retaining essential trial documents at the study site.

"The investigator should maintain records of trial participants, including the enrollment log, as part of the essential documents for trial conduct." Objectives:
* Maintain data integrity and compliance with record-keeping requirements.
* Ensure secure and accessible storage of participant information.

NEW QUESTION # 91
A study drug will be shipped, stored, and mixed at the hospital pharmacy and will be transferred to the study site for infusion. Which document describes how the transfer will occur?

- A. Standard Operating Procedure
- B. Data & Safety Monitoring Plan
- C. Investigator's Brochure
- D. Clinical Monitoring Plan

Answer: A

Explanation:
The Standard Operating Procedure (SOP) outlines the process for shipping, storing, mixing, and transferring the investigational product (IP) between locations. SOPs ensure that all steps are consistently followed and documented, maintaining the integrity and quality of the IP throughout the handling process. This is critical for maintaining compliance with Good Clinical Practice (GCP) and ensuring patient safety.
GCP guidelines specify that SOPs should cover the handling, transfer, and storage of investigational products to ensure quality control.
"SOPs provide detailed guidance on the handling and transfer of investigational products to ensure consistency and compliance." Objectives:
* Maintain the integrity of IP during transport and handling.
* Ensure compliance through standardized procedures.

NEW QUESTION # 92
All of the following are steps to assure an effective risk management approach while conducting a clinical study EXCEPT:

- A. Assessing risk based on study impact.
- B. Controlling risk by setting thresholds of risk acceptability.
- C. Documenting all possible risk scenarios.
- D. Identifying potential study risks.

Answer: C

Explanation:
While identifying potential risks, assessing them based on their impact, and setting risk acceptability thresholds are integral parts of a risk management approach, documenting every possible risk scenario is impractical and unnecessary. Instead, focus should be on identifying and managing the most significant and likely risks that could affect the study's quality and safety.
GCP guidelines emphasize identifying, assessing, and controlling critical risks rather than exhaustively documenting all hypothetical scenarios.
"Effective risk management involves identifying key risks, evaluating their impact, and setting control measures, rather than documenting every possible risk." Objectives:
* Implement practical and targeted risk management strategies.
* Focus on significant and likely risks rather than hypothetical ones.

NEW QUESTION # 93
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