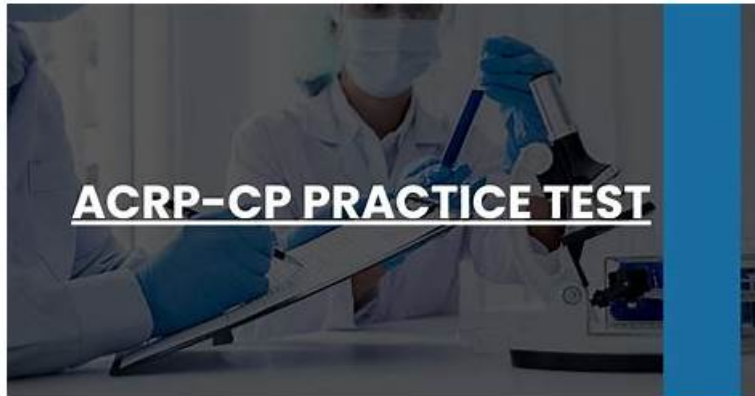


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ACRP Certified Professional Exam Sample Questions (Q95-Q100):

NEW QUESTION # 95

A printed, optical, or electronic document designed to record all of the protocol-required information and is transmitted to the sponsor is called a:

- A. CRF.
- B. Worksheet.
- C. Source document.
- D. PRO.

Answer: A

Explanation:

A Case Report Form (CRF) is a tool used in clinical trials to collect data as specified by the protocol. It is a printed, optical, or electronic document designed to record all protocol-required information for each trial subject. CRFs are crucial for ensuring that the data collected during the trial is accurate, complete, and consistent with the protocol.

This answer follows GCP guidelines, which describe CRFs as essential documents for capturing and transmitting study data to the

sponsor.

"A Case Report Form (CRF) is a printed, optical, or electronic document specifically designed to record all protocol-required information to be reported to the sponsor on each trial subject." Objectives:

- * Understand the role of CRFs in clinical trials.
- * Ensure accurate and complete data collection.

NEW QUESTION # 96

Upon receipt of temperature-controlled IP, the study staff noticed the IP incurred a temperature excursion during transport. What should the staff do NEXT?

- A. Quarantine IP without registering in IWRS and request replacement from sponsor.
- B. Register IP in IWRS and continue with subject allocation.
- **C. Register IP in IWRS, quarantine and notify sponsor of the excursion.**
- D. Dispose of IP and request replacement from sponsor.

Answer: C

Explanation:

If a temperature-controlled IP has experienced a temperature excursion during transport, the appropriate action is to register the IP in the Interactive Web Response System (IWRS), quarantine it to prevent use, and immediately notify the sponsor. This procedure ensures that the IP is not used until the sponsor evaluates its stability and suitability.

GCP guidelines state that any IP affected by a temperature excursion should be quarantined and reported to the sponsor for evaluation.

"Upon identification of a temperature excursion, the IP must be quarantined and reported to the sponsor to determine its usability."

Objectives:

- * Maintain IP integrity and compliance with storage conditions.
- * Follow protocol for managing temperature excursions.

NEW QUESTION # 97

In a quality management system, in which category do risk reduction activities belong?

- **A. Risk Control**
- B. Risk Evaluation
- C. Risk Review
- D. Risk Communication

Answer: A

Explanation:

Risk reduction activities fall under Risk Control within a Quality Management System (QMS). Risk control involves implementing measures to reduce identified risks to an acceptable level, including corrective actions, preventive measures, and continuous monitoring. It aims to mitigate potential negative impacts on trial integrity and participant safety.

GCP guidelines highlight that risk control encompasses actions taken to minimize the likelihood and impact of identified risks.

"Risk control is the process of implementing measures to mitigate risks identified during the risk assessment phase." Objectives:

- * Implement effective risk management strategies.
- * Ensure proactive risk mitigation in clinical trials.

NEW QUESTION # 98

In order to conduct open-label, parallel group clinical trials according to sound scientific principles, which of the following design elements should be included?

- **A. Randomization**
- B. Placebo-controlled
- C. Privacy controls
- D. Blinding

Answer: A

Explanation:

Randomization is a key element in open-label, parallel group clinical trials to reduce selection bias and ensure that participant allocation is not influenced by investigators. Despite the absence of blinding in open-label studies, randomization maintains the validity and reliability of the results by evenly distributing confounding factors between groups.

GCP guidelines recommend randomization as a core element in clinical trial design to ensure unbiased allocation of participants.

"Randomization in parallel group trials helps minimize selection bias and ensures the comparability of intervention groups."

Objectives:

- * Maintain scientific rigor through randomization.
- * Minimize selection bias in clinical studies.

NEW QUESTION # 99

Who is responsible for securing agreement from all involved parties to ensure direct access of all trial-related source documents?

- A. CRC
- B. CRO
- C. Investigator
- **D. Sponsor**

Answer: D

Explanation:

The sponsor is responsible for ensuring that agreements are in place with all involved parties (including investigators and institutions) to grant direct access to trial-related source documents. This is crucial for monitoring, auditing, and inspection purposes, ensuring transparency and compliance with regulatory requirements.

According to GCP guidelines, the sponsor must establish agreements to secure direct access to trial data for verification and compliance checks.

"The sponsor should ensure that agreements are in place to permit direct access to source data and documents for monitoring and inspection." Objectives:

- * Maintain compliance with regulatory requirements.
- * Facilitate data verification and quality assurance.

NEW QUESTION # 100

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