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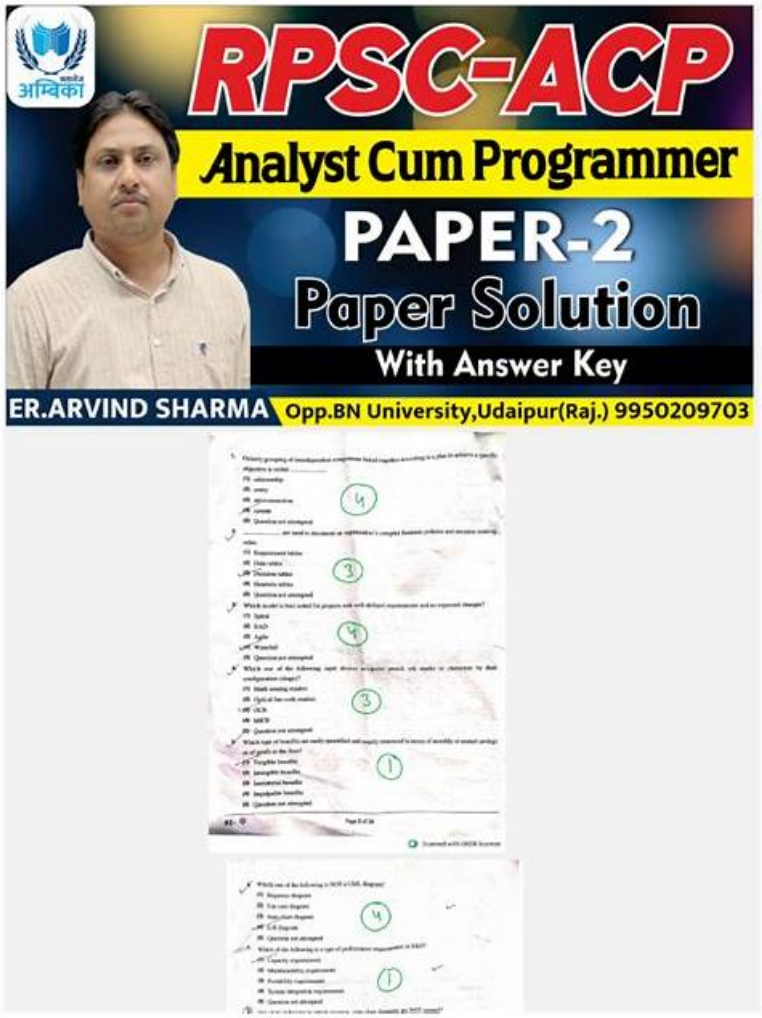


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## ACRP Certified Professional Exam Sample Questions (Q92-Q97):

**NEW QUESTION # 92**
An audit was recently completed and identified non-compliance that could potentially affect the reliability of study results. Who should perform a root cause analysis and implement appropriatecorrective and preventive actions?

- A. IRB/IEC
- B. Sponsor
- C. PI
- D. DSMB/IDMC

**Answer: C**

Explanation:
The Principal Investigator (PI) is responsible for conducting a root cause analysis when non-compliance is identified at the site. The PI must identify the reasons for non-compliance and develop a Corrective and Preventive Action (CAPA) plan to address and prevent future occurrences.
This answer aligns with GCP principles that designate the PI as responsible for site-level compliance and corrective actions.
"The PI must take responsibility for investigating the cause of non-compliance and developing a CAPA plan to mitigate recurrence."
Objectives:
* Maintaining compliance and data integrity
* Addressing non-compliance proactively

**NEW QUESTION # 93**
A clinical trial where participants will be randomized to receive a sequence of two medications has which design configuration?

- A. Crossover
- B. Parallel Group
- C. Factorial
- D. Group sequential

**Answer: A**

Explanation:
A crossover study design involves participants receiving multiple interventions sequentially, with a washout period in between to minimize carryover effects. This design allows each participant to serve as their own control, increasing statistical power while reducing variability. It is commonly used when comparing two treatments or interventions.
GCP guidelines classify a crossover design as one where subjects receive multiple treatments in a specified sequence.
"In crossover trials, participants receive each intervention in a specific order, allowing for within-subject comparison." Objectives:
* Understand the structure of crossover studies.
* Improve statistical efficiency through self-control comparisons.

**NEW QUESTION # 94**
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. Dispose of IP 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. Quarantine IP without registering in IWRS 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 # 95**
A hospital site is being considered for a trial that requires the IP refrigerator to be continuously monitored using the sponsor-provided Wi-Fi-enabled thermometer. The hospital's Wi-Fi connectivity is inconsistent.
During site selection, how should the CRA proceed?

- A. Before accepting this site, report the risk to the trial sponsor and await their decision.
- B. Accept this site and implement and maintain QA and QC systems with written SOPs.
- C. Before accepting this site, ensure the refrigerator is calibrated and functioning properly.
- D. Accept this site and plan to undertake routine safety evaluations of the IP.

**Answer: A**

Explanation:
Since the Wi-Fi connectivity is inconsistent, the CRA must assess the risk and report it to the trial sponsor for a decision. Accepting the site without proper risk evaluation may compromise the monitoring of the investigational product (IP) storage conditions, affecting trial integrity.
The answer follows GCP guidelines that emphasize assessing potential risks during site selection and involving the sponsor when critical issues arise.
"When faced with site-specific issues that may affect data integrity or product safety, the CRA should consult with the sponsor before making a final decision." Objectives:
* Ensuring proper site selection
* Managing potential risks proactively

**NEW QUESTION # 96**
AEs that occur between study visits of a clinical trial should be evaluated by the:

- A. Subject's primary care physician
- B. Medical monitor
- C. Study pharmacovigilance physician
- D. Principal Investigator

**Answer: D**

Explanation:
The Principal Investigator (PI) is responsible for evaluating Adverse Events (AEs) that occur between study visits. The PI must assess the severity, causality, and potential relationship to the investigational product (IP).
Proper evaluation ensures that any necessary medical interventions are promptly administered and that relevant information is recorded and reported accurately.
GCP guidelines specify that the PI is accountable for the medical care of trial subjects, including evaluating AEs and ensuring their safety.
"The PI must evaluate any adverse events occurring between study visits to determine their relevance to the investigational product and manage patient care." Objectives:
* Ensure prompt and accurate evaluation of AEs.
* Maintain the safety and well-being of study participants.

**NEW QUESTION # 97**
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