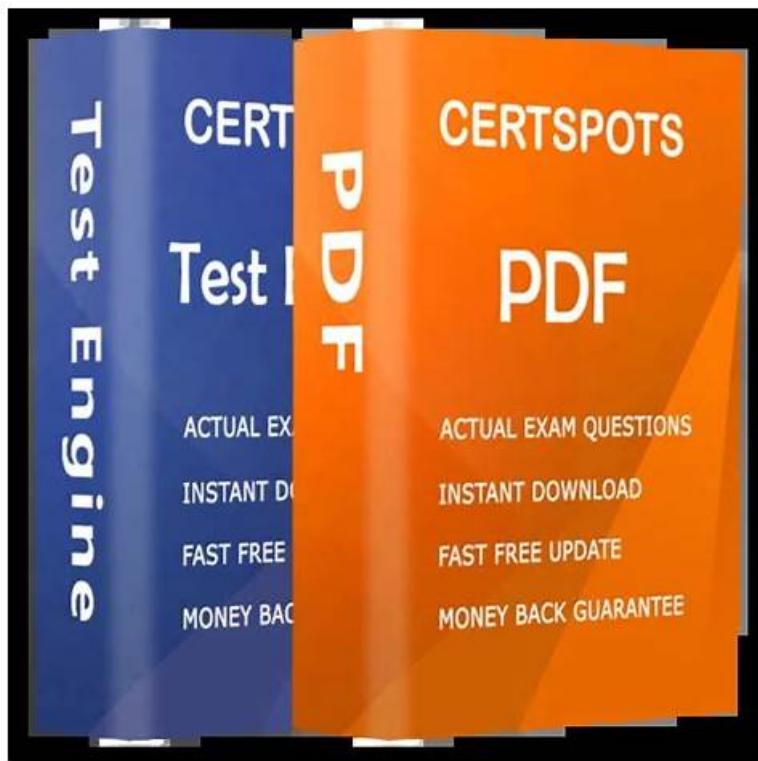


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ACRP Certified Professional Exam Sample Questions (Q47-Q52):

NEW QUESTION # 47

In an investigator-initiated study, who is responsible for implementing appropriate corrective and preventive actions when significant non-compliance is discovered?

- A. CRA

- B. IRB/IEC
- C. CRC
- D. PI

Answer: D

Explanation:

In investigator-initiated studies, the PI holds primary responsibility for addressing non-compliance, including root cause analysis and implementation of CAPA plans. This ensures that any issues affecting the study's integrity are adequately addressed and prevented in the future.

The answer is verified based on ICH E6(R2) guidelines which emphasize the PI's responsibility for maintaining compliance at the study site.

"The PI must develop and implement corrective and preventive actions when non-compliance is identified during the study."

Objectives:

- * Maintain compliance in investigator-initiated studies.
- * Address non-compliance through CAPA.

NEW QUESTION # 48

A PI is reviewing the CRF for a recent subject visit and notices the participant's heart rate and temperature are not recorded. Which of the following study documentation practices was neglected?

- A. Attributable
- B. Complete
- C. Original
- D. Contemporaneous

Answer: B

Explanation:

The missing data indicates a lack of completeness in the study documentation. Completeness is a fundamental requirement in clinical trials, as all necessary information must be recorded accurately and in full. Missing vital signs such as heart rate and temperature can compromise the validity of the data and affect the study's outcomes.

GCP guidelines state that all data collected during the study must be complete, accurate, and consistent with source documents.

"Clinical trial documentation must be complete, containing all data as required by the protocol to ensure data integrity." Objectives:

- * Ensure comprehensive data recording.
- * Maintain accuracy and completeness in study records.

NEW QUESTION # 49

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

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

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 # 50

The CRC is prepared to consent a cognitively impaired participant to an Alzheimer's clinical trial. The CRC is required to utilize

which of the following in the consent process?

- A. A member of the research team
- B. A witness
- C. A family member
- D. A legally acceptable representative

Answer: D

Explanation:

For cognitively impaired participants who may not fully understand the informed consent process, a legally acceptable representative (LAR) must be involved. This ensures that the participant's rights and interests are protected and that consent is obtained ethically and legally.

GCP guidelines mandate that, in cases where participants are unable to provide informed consent, an LAR must be involved to make decisions on their behalf.

"When a participant is cognitively impaired, informed consent must be obtained from a legally acceptable representative to ensure ethical participation." Objectives:

- * Safeguard the rights of vulnerable populations.
- * Maintain ethical standards in the consent process.

NEW QUESTION # 51

Which of the following should be reviewed and evaluated by qualified experts to assess implications for the safety of the trial subjects?

- A. Sample collection storage, disposal, and shipment requirements
- B. PI roles and responsibilities
- C. Emerging animal toxicological and clinical data
- D. Project feasibility considerations

Answer: C

Explanation:

Qualified experts should evaluate emerging animal toxicological and clinical data to assess potential safety implications for trial subjects. These data are critical in identifying potential risks, adverse effects, or safety concerns before exposing human subjects to the investigational product. Early detection of safety issues through expert evaluation helps protect participant well-being.

GCP guidelines stress the importance of expert assessment of preclinical and clinical data to identify risks and ensure participant safety.

"Emerging toxicological and clinical data should be carefully reviewed by qualified experts to identify safety concerns before clinical use." Objectives:

- * Ensure participant safety through expert data analysis.
- * Identify potential safety risks early in the trial process.

NEW QUESTION # 52

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