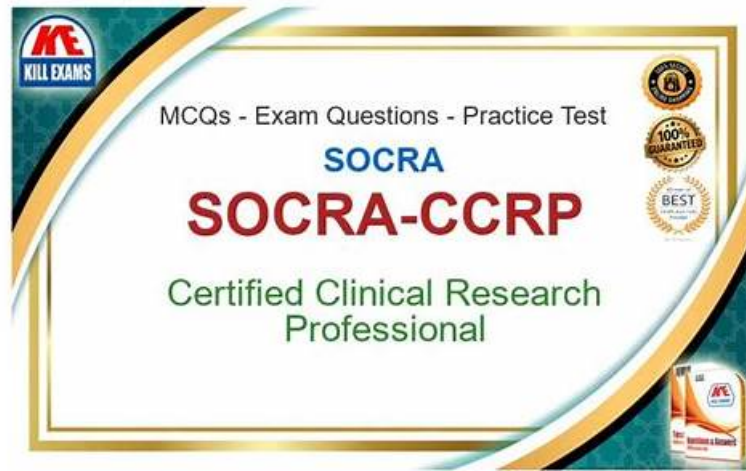


100% Pass Quiz SOCRA - CCRP - Certified Clinical Research Professional (CCRP) Brain Exam



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SOCRA CCRP Exam Syllabus Topics:

Topic	Details

Topic 1	<ul style="list-style-type: none"> • Research Study Start-Up: This section of the exam measures the skills of Clinical Research Coordinators and covers the initial planning and setup of a clinical trial. It involves coordinating the development of the study protocol, ensuring it considers ethical guidelines and regulatory pathways like IND or IDE. It also includes creating essential study documents like informed consent forms and case report forms. The domain covers obtaining necessary approvals from stakeholders like the IRB and sponsor, selecting study sites, training staff, and ensuring the study's compliance with various laws. Additionally, it involves obtaining the research product and preparing all necessary tools and documentation for the study's commencement. • Research Study Implementation: This section of the exam measures the skills of Clinical Research Associates and covers the active management and execution of the clinical trial. It focuses on following the study protocol and standard operating procedures, managing the investigational product, and ensuring ongoing regulatory compliance. The domain includes identifying, documenting, and reporting any study anomalies such as adverse events or protocol deviations. It also involves managing subject recruitment, consent, and retention, as well as maintaining all study records and essential documents. Furthermore, it covers communicating with all study stakeholders and participating in study audits to ensure quality and adherence to regulations.
Topic 2	<ul style="list-style-type: none"> • Research Study Closure: This section of the exam measures the skills of Clinical Research Coordinators and covers the activities required to properly conclude a clinical trial. It involves participating in the study closeout visit to verify documentation and account for the investigational product. The domain also includes developing and submitting final closure reports to the IRB, study sponsor, regulatory authorities, and clinicaltrials.gov. Finally, it covers the procedures for archiving study records.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q43-Q48):

NEW QUESTION # 43

Which document was created as a response to unethical WWII human experiments?

- A. Food, Drug, and Cosmetic Act
- B. Declaration of Helsinki
- C. Belmont Report
- **D. Nuremberg Code**

Answer: D

Explanation:

* The Nuremberg Code (1947) established voluntary consent as essential following Nazi war crimes.

* Helsinki (1964) built upon it; Belmont Report (1979) refined U.S. ethics.

Thus, the correct foundational WWII document is the Nuremberg Code.

References: Nuremberg Code, 1947.

NEW QUESTION # 44

A study subject in a double-blinded, placebo-controlled Phase III study experienced a serious adverse event that could be related to the study drug. The clinical investigator is out of town, and the sub-investigator needs to break the blind. Where can the sub-investigator find a description of the unblinding procedure?

- **A. The study protocol**
- B. The case report form
- C. The Investigator's Brochure
- D. The informed consent form

Answer: A

Explanation:

Unblinding procedures are a protocol-level responsibility because they involve trial design, safety management, and subject protection.

* ICH E6(R2) 6.0 (Protocol and amendments): Requires the protocol to specify "the treatment(s) and treatment periods, procedures

for randomization and blinding, and procedures for breaking codes."

* ICH E6(R2) 4.7: "The investigator should follow the trial's randomization procedure, if any, and should ensure that the code is broken only in accordance with the protocol." The informed consent (A) explains risks and rights but does not include operational unblinding procedures.

The Investigator's Brochure (B) summarizes preclinical/clinical data but does not dictate site-specific trial management. The CRF (D) is for data capture and has no procedural detail.

Therefore, the correct answer is C (The study protocol), as it outlines unblinding steps and documentation requirements.

References:

ICH E6(R2), §6.0 (Protocol content).

ICH E6(R2), §4.7 (Randomization and unblinding).

NEW QUESTION # 45

In an IND study, the specified dosage of an investigational product is 2 mg twice a day for 10 days. The product is available in 1 mg tablets. The subject was given 45 tablets and was instructed to take 2 mg of the product twice a day for 10 days. How many tablets should the subject have after the 10 days?

- A. 0
- B. 1
- C. 2
- **D. 3**

Answer: D

Explanation:

This question tests drug accountability and dosing calculation, which is central to ICH E6(R2) 4.6 (Investigational product management). Subjects must receive the correct supply and any discrepancy must be reconciled.

The prescribed regimen is 2 mg twice daily = 4 mg per day. With 1 mg tablets, this equals 4 tablets daily.

Over 10 days, the subject should consume 40 tablets ($4 \times 10 = 40$). Since 45 tablets were dispensed, the subject should have 5 tablets remaining after 10 days.

Accurate accountability ensures trial integrity and subject safety. Investigators are responsible for maintaining investigational product (IP) records, including dispensing, usage, and returns. According to ICH:

4.6.3: "The investigator/institution should maintain records of the product's delivery to the trial site, the inventory, the use by each subject, and the return to the sponsor or alternative disposition."

4.6.5: "The investigator should ensure that investigational products are used only in accordance with the approved protocol." Thus, the correct answer is C (5 tablets remain). This reflects proper dosing compliance and highlights the importance of meticulous IP tracking in clinical trials.

References:

ICH E6(R2), §4.6 (Investigational Product(s)).

NEW QUESTION # 46

While reviewing site records during a monitoring visit, a monitor can cite which of the following as a site violation of informed consent regulations?

- A. The sponsor-generated informed consent template is missing required elements
- B. Only the signatures of the person obtaining consent and the witness appear on the copy of the summary of the short form consent
- **C. A copy of the consent document was not provided to a subject**
- D. A subject's signature is missing on the copy of the summary of the short form consent

Answer: C

Explanation:

Providing a copy of the signed consent form to subjects is a mandatory requirement.

* 21 CFR 50.27(a): "A copy shall be given to the person signing the form."

* ICH E6(R2) 4.8.11: Reinforces that "a copy of the signed and dated written informed consent form should be given to the subject."

Failure to provide this copy constitutes a direct violation of informed consent regulations.

Other issues:

* A & C concern proper short form process but do not invalidate informed consent if a copy was provided.

* D concerns sponsor template, but the site's responsibility is ensuring use of IRB-approved version.

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