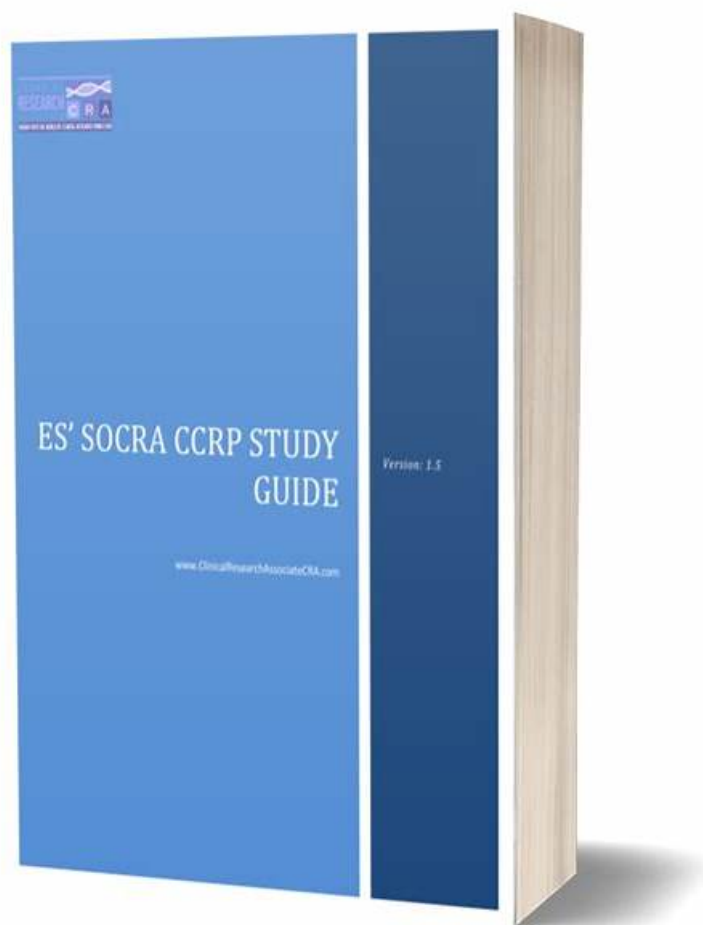


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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<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.
Topic 2	<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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q78-Q83):

NEW QUESTION # 78

An investigator's responsibilities for conducting clinical trials include:

- A. Maintaining IRB meeting minutes
- B. Maintaining financial documentation for study staff
- C. Observing preclinical drug effects
- **D. Administering or overseeing investigational drug administration**

Answer: D

Explanation:

* ICH E6(R2) 4.6.1: The investigator is responsible for investigational product accountability at the site.

* 21 CFR 312.61: Investigators must administer the investigational drug only to subjects under their supervision.

The IRB maintains meeting minutes (A), preclinical studies are sponsor tasks (B), and financial interest documentation (C) is covered under sponsor reporting. Thus, D is correct.

References: ICH E6(R2) §4.6.1; 21 CFR 312.61.

NEW QUESTION # 79

After randomization, investigational drug is shipped to site. Who is responsible for accountability?

- **A. Investigator**
- B. Research coordinator
- C. Sponsor
- D. Investigational pharmacist

Answer: A

Explanation:

* ICH E6(R2) 4.6.1: "Responsibility for investigational product accountability at the trial site rests with the investigator."

* May delegate to pharmacist or coordinator, but ultimate responsibility lies with investigator.

References: ICH E6(R2) §4.6.1.

NEW QUESTION # 80

In accordance with the ICH GCP Guideline, which of the following should the investigator refer to when a subject returns unused medication at the completion of a study?

- A. The Investigator's Brochure
- **B. The sponsor's written procedures**
- C. The CRO/site agreements
- D. The investigational pharmacy's requirements

Answer: B

Explanation:

Handling of investigational product (IP), including returns, is governed by sponsor's written procedures.

* ICH E6(R2) 4.6.3: "The investigator/institution should maintain records of the product's delivery, the inventory, the use by each subject, and the return to the sponsor or alternative disposition."

* ICH E6(R2) 5.13.3: "The sponsor should ensure that written procedures include instructions for... the return or alternative disposition of unused product(s)." The IB (A) describes pharmacology and safety, not IP logistics. CRO agreements (C) cover contractual duties, not product return processes. Local pharmacy policies (D) may apply operationally but do not override sponsor-required procedures.

Thus, the correct answer is B (The sponsor's written procedures).

References:

ICH E6(R2), §4.6.3 (Investigator product accountability).

ICH E6(R2), §5.13.3 (Sponsor product return procedures).

NEW QUESTION # 81

After the sponsor's auditor completes the final audit report for a Phase II trial with an investigational new drug, which of the following is responsible for providing the audit certificate to the clinical site?

- A. The regulatory authority
- B. The Data Safety Monitoring Board
- C. The IRB/IEC
- **D. The sponsor**

Answer: D

Explanation:

Audits are part of sponsor quality assurance to ensure trial compliance.

* ICH E6(R2) 5.19.3: "The sponsor's auditing procedures should include the provision of an audit certificate where required."

* ICH E6(R2) 8.2.20: Audit certificates are essential documents generated and retained by the sponsor.

IRBs (A), regulators (B), and DSMBs (C) are not responsible for audit documentation. Therefore, only the sponsor issues and maintains audit certificates, providing them to sites when appropriate.

Correct answer: D.

References:

ICH E6(R2), §5.19.3.

ICH E6(R2), §8.2.20.

NEW QUESTION # 82

In a Phase III cardiovascular trial, who is responsible for ongoing clinical trial safety evaluation?

- A. FDA
- B. IRB/IEC
- C. Pharmacist

- D. Sponsor

Answer: D

Explanation:

* ICH E6(R2) 5.16: Sponsors must implement ongoing safety evaluation, including expedited and periodic reporting. FDA and IRB review but do not conduct active monitoring.

References: ICH E6(R2), §5.16.

NEW QUESTION # 83

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