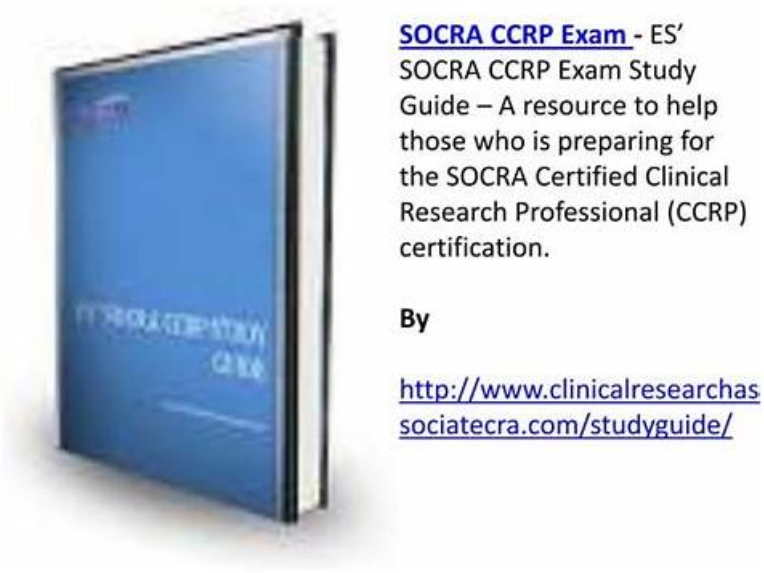
CCRP Best Preparation Materials - CCRP Test Question



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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• 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	• 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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q69-Q74):

NEW QUESTION # 69
The sponsor withdrew an IND due to safety. Who must be notified promptly, in addition to FDA?

- A. Reviewing IRBs/IECs
- B. OHRP
- C. Investigational pharmacies
- D. Site coordinator

Answer: A

Explanation:
* 21 CFR 312.56(d):If an IND is withdrawn for safety, the sponsor must notifyFDA and all participating investigators, who in turn notify IRBs.
* Ensures subjects are protected and sites stop enrollment.
References:21 CFR 312.56(d).

NEW QUESTION # 70
A research site was invited to participate in an investigational drug study. Which of the following parties is responsible for determining the risk-benefit ratio at the site?

- A. The clinical investigator
- B. The sponsor
- C. The site's legal counsel
- D. The IRB/IEC

Answer: D

Explanation:
Therisk-benefit ratiois a core responsibility of the IRB/IEC.
* 21 CFR 56.111(a)(2):"Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."
* ICH E6(R2) 3.1.2:IRB/IEC must safeguard rights, safety, and well-being of subjects, with special attention to risk-benefit evaluation.
Investigators (A) provide medical judgment but do not formally approve the risk-benefit balance. Sponsors (D) design studies but must submit to IRB for independent review. Legal counsel (C) is not part of the scientific/ethical evaluation.
Thus,IRB/IEC is directly responsible for approving the risk-benefit ratio.
References:
21 CFR 56.111(a)(2).
ICH E6(R2), §3.1.2.

NEW QUESTION # 71
A Phase I clinical trial is initiating. Who is responsible for ensuring that site staff are adequately informed about trial duties?

- A. Program manager
- B. Sponsor
- C. Clinical investigator
- D. IRB/IEC

Answer: C

Explanation:
* ICH E6(R2) 4.2.4:"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, investigational product, and trial-related duties."This responsibility cannot be delegated to sponsor or IRB.
References:ICH E6(R2), §4.2.4.

NEW QUESTION # 72
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 IRB/IEC
- B. The regulatory authority
- C. The sponsor
- D. The Data Safety Monitoring Board

Answer: C

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 anaudit certificatewhere 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 sponsorissues 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 # 73
A sponsor became aware of a new serious adverse event related to a drug. Who must be notified in addition to FDA?

- A. All IRBs/IECs of record
- B. OHRP
- C. All investigational pharmacists
- D. All participating investigators

Answer: D

Explanation:
* 21 CFR 312.32(c)(1)(ii):Sponsors must notifyall participating investigatorsof any serious and unexpected suspected adverse reactions.
* Investigators then inform IRBs and subjects as appropriate.
References:21 CFR 312.32(c)(1)(ii).

NEW QUESTION # 74
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Questions Answers

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