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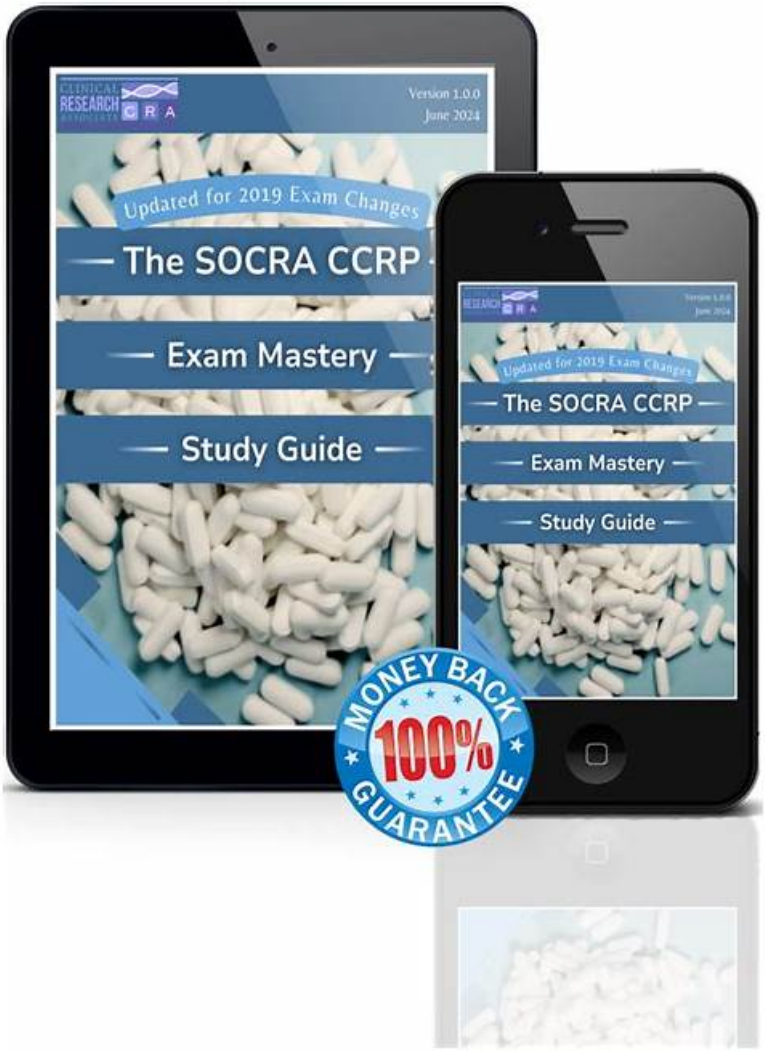

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• 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	• 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 (Q119-Q124):

NEW QUESTION # 119
In accordance with the ICH E2A Guideline, the sponsor must report an adverse event that is life-threatening, unexpected, and associated with the investigational drug to the regulatory authority as soon as possible but no later than how many calendar days after first knowledge of the event?

- A. 15 days
- B. 10 days
- C. 1 day
- D. 7 days

Answer: D

Explanation:
Serious adverse events are subject to expedited reporting requirements.
* ICH E2A 3.2.2:"Fatal or life-threatening unexpected ADRs should be reported as soon as possible but no later than7 calendar daysafter first knowledge."
* ICH E2A 3.2.3:Other serious unexpected events must be reported within 15 days.
Thus, the 7-day rule applies tolife-threatening and unexpected events(as in this case).
Correct answer:B (7 days).
References:
ICH E2A, §3.2.2.

NEW QUESTION # 120
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. All investigational pharmacists
- C. All participating investigators
- D. OHRP

Answer: C

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 # 121
In accordance with the CFR, which body must determine that a study meets the criteria for minimal risk?

- A. The reviewing IRB/IEC
- B. The clinical investigator
- C. A data safety monitoring board
- D. The medical monitor

Answer: A

Explanation:
Minimal risk determination is a regulatory function of the IRB/IEC.
* 45 CFR 46.102(j):Defines minimal risk as harm or discomfort not greater than those ordinarily encountered in daily life.
* 45 CFR 46.109(a):The IRB has authority to approve, require modifications, or disapprove research, including assessment ofrisk level.
* Investigators may propose a study as minimal risk, but only theIRB/IEC can formally classify it.
This ensures independent, unbiased evaluation of risk, protecting participants from investigator or sponsor bias.
References:45 CFR 46.102(j), 46.109(a).

NEW QUESTION # 122
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 Data Safety Monitoring Board
- B. The regulatory authority
- C. The sponsor
- D. The IRB/IEC

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 # 123
A research assistant on a study was recently promoted to a clinical research coordinator (CRC) role after one year on the study. In order to fulfill the significant new responsibilities, the CRC completed additional institutional training. According to ICH GCP Guidelines and 21 CFR, which of the following must be filed in the regulatory binder?

- A. An updated curriculum vitae
- B. An updated performance review summary
- C. A brochure from the training course

- D. The letter documenting the promotion to a CRC

Answer: A

Explanation:
The regulatory binder (investigator site file) must contain documents verifying qualifications of all personnel.
These include curricula vitae (CVs), professional licenses, and training certificates.
ICH E6(R2) 4.1.5: "The investigator should ensure that all persons assisting with the trial are qualified by education, training, and experience... Current curriculum vitae and/or other relevant documents evidencing qualifications should be maintained."
21 CFR 312.53(c)(1): Sponsors must select investigators qualified "by training and experience," and investigators must provide sufficient documentation, typically updated CVs.
Letters of promotion (A), training brochures (B), or performance reviews (C) may remain in personnel files but are not required regulatory documents. The only acceptable regulatory proof is an updated CV (D), which reflects the individual's training and qualifications for their new role.
Therefore, the correct answer is D (Updated CV). This ensures compliance with ICH and FDA requirements for staff qualification documentation in clinical research.
References:
ICH E6(R2) Good Clinical Practice, §4.1.5 (Investigator responsibilities for staff qualification).
21 CFR 312.53(c)(1) (Investigator qualifications and documentation).

NEW QUESTION # 124
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