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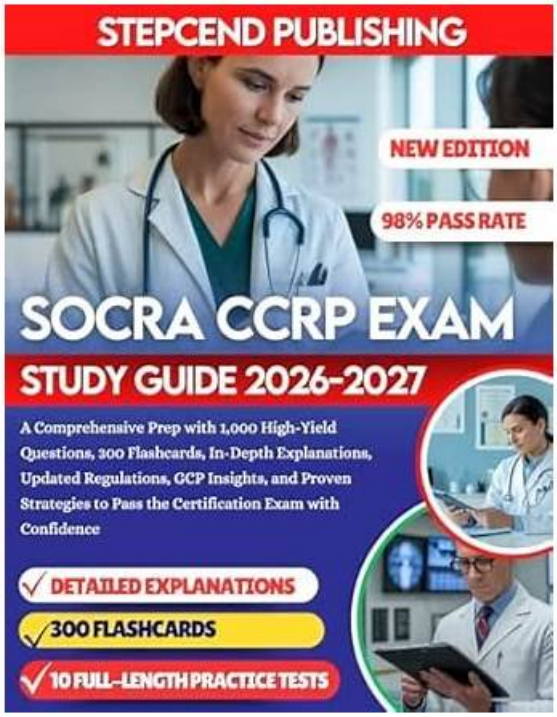

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With the number of people who take the exam increasing, the CCRP exam has become more and more difficult for many people. A growing number of people have had difficulty in preparing for the CCRP exam, and they have a tendency to turn to the study materials. However, a lot of people do not know how to choose the suitable study materials. We are willing to recommend the CCRP Study Materials from our company to you.

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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q117-Q122):

NEW QUESTION # 117
Which of the following statements about the FDA's authority to inspect IRB/IEC records is correct?

- A. The FDA does not have regulatory authority to inspect them
- B. The FDA may inspect them at reasonable times, in a reasonable manner, but may not take copies unless requested with an affidavit
- C. The FDA may inspect them only if the IRB/IEC formally requests inspection
- D. The FDA may inspect them at reasonable times, in a reasonable manner, and may take copies of IRB /IEC records

Answer: D

Explanation:
The FDA has full regulatory authority to inspect IRB/IEC records.
* 21 CFR 56.115(b):"The IRB shall permit representatives of the Food and Drug Administration to inspect and copy all records maintained... at reasonable times and in a reasonable manner." Thus, FDA mayinspect and copyIRB/IEC records without requiring an affidavit or invitation. This ensures regulatory oversight and human subject protection.
Incorrect options:
* (A) limits authority incorrectly.
* (C) is false - FDA explicitly regulates IRBs.
* (D) is false - FDA does not need IRB invitation.
Correct answer:B.
References:
21 CFR 56.115(b).

NEW QUESTION # 118

The sponsor of a multi-institutional clinical trial provided a site with information regarding a newly identified unanticipated adverse event attributed to study drug administration. The site's investigator has a subject actively receiving this study drug. Which of the following is the site investigator's responsibility to the subject?

- A. To provide the subject with information regarding the significant new findings
- B. To submit this safety update to the regulatory authority
- C. To discontinue the subject's study drug
- D. To give the subject's contact information to the sponsor in order to allow the sponsor to contact the subject

Answer: A

Explanation:
Investigators are obligated to inform subjects ofnew informationthat may affect their willingness to continue.
* ICH E6(R2) 4.8.2:"If new information becomes available that may be relevant to a subject's willingness to continue participation, the informed consent document should be revised, and the subject should be informed in a timely manner."
* 21 CFR 50.25(b)(5):Consent must include a statement that "significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided." Thus, the investigator mustcommunicate new risk information to the subject.
Discontinuation (A) may not be warranted unless medically indicated. Reporting to FDA (B) is the sponsor's role. Sharing subject contact with sponsor (D) would violate confidentiality.
Correct answer:C.
References:
ICH E6(R2), §4.8.2.
21 CFR 50.25(b)(5).

NEW QUESTION # 119
Upon completion of a study, the investigator should do which of the following?

- A. Provide the IRB/IEC a final report, but only if the study has a positive outcome
- B. As soon as possible, provide the IRB/IEC with a final report that summarizes the trial's outcome
- C. Compile site data, publish the study results, and submit the publication to the IRB/IEC as the final report
- D. Ensure that all payments from sponsor have been received

Answer: B

Explanation:
Investigators must formally close out a trial with the IRB/IEC.
* ICH E6(R2) 4.13.2:"Upon completion of the trial, the investigator/institution should provide the IRB /IEC with a summary of the trial's outcome."
* 21 CFR 312.66:Reinforces investigator's duty to keep IRB informed throughout study lifecycle.
This applies regardless of whether outcomes were positive, negative, or inconclusive. IRBs are not concerned with sponsor payments (B) or publications (D).
Thus, the correct answer isA (Provide final report to IRB/IEC).
References:
ICH E6(R2), §4.13.2 (Final reporting requirement).

NEW QUESTION # 120
A clinical investigator wants to publish a subject's unique results. The consent form did not mention publication. What is required?

- A. Approval from monitor
- B. Nothing further
- C. IRB chair approval
- D. Consent from subject

Answer: D

Explanation:
* ICH E6(R2) 4.8.10(n):Consent must include explanation about confidentiality and possible publication.
* If not included, specificsubject consentmust be obtained before publishing identifiable results.

Thus, subject's explicit permission is required.
References:ICH E6(R2) §4.8.10(n).

NEW QUESTION # 121
A sponsor is permitted to charge for an investigational drug but must provide what documentation?

- A. CMS approval letter
- B. Orphan product evidence
- C. Evidence of potential clinical benefit and significant advantage
- D. IRB attestation of institutional cost burden

Answer: C

Explanation:
* 21 CFR 312.8(b):Sponsors may charge for investigational drugs only if they demonstrate that the drug providespotential clinical benefitand asignificant advantageover existing therapy.
* FDA must approve charging requests.
References:21 CFR 312.8(b).

NEW QUESTION # 122
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