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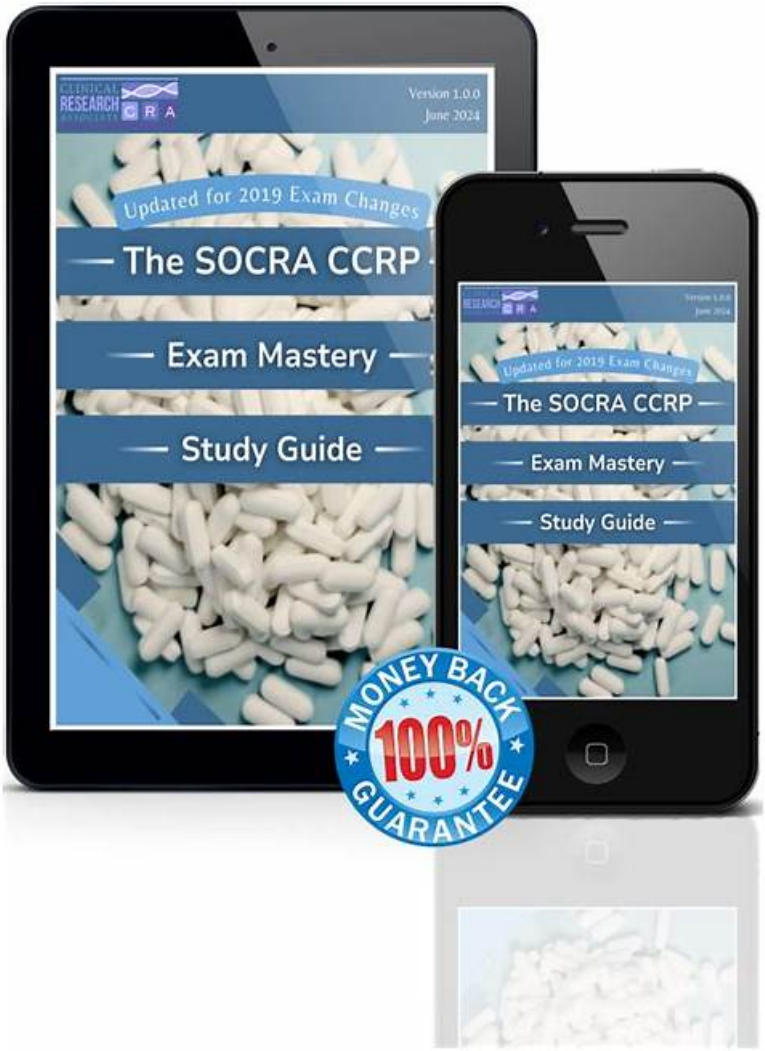

A steadily rising competition has been noted in the tech field. Countless candidates around the globe aspire to be Certified Clinical Research Professional (CCRP) in this field. Once you become SOCRA certified, a whole new scope opens up to you and you are immediately hired by reputed firms. Even though the Certified Clinical Research Professional (CCRP) certification boosts your career options, you have to pass the CCRP Exam.

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 (Q127-Q132):

NEW QUESTION # 127
A revised protocol added genomic testing to banked tissue samples. Before shipping samples, what must the site do?

- A. Execute material transfer agreement
- B. Notify enrolled subjects
- C. Ship under dangerous goods requirements
- D. Obtain IRB/IEC approval for revised protocol and ICF

Answer: D

Explanation:
* 21 CFR 56.109(a):IRB must review and approve any protocol amendments before implementation.
* ICH E6(R2) 4.5.2:Changes affecting subjects (e.g., genomic testing) require IRB/IEC approval and updated consent.
Thus, site must first obtainIRB approval for revised protocol and ICF.
References:21 CFR 56.109(a); ICH E6(R2) §4.5.2.

NEW QUESTION # 128
Which of the following is an adequate definition of quality assurance for the conduct of a clinical trial?

- A. The act of reviewing and approving the investigational protocol and informed consent document
- B. The planned and systematic actions established to ensure that the trial is performed and the data are generated, documented, and reported in compliance with GCP and the applicable regulatory requirements
- C. The systematic plan to review, approve, and monitor biomedical and behavioral research involving human subjects
- D. An official review by a regulatory authority of documents, facilities, records, and any other resources that are deemed to be related to the trial

Answer: B

Explanation:
Quality assurance (QA)is proactive and systematic, designed to prevent errors and ensure compliance.
* ICH E6(R2) 1.46:Defines QA as "all those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented, and reported in compliance with GCP and applicable regulatory requirements." Option A describes IRB responsibilities, Option C describesaudit, and Option D describes protocol approval processes. OnlyBaccurately matches the ICH definition of QA. QA is distinct fromquality control (QC), which is operational and focused on detection of issues during conduct.
Thus, the correct answer isB.
References:
ICH E6(R2), §1.46 (Definition of Quality Assurance).

NEW QUESTION # 129
When can the IRB/IEC require that additional information be given to subjects as part of informed consent?

- A. At any time, but only if the sponsor and investigator agree that the information is essential
- B. At any time, but only if the sponsor agrees that the information is essential
- C. At any time, at the discretion of the IRB/IEC
- D. At any time, but only if the investigator agrees that the information is essential

Answer: C

Explanation:
The IRB/IEC is empowered to protect subjects and ensure informed consent remains accurate, complete, and understandable.
* ICH E6(R2) 3.1.2:"The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid... when considering the adequacy and completeness of the written information to be provided to the subjects."
* 21 CFR 56.109(b):"The IRB shall require that information given to subjects as part of informed consent is in accordance with §50.25.The IRB may require that information, in addition to that specifically mentioned in §50.25, be given to the subjects when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects." This confirms that the IRB/IEC has unilateral authority to request additional information at any time, regardless of sponsor or investigator agreement.
Thus, the correct answer isA (At any time, at the discretion of the IRB/IEC).
References:
ICH E6(R2), §3.1.2 (IRB responsibilities).
21 CFR 56.109(b) (IRB review of informed consent).

NEW QUESTION # 130
In order to adequately monitor a clinical trial, the monitor must be familiar with each of the following, EXCEPT the:

- A. Sponsor's SOPs
- B. IRB/IEC requirements for reporting to the regulatory authority
- C. Requirements for storage of the investigational product
- D. Written information to be provided to the subjects

Answer: B

Explanation:
Monitors verify compliance with protocol, sponsor SOPs, GCP, and regulations.
* ICH E6(R2) 5.18.4:Outlines monitor responsibilities, including verifying informed consent, protocol compliance, investigational product accountability, and adherence to sponsor SOPs.
* Monitors must also be familiar with subject-facing documents (A) and storage requirements for investigational product (B). However,IRB/IEC requirements for reporting to regulatory authoritiesare outside a monitor's scope.
That responsibility lies with investigators and IRBs under21 CFR 56.108(b).
Thus, the correct answer isD.
References:
ICH E6(R2), §5.18.4.
21 CFR 56.108(b).

NEW QUESTION # 131

An investigator received an updated investigator's brochure from the sponsor; the update did not include changes related to subject safety. Which of the following parties, if any, is the investigator required to notify?

- A. The regulatory authority
- B. No notification is required
- C. The IRB/IEC
- D. The Data Safety Monitoring Board (DSMB)

Answer: B

Explanation:
TheInvestigator's Brochure (IB)is updated by the sponsor to reflect new scientific or clinical information.
* ICH E6(R2) 7.3:"The sponsor should revise the IB as soon as new, significant information becomes available."
* ICH E6(R2) 4.1.5:Requires the investigator to ensure staff are informed, but there isno requirementto notify IRB/IEC unless subject safety, rights, or risk profile is affected.
Since this update containedno changes related to subject safety, the investigator is not obligated to notify IRB/IEC, DSMB, or regulators. The updated IB must simply be filed in theregulatory binderand implemented at the site.
Thus, the correct answer isD (No notification is required).
References:
ICH E6(R2), §7.3 (Updating the Investigator's Brochure).
ICH E6(R2), §4.1.5 (Investigator responsibilities for informing staff).

NEW QUESTION # 132
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Just like the old saying goes, there is no royal road to success, and only those who do not dread the fatiguing climb of gaining its numinous summits. In a similar way, there is no smoothly paved road to the CCRP certification. You have to work on it and get started from now. If you want to gain the related certification, it is very necessary that you are bound to spend some time on carefully preparing for the CCRP Exam, including choosing the convenient and practical study materials, sticking to study and keep an optimistic attitude and so on.

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