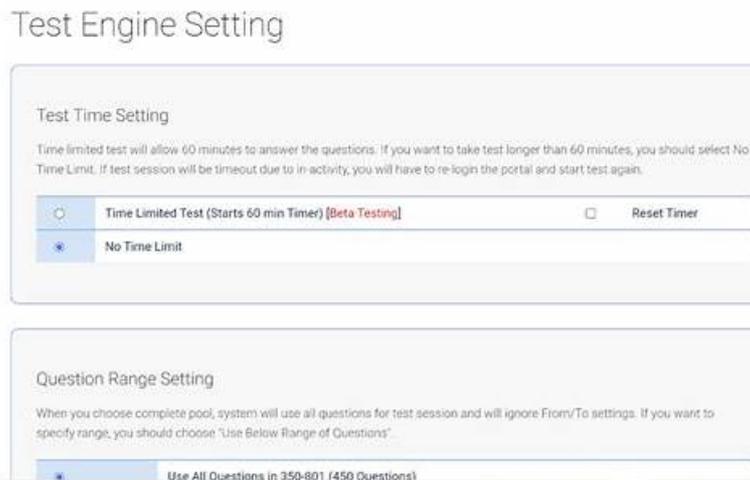


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SOCR A CCRP Exam Syllabus Topics:

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.
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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q27-Q32):

NEW QUESTION # 27

After the completion of a Phase II IND study closeout monitoring visit, which of the following parties is responsible for maintaining the closeout monitoring report?

- A. The IRB/IEC
- B. The study coordinator
- C. The investigator
- **D. The sponsor**

Answer: D

Explanation:

Monitoring reports are sponsor-controlled documents.

* ICH E6(R2) 5.18.6: "The monitor should submit a written report to the sponsor after each trial-site visit... The sponsor should review and follow up on the monitoring report."

* ICH E6(R2) 8.1 & 8.2.22: Monitoring visit reports are essential documents maintained by the sponsor.

Investigators are not required to retain monitoring reports; they maintain site regulatory binders and subject records. The study coordinator assists investigators, but does not hold sponsor-owned reports. IRBs also do not receive sponsor monitoring reports. Thus, the correct answer is B (The sponsor).

References:

ICH E6(R2), §5.18.6 (Monitoring reports).

ICH E6(R2), §8.2.22 (Essential documents: monitoring visit reports).

NEW QUESTION # 28

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

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

Answer: A

Explanation:

* 21 CFR 312.32(c)(1)(ii): Sponsors must notify all participating investigators of 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 # 29

In accordance with the ICH GCP Guideline, prior to initiating a trial, which of the following should define, establish, and allocate all trial-related duties and functions?

- A. The IRB/IEC
- B. The institutional administrator
- C. The study coordinator
- **D. The sponsor**

Answer: D

Explanation:

* ICH E6(R2) 5.2.1: "The sponsor is responsible for implementing and maintaining quality assurance and quality control systems... including allocation of trial-related duties."

* Although tasks may be delegated to CROs or site staff, accountability remains with the sponsor.

References: ICH E6(R2), §5.2.1.

NEW QUESTION # 30

In accordance with 45 CFR 46, in addition to the Office for Human Research Protections (OHRP), a suspension of IRB/IEC approval must be reported to which of the following?

- A. The Scientific Review Committee
- **B. The appropriate institutional officials**
- C. The local hospital's medical director
- D. The local hospital's bioethics committee

Answer: B

Explanation:

If IRB/IEC approval is suspended or terminated, reporting is required to protect oversight and accountability.

* 45 CFR 46.113: "An IRB shall notify the institutional officials, the department or agency head, and OHRP (when applicable) of any suspension or termination of IRB approval." This ensures transparency and institutional responsibility for compliance. Internal hospital committees or directors (A, C, D) are not mandated reporting entities.

Thus, the correct answer is B (Appropriate institutional officials).

References:

45 CFR 46.113 (Suspension or termination of IRB approval).

NEW QUESTION # 31

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

- A. An official review by a regulatory authority of documents, facilities, records, and any other resources that are deemed to be related to the trial
- B. The systematic plan to review, approve, and monitor biomedical and behavioral research involving human subjects
- C. The act of reviewing and approving the investigational protocol and informed consent document
- **D. 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**

Answer: D

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 describes audit, and Option D describes protocol approval processes. Only B accurately matches the ICH definition of QA. QA is distinct from quality control (QC), which is operational and focused on detection of issues during conduct.

Thus, the correct answer is B.

References:

