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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 (Q105-Q110):

NEW QUESTION # 105
Upon completion of a study, the investigator should do which of the following?

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

Answer: A

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 # 106
The sponsor discontinued the clinical development of an investigational product. In accordance with the ICH GCP Guidance, at least how long should the sponsor maintain all sponsor-specific essential documents?

- A. 3 years
- B. 2 years
- C. 15 years
- D. 5 years

Answer: B

Explanation:
Retention of essential documents ensures accountability and inspection readiness.
* ICH E6(R2) 5.5.12 & 8.1:Sponsors should retain essential documents "until at least2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applicationsor at least 2 years after formal discontinuation of clinical development of the investigational product." This standard balances subject protection with practical recordkeeping. Longer durations (B-D) may apply under institutional or national rules, but ICH establishes2 years minimum.
Correct answer:A (2 years).
References:
ICH E6(R2), §5.5.12, §8.1.

NEW QUESTION # 107
An investigator reports a serious adverse event suspected to be drug-related. By CFR, the sponsor must notify FDA no later than:

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

Answer: D

Explanation:
* 21 CFR 312.32(c)(2):Life-threatening or fatal unexpected adverse events must be reported within7 calendar days.Other serious unexpected events are reported within 15 days.
References:21 CFR 312.32(c)(2).

NEW QUESTION # 108

During an IND study closeout, a monitor discovered remaining investigational product. Which procedures must be followed for disposition?

- A. Regulatory authority's procedures
- B. Sponsor's procedures
- C. Dispensing pharmacy's procedures
- D. IRB/IEC's procedures

Answer: B

Explanation:
* ICH E6(R2) 5.13.3:The sponsor is responsible for the supply, storage, and final disposition of investigational product.
* 21 CFR 312.59:Sponsors must assure return or proper disposition of unused supplies.
* Sites must followsponsor's written proceduresfor reconciliation, return, or destruction, not IRB or pharmacy processes.
References:ICH E6(R2) §5.13.3; 21 CFR 312.59.

NEW QUESTION # 109
A revised protocol added genomic testing to banked tissue samples. Before shipping samples, what must the site do?

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

Answer: A

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 # 110
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