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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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q51-Q56):

NEW QUESTION # 51
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 sponsor
- D. The investigator

Answer: C

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 isB (The sponsor).
References:
ICH E6(R2), §5.18.6 (Monitoring reports).
ICH E6(R2), §8.2.22 (Essential documents: monitoring visit reports).

NEW QUESTION # 52
In determining the classification of risk for a study involving a medical device, it is necessary to consider the:

- A. Use of the device in the particular study
- B. Investigators' prior training and experience
- C. Cost of device
- D. Number of patients to be treated with the device

Answer: A

Explanation:
FDA regulations for investigational devices are found under 21 CFR 812. Risk classification determines whether a device is considered Significant Risk (SR) or Non-Significant Risk (NSR). The critical factor is how the device will be used in the specific study.
21 CFR 812.3(m): Defines a "significant risk device study" as one that "is intended as an implant, is purported or represented to be for a use in supporting or sustaining human life, or otherwise presents a potential for serious risk to the health, safety, or welfare of a

subject." Risk is judged within the context of the protocol - i.e., use of the device in that particular study (D).
Number of patients (A), device cost (B), or investigator experience (C) are irrelevant to FDA's risk classification. For example, a stent used in an approved indication may be NSR, but if used in a new anatomical location, it may be SR.
Therefore, the correct answer is D. This ensures ethical review bodies and FDA assess safety in the intended clinical context rather than device attributes alone.
References:
21 CFR 812.3(m) (Definition of significant risk device).
FDA Guidance on Significant Risk and Nonsignificant Risk Medical Device Studies.

NEW QUESTION # 53
In accordance with ICH/GCP Guidance, how long should an IRB/IEC retain all relevant study-related records pertaining to the IRB/IEC's review after a trial has been completed?

- A. Indefinitely
- B. At least 3 years
- C. Until the regulatory authority has approved the investigational product for use
- D. At least 15 years

Answer: B

Explanation:
IRBs/IECs must retain records to permit evaluation of compliance.
* ICH E6(R2) 3.4.2:"IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for at least3 years after completion of the trial." Extended retention (B-D) may occur institutionally, but ICH minimum is3 years.
Correct answer:A (At least 3 years).
References:
ICH E6(R2), §3.4.2.

NEW QUESTION # 54
A study team is preparing to initiate a Phase II trial for a novel colon cancer therapy. By signing the Form FDA 1572, the investigator is certifying that the investigator has:

- A. Read and understood the investigator's brochure
- B. Confirmed that the site's SOPs are in place
- C. Completed other relevant research projects
- D. Obtained malpractice insurance

Answer: A

Explanation:
Form FDA 1572 is the "Statement of Investigator" for IND studies.
* 21 CFR 312.53(c)(1)(vi)(b):Requires investigators to "read and understand the Investigator's Brochure."
* By signing, the investigator also agrees to comply with regulations, maintain records, and supervise study conduct.
Other options (B-D) are not part of 1572 requirements.
Correct answer:A.
References:
21 CFR 312.53(c)(1)(vi)(b).

NEW QUESTION # 55
The sponsor withdrew an IND due to safety. Who must be notified promptly, in addition to FDA?

- A. Site coordinator
- B. OHRP
- C. Reviewing IRBs/IECs
- D. Investigational pharmacies

Answer: C

Explanation:
* 21 CFR 312.56(d):If an IND is withdrawn for safety, the sponsor must notifyFDA and all participating investigators, who in turn notify IRBs.
* Ensures subjects are protected and sites stop enrollment.
References:21 CFR 312.56(d).

NEW QUESTION # 56
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