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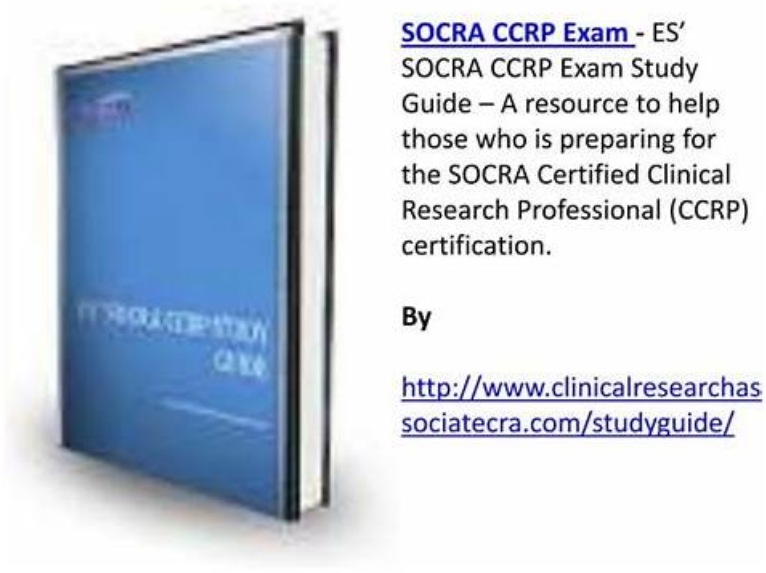

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• 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.
Topic 2	• 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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q115-Q120):

NEW QUESTION # 115
A sponsor-investigator implemented a protocol deviation in a device trial to eliminate an immediate hazard.
Before applying this change to all subjects, what must occur?

- A. Inform all subjects
- B. Train sub-investigators
- C. Obtain IRB/IEC approval
- D. Document change in study file

Answer: C

Explanation:
* 21 CFR 812.35(a)(2):Allows deviation without prior approval only to eliminate immediate hazards.
* Before applying broadly,IRB approvalmust be obtained.
References:21 CFR 812.35(a)(2).

NEW QUESTION # 116
In order to meet recruitment goals, a sponsor is adding a new site to a multi-center study. Which of the following documents should the sponsor obtain from a new site prior to starting research at the site?

- A. The delegation of duties log
- B. The site's accreditation certificate
- C. The IRB/IEC trial approval documentation
- D. The site's SOPs

Answer: C

Explanation:
* ICH E6(R2) 4.4.1:"Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC."
* Sponsors must confirm IRB approval before authorizing initiation.
References:ICH E6(R2), §4.4.1.

NEW QUESTION # 117
After randomization, investigational drug is shipped to site. Who is responsible for accountability?

- A. Sponsor
- B. Investigator
- C. Research coordinator
- D. Investigational pharmacist

Answer: B

Explanation:

* ICH E6(R2) 4.6.1:"Responsibility for investigational product accountability at the trial site rests with the investigator."
* May delegate to pharmacist or coordinator, butultimate responsibilitylies with investigator.
References:ICH E6(R2) §4.6.1.

NEW QUESTION # 118
In determining the classification of risk for a study involving a medical device, it is necessary to consider the:

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

Answer: D

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 # 119
A physician wants to conduct research using an approved/marketed cardiac stent for use in the carotid artery, which is not an indication for which the device is approved. In this case, the physician must obtain which of the following?

- A. IRB/IEC and manufacturer approval
- B. The Office for Human Research Protections (OHRP) and manufacturer approvals
- C. IRB/IEC approval and an FDA IND
- D. IRB/IEC approval and an FDA IDE

Answer: D

Explanation:
When a physician investigates amedical device for a new use (off-label indication), FDA regulations classify this as aSignificant Risk Device Study, requiring anInvestigational Device Exemption (IDE)in addition to IRB approval.
* 21 CFR 812.20(a):"A sponsor shall submit an application to FDA for aninvestigational device exemption (IDE)if the device is to be used in a clinical investigation to determine safety and effectiveness."
* 21 CFR 812.2(b):Significant Risk device studies requireboth FDA and IRB approvalbefore initiation.
An IND (B) applies to drugs and biologics, not devices. Manufacturer permission (A, D) is not a regulatory requirement, although collaboration may be necessary. OHRP approval is not applicable.
Thus, the correct answer isC (IRB/IEC approval and an FDA IDE).
References:
21 CFR 812.20(a) (IDE submission requirements).
21 CFR 812.2(b) (Significant risk device studies).

NEW QUESTION # 120
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