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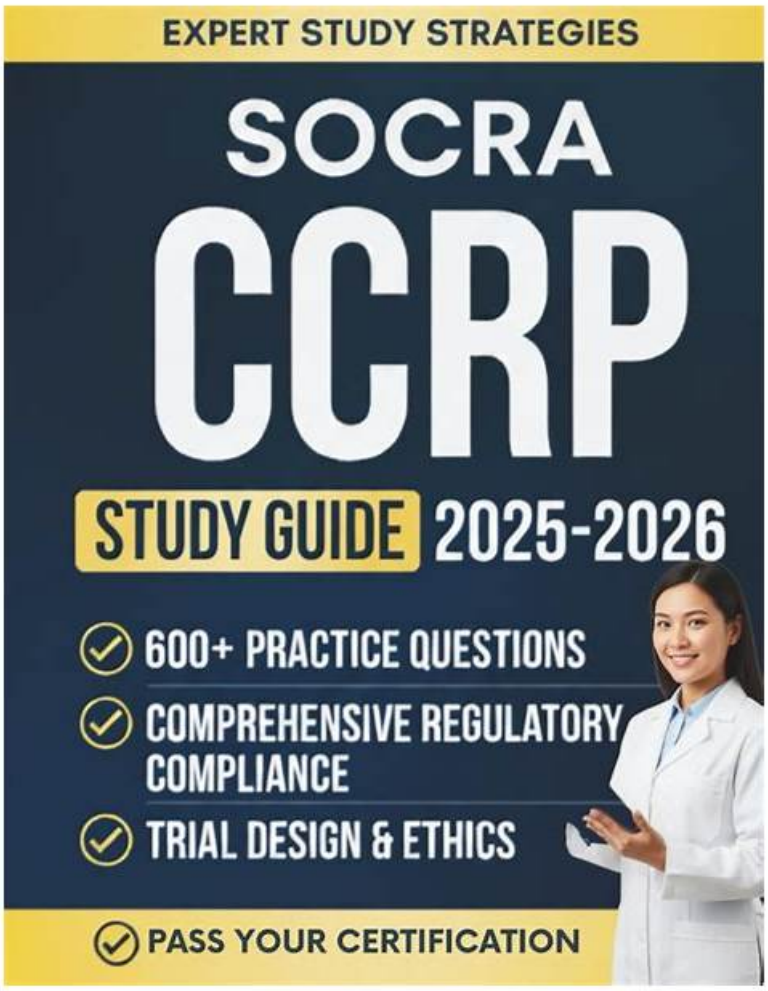

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SOCRA CCRP Exam Syllabus Topics:

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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q129-Q134):

NEW QUESTION # 129
A subject has creatinine 1.6 mg/dL, slightly above eligibility (#1.5). Investigator believes this is normal for size. When can subject be enrolled?

- A. After repeat test confirms 1.6
- B. After sponsor revises eligibility and IRB approves amendment
- C. After investigator documents explanation in chart
- D. After monitor approves deviation

Answer: B

Explanation:
* ICH E6(R2) 4.5.1:"The investigator should conduct the trial in compliance with the protocol approved by IRB/IEC."
* Deviations must not occur unless to eliminate hazard. Eligibility criteria cannot be overridden by investigator opinion.
Thus, enrollment requires protocol amendment and IRB approval.
References:ICH E6(R2), §4.5.1.

NEW QUESTION # 130
After completion of a Phase III trial, which document should IRB/IEC retain?

- A. Sponsor/investigator contracts
- B. Investigational product labels
- C. Occupations and affiliations of IRB members
- D. Subject enrollment logs

Answer: C

Explanation:
* 21 CFR 56.115(a)(5):IRBs must retain records of IRB membership (names, qualifications, affiliations, occupations).
* Other documents (contracts, enrollment logs, product labels) are site or sponsor responsibilities, not IRB's.
References:21 CFR 56.115(a)(5).

NEW QUESTION # 131
According to the ICH/GCP Guideline, which of the following should a sponsor provide to the clinical investigator before entering into a clinical trial agreement?

- A. Proper equipment
- B. Staff training
- C. Adequate resources
- D. The protocol

Answer: D

Explanation:
Before an investigator can commit to conducting a trial, they must review thestudy protocol.
* ICH E6(R2) 4.5.1:The investigator should conduct the trial in compliance with theprotocol approved by the IRB/IEC and sponsor.
* ICH E6(R2) 4.2.3:The investigator should be thoroughly familiar with the appropriate use of the investigational product as described in the investigator's brochure and the current approved protocol.
Although resources, training, and equipment are important, the fundamental step is provision of theprotocol, which forms the legal and ethical framework for study conduct. No trial agreement can be finalized until both parties agree on theprotocol details.
References:ICH E6(R2), §§4.2.3, 4.5.1.

NEW QUESTION # 132
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. Use of the device in the particular study
- D. Investigators' prior training and experience

Answer: C

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 # 133
A Phase I clinical trial is initiating. Who is responsible for ensuring that site staff are adequately informed about trial duties?

- A. Sponsor
- B. Clinical investigator
- C. IRB/IEC

- D. Program manager

Answer: B

Explanation:
* ICH E6(R2) 4.2.4:"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, investigational product, and trial-related duties."This responsibility cannot be delegated to sponsor or IRB.
References:ICH E6(R2), §4.2.4.

NEW QUESTION # 134
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