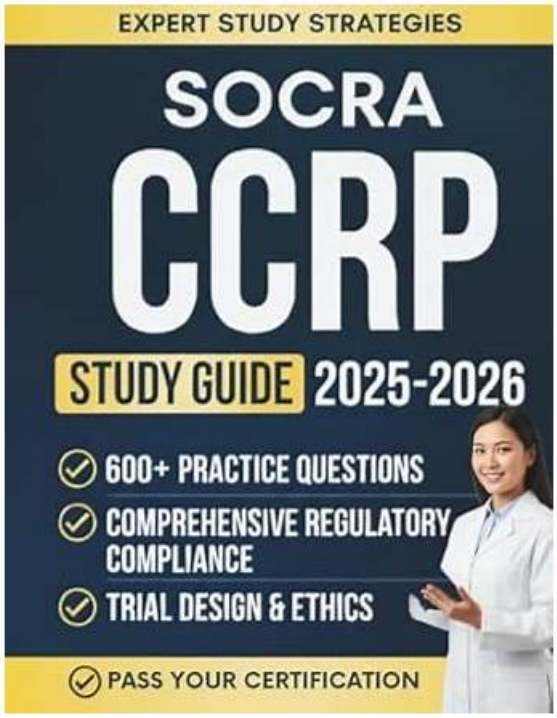
SOCRA CCRP Prep Guide - CCRP Reliable Test Camp



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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 (Q112-Q117):

NEW QUESTION # 112
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. 15 years
- B. 3 years
- C. 2 years
- D. 5 years

Answer: C

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 # 113
In accordance with the CFR and the ICH GCP Guideline, which of the following is directly responsible for submitting protocols and amendments to the IRB/IEC for review?

- A. The contract research organization
- B. The investigator

- C. The sponsor
- D. The Food and Drug Administration

Answer: B

Explanation:
Theinvestigatorbears direct responsibility for ensuring IRB/IEC review and approval before initiating a study or implementing any amendments.
* 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 for the trial protocol, written informed consent form, and any other written information to be provided to subjects."
* 21 CFR 312.66:"An investigator shall assure that an IRB that complies with the requirements... will be responsible for the initial and continuing review and approval of the proposed clinical study." While sponsors may provide protocol documents, the legal obligation to submit and maintain IRB/IEC approval rests with the investigator at each site. CROs act under sponsor delegation but cannot replace investigator accountability.
Thus, the correct answer isB (The investigator).
References:
ICH E6(R2), §4.4.1 (Investigator responsibilities).
21 CFR 312.66 (Investigator assurance of IRB oversight).

NEW QUESTION # 114
A study coordinator is preparing an IRB submission for a Phase II oncology study. Which document must be included?

- A. Case report forms
- B. Record storage plan
- C. Recruitment materials
- D. List of potential subjects

Answer: C

Explanation:
* ICH E6(R2) 3.1.2 & FDA Recruitment Guidance (1998):Recruitment materials must be reviewed by IRB to ensure no coercion or misleading claims.
* CRFs and storage plans are sponsor/site tools, not IRB-reviewed documents.
References:ICH E6(R2) §3.1.2; FDA Recruitment Guidance, 1998.

NEW QUESTION # 115
In accordance with the Belmont Report, obtaining voluntary informed consent from subjects prior to enrolling them in a clinical trial is an example of which of the following ethical principles?

- A. Beneficence
- B. Respect for persons
- C. Do no harm
- D. Justice

Answer: B

Explanation:
TheBelmont Report (1979)establishedthree key ethical principles:
* Respect for Persons:Requires informed consent, recognition of autonomy, and protection of vulnerable individuals.
* Beneficence:Obligation to maximize benefits and minimize harm.
* Justice:Ensuring fairness in subject selection and distribution of research burdens/benefits.
Voluntary informed consent embodiesRespect for Persons, as subjects are given adequate information and freedom of choice. "Do no harm" (A) is a Hippocratic principle but not Belmont terminology.
Thus, the correct answer isB (Respect for persons).
References:
The Belmont Report (1979), Part B: Basic Ethical Principles.

NEW QUESTION # 116
Which of the following statements about the initial IND application submission by a sponsor to the U.S. Food and Drug Administration is correct?

- A. It is an application to export the investigational drug
- B. It is an application for the sponsor to sell the drug for profit
- C. It includes the rationale for human testing and a description of the general investigational plan
- D. It includes a disclosure of the financial interests and arrangements of clinical investigators

Answer: C

Explanation:
AnInvestigational New Drug (IND) applicationprovides FDA with data to justify human testing.
* 21 CFR 312.23(a)(3):The IND must contain "a description of the general investigational plan, including the rationale for the drug or the research study."
* The IND also includes preclinical safety data, manufacturing details, investigator qualifications, and study protocols.
Financial disclosures (D) are reported separately under21 CFR Part 54, not as part of the initial IND. Export applications (A) are covered under21 CFR 312 Subpart E. Profit sales (C) are not permitted under INDs.
Thus, the correct answer isB (Rationale and plan for human testing).
References:
21 CFR 312.23(a)(3) (IND contents).
21 CFR 312.20 (General IND requirements).

NEW QUESTION # 117
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