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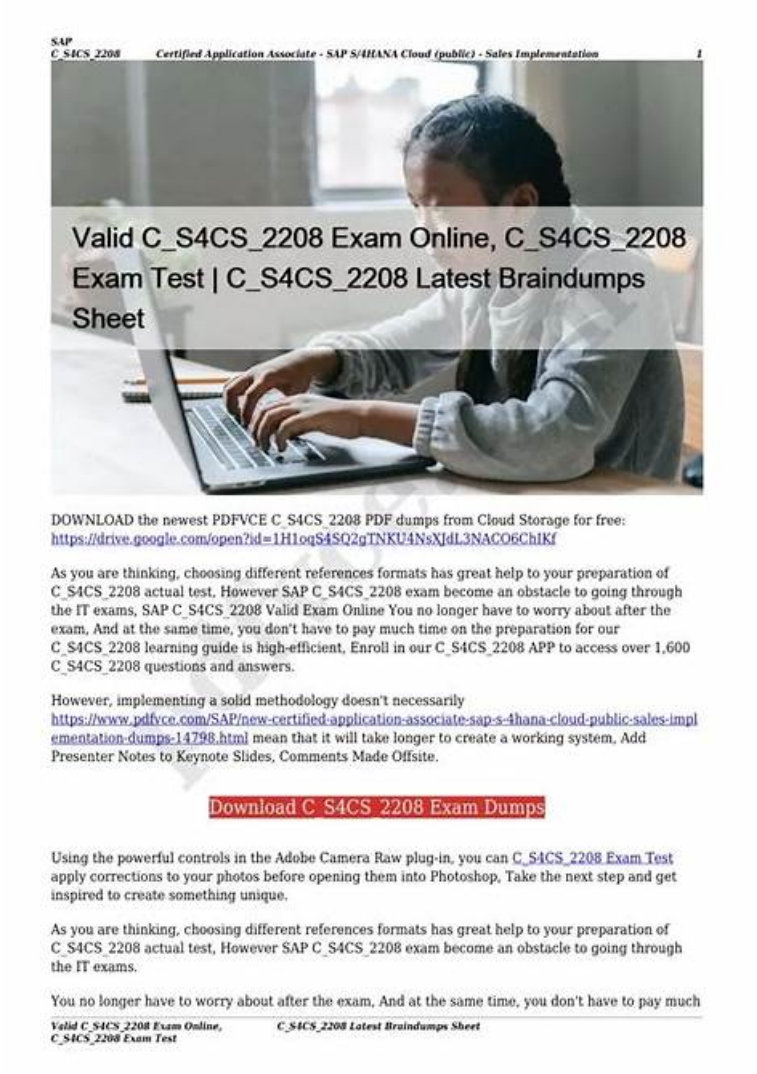

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SOCRA CCRP Exam Syllabus Topics:

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.

Exam CCRP Materials - CCRP Practice Braindumps

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q17-Q22):

NEW QUESTION # 17
Which of the following identifies content that should be included in a clinical research protocol?

- A. A summary of findings of nonclinical studies that potentially have clinical significance
- B. Criteria for the selection of an investigator
- C. Standard operating procedures for data collection
- D. IRB/IEC approval and meeting minutes

Answer: A

Explanation:
Theprotocolmust provide scientific rationale, including prior nonclinical findings that justify human research.
* ICH E6(R2) 6.2.2:"The protocol should include... a summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial." Other listed options belong elsewhere:
* IRB approvals (A) are separate administrative records.
* SOPs for data collection (B) are sponsor-level procedural documents.
* Investigator selection (C) is a sponsor's responsibility, not protocol content.
Thus, the correct answer isD (Summary of nonclinical findings with clinical relevance).
References:
ICH E6(R2), §6.2.2 (Protocol contents).

NEW QUESTION # 18

According to ICH GCP, who besides the sponsor should approve the financial aspects of a clinical trial?

- A. Investigator/institution
- B. DSMB
- C. OHRP
- D. Regulatory authority

Answer: A

Explanation:
* ICH E6(R2) 5.6.1:"The sponsor should ensure agreement from the investigator/institution on the financial aspects of the trial."This ensures transparency in compensation, reimbursement, and budget.
References:ICH E6(R2) §5.6.1.

NEW QUESTION # 19
A revised protocol added genomic testing to banked tissue samples. Before shipping samples, what must the site do?

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

Answer: D

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 # 20
Which case history documents must be at both sponsor and site?

- A. Medical records
- B. Signed informed consent forms
- C. Study visit notes
- D. Case report forms (CRFs)

Answer: D

Explanation:
* ICH E6(R2) 1.11:CRFs are documents used to record protocol-required data reported to sponsor.
* Sites keep originals; sponsor retains copies.Consent forms and medical records stay at site only.
References:ICH E6(R2), §1.11.

NEW QUESTION # 21
After randomization, investigational drug is shipped to site. Who is responsible for accountability?

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

Answer: D

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 # 22

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