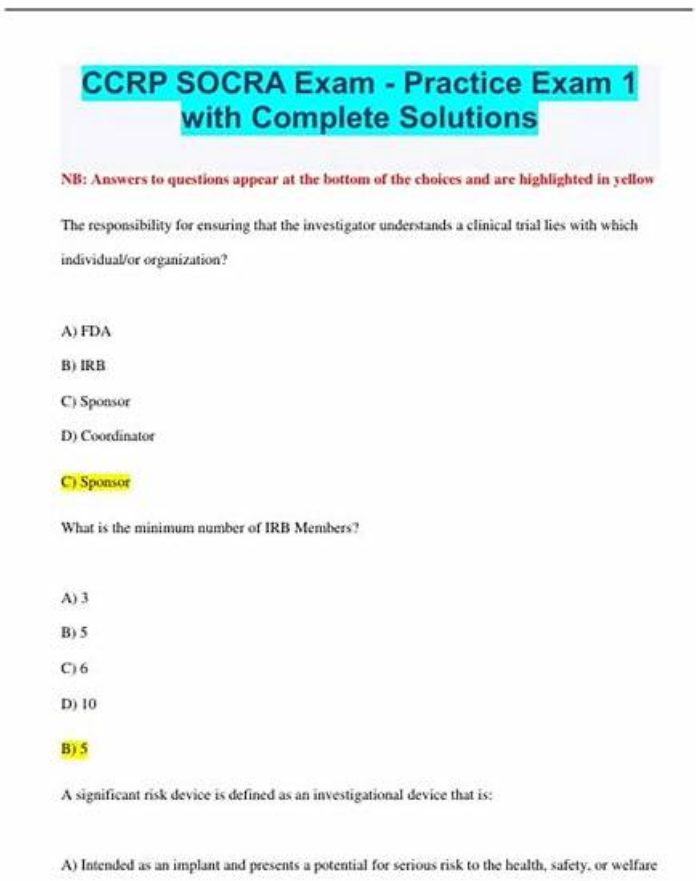
SOCRA CCRP Exam Questions 2026 - Instant Access, just revised



CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

NB: Answers to questions appear at the bottom of the choices and are highlighted in yellow

The responsibility for ensuring that the investigator understands a clinical trial lies with which individual/or organization?

A) FDA
B) IRB
C) Sponsor
D) Coordinator

C) Sponsor

What is the minimum number of IRB Members?

A) 3
B) 5
C) 6
D) 10

B) 5

A significant risk device is defined as an investigational device that is:

A) Intended as an implant and presents a potential for serious risk to the health, safety, or welfare

As we all know it is not easy to obtain the SOCRA CCRP certification, and especially for those who cannot make full use of their sporadic time. But you are lucky, we can provide you with well-rounded services on SOCRA CCRP Practice Braindumps to help you improve ability.

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.

CCRP - Certified Clinical Research Professional (CCRP) Authoritative New Test Online

Itcerttest team of professionals made this product after working day and night so that users can prepare from it for the SOCRA CCRP certification test successfully. Itcerttest even guarantees that you will pass the Certified Clinical Research Professional (CCRP) (CCRP) test on the first try by preparing with real questions. If you fail to pass the certification exam, despite all your efforts, you could get a full refund from Itcerttest according to terms and conditions.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q61-Q66):

NEW QUESTION # 61
After the sponsor's auditor completes the final audit report for a Phase II trial with an investigational new drug, which of the following is responsible for providing the audit certificate to the clinical site?

- A. The Data Safety Monitoring Board
- B. The regulatory authority
- C. The sponsor
- D. The IRB/IEC

Answer: C

Explanation:
Audits are part of sponsor quality assurance to ensure trial compliance.
* ICH E6(R2) 5.19.3:"The sponsor's auditing procedures should include the provision of anaudit certificatewhere required."
* ICH E6(R2) 8.2.20:Audit certificates are essential documents generated and retained by the sponsor.
IRBs (A), regulators (B), and DSMBs (C) are not responsible for audit documentation. Therefore, only the sponsorissues and maintains audit certificates, providing them to sites when appropriate.
Correct answer:D.
References:
ICH E6(R2), §5.19.3.
ICH E6(R2), §8.2.20.

NEW QUESTION # 62
A coordinator for an ongoing industry-sponsored, multi-site Phase II clinical trial is taking an unexpected, long-term medical absence. The trial site retains coordinator services from an external source to support clinical trial activities. According to the ICH GCP Guideline, which of the following is responsible for implementing procedures to ensure the integrity of the clinical trial-related

duties?

- A. The sponsor
- B. The IRB/IEC
- C. The investigator/institution
- D. The external source

Answer: C

Explanation:
The investigator/institution bears responsibility for site conduct, oversight of delegated tasks, and ensuring qualified, trained staff-regardless of employment source. Exact extracts:
* ICH E6(R2) 4.1.1: "The investigator should bequalified... and haveadequate resourcesto properly conduct the trial."
* ICH E6(R2) 4.1.5: "The investigatorshould ensure that all persons assistingwith the trial are adequately informedabout the protocol, the investigational product(s), and their trial-related duties and functions."
* ICH E6(R2) 4.2.5: "The investigatormay delegate... butretains responsibilityfor the conduct of the trial at the site."Therefore, the investigator/institution (B) must implement procedures and oversight to maintain integrity of trial duties.
References:
ICH E6(R2) Good Clinical Practice, §4.1.1; §4.1.5; §4.2.5 (Investigator responsibilities; delegation and oversight).==========

NEW QUESTION # 63
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 # 64
A sponsor received a report from an investigator regarding the investigator's use of an investigational device without having obtained informed consent. The sponsor must submit a copy of the report to the FDA within:

- A. 5 working days
- B. 30 working days
- C. 1 day
- D. 10 working days

Answer: A

Explanation:
Informed consent is a fundamental ethical requirement. If it is violated in a device trial, the FDA requires rapid reporting.
* 21 CFR 812.150(b)(5):States that a sponsor shall submit to FDA "any report of use of a device without obtaining informed consent, within5 working daysafter the sponsor first receives notice of such use."
* This expedited reporting ensures FDA oversight of serious violations and protection of human subjects.
Incorrect options:
* A (1 day) is overly strict and not codified.

* C (10 days) and D (30 days) are too delayed to meet regulatory intent of immediate oversight.
Thus, the correct timeline iswithin 5 working days.
References:
21 CFR 812.150(b)(5).

NEW QUESTION # 65
A clinical investigator received an honorarium from the sponsor of a covered study. At what payment value must this be reported?

- A. >$25,000
- B. $5,000
- C. Any amount
- D. $10,000

Answer: D

Explanation:
* 21 CFR 54.2(f) & 54.4(a):Requires disclosure of "significant payments of other sorts" (SPOOS) that exceed$25,000or equity interests exceeding$50,000.
* However,honoraria or consulting exceeding $10,000 annuallyalso trigger disclosure.
Thus, the reporting threshold is$10,000.
References:21 CFR 54.2(f), 54.4(a).

NEW QUESTION # 66
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