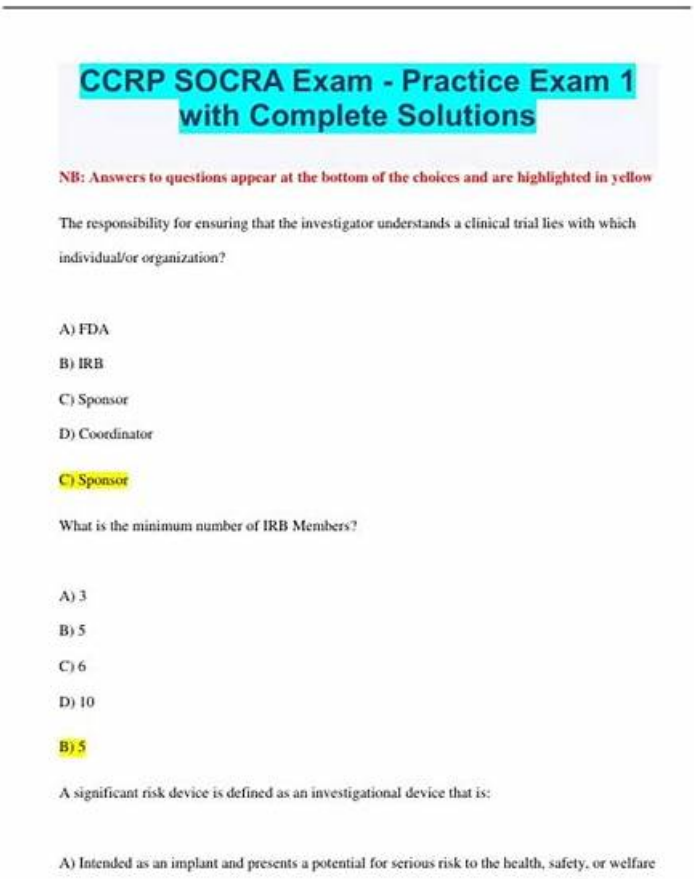
CCRP Exam Study Solutions - CCRP Exam Sample Questions



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

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certification, but the qualification examination of the learning process is very wasted energy, so how to achieve the balance? The CCRP Exam Prep can help you make it. With the high-effective CCRP exam questions, we can claim that you can attend the exam and pass it after you focus on them for 20 to 30 hours.

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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q62-Q67):

NEW QUESTION # 62
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. Respect for persons
- B. Beneficence
- C. Justice
- D. Do no harm

Answer: A

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 # 63
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 regulatory authority
- B. The IRB/IEC
- C. The Data Safety Monitoring Board
- D. The sponsor

Answer: D

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 # 64
Protocol increases drug dose by 20%. Baseline: 370 mg/m². New dose = ?

- A. 420 mg/m²
- B. 444 mg/m²
- C. 400 mg/m²
- D. 492 mg/m²

Answer: B

Explanation:
370 × 1.20 =444 mg/m².
Accurate dosing calculations are critical for protocol adherence and patient safety.
References:Standard pharmacology dose adjustment principles; ICH E6(R2) §4.5.1.

NEW QUESTION # 65
A subject enrolled in a drug clinical trial has withdrawn from the study. In accordance with ICH GCP, which of the following documents should be consulted to determine whether the participant should be replaced?

- A. The data safety monitoring plan
- B. The Investigator's Brochure
- C. The protocol
- D. The informed consent document

Answer: C

Explanation:
Theprotocolgoverns all trial conduct, including whether subjects should be replaced when they withdraw.
* ICH E6(R2) 6.0:The protocol must contain "detailed information on trial design, methodology, statistical considerations, and the organization of the trial."
* ICH E6(R2) 6.9.2:The section on "Subject withdrawal or discontinuation" specifies "whether and under what conditions subjects may be replaced." Other documents serve different functions: the DSM plan (A) manages safety oversight, the IB (C) summarizes product background, and the consent form (D) explains subject rights but does not guide study conduct. Only theprotocolprovides the operational answer regarding replacement.
Thus, the correct answer isB (The protocol).
References:
ICH E6(R2), §6.0 (Protocol content).
ICH E6(R2), §6.9.2 (Subject withdrawal/discontinuation).

NEW QUESTION # 66
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 includes a disclosure of the financial interests and arrangements of clinical investigators
- B. It includes the rationale for human testing and a description of the general investigational plan
- C. It is an application for the sponsor to sell the drug for profit
- D. It is an application to export the investigational drug

Answer: B

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 # 67
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