

Free PDF Quiz SOCRA - CCRP Updated Latest Exam

CCRP SOCRA Exam Graded A+

April 30 1996 - ANSWER ICH GCP Development Date

Quality - ANSWER ICH Q

Efficacy - ANSWER ICH E

Safety - ANSWER ICH S

Multidisciplinary - ANSWER ICH M

guidance for industry, consolidated guidance - ANSWER ICH E 6

Clinical Safety Data Management Definitions and Standards - ANSWER ICH E2A

Safety pharmacology studies for human pharmaceuticals - ANSWER ICH S7A

Electronic records, electronic signatures - ANSWER 21 CFR Part 11

Informed Consent - ANSWER 21 CFR Part 50

Financial Disclosures - ANSWER 21 CFR Part 54

Institutional Review Board - ANSWER 21 CFR Part 56

IND Application - ANSWER 21 CFR 312

New Drug Application - ANSWER 21 CFR 314

Investigational Device Exemption - ANSWER 21 CFR 812

21 CFR Part 814 - ANSWER pre market approval of medical devices

45 CFR Part 46 - ANSWER Federal Research

Studies that investigate the potential undesirable PD effects of a substance on physiological functions in relation to exposure in the therapeutic range or above - ANSWER Safety Pharmacology Studies (Pre-Clinical)

- 1) To identify undesirable PD properties of a substance that may have relevance to its human safety.
- 2) To evaluate adverse PD and/or pathophysiological effects of a substance observed in toxicology studies

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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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q40-Q45):

NEW QUESTION # 40

An investigator received \$60,000 equity interest three years after study completion. What is the financial reporting requirement?

- **A. None**
- B. Report to OHRP
- C. Report to FDA
- D. Report to sponsor

Answer: A

Explanation:

* 21 CFR 54.4(b): Requires disclosure during the study and for 1 year after completion.

* After three years, no disclosure is required.

References: 21 CFR 54.4(b).

NEW QUESTION # 41

Which of the following elements should NOT influence the investigator's ability to obtain endpoint data?

- **A. Complexity of CRFs**
- B. Participant compliance
- C. Complexity of study
- D. Length of study follow-up

Answer: A

Explanation:

* Endpoint data collection is based on protocol design and subject compliance, not CRF formatting.

* ICH E6(R2) 4.9.0: Investigator responsible for data accuracy regardless of CRF complexity.

References: ICH E6(R2), §4.9.0.

NEW QUESTION # 42

What is included in the Statement of Investigator (Form FDA 1572)?

- A. A statement describing preclinical and human safety data
- B. A statement disclosing investigator financial interests
- **C. A statement agreeing to comply with FDA regulations**
- D. A statement responding to FDA inspection observations

Answer: C

Explanation:

Form FDA 1572 is the investigator's signed agreement to follow regulations.

* 21 CFR 312.53(c)(1)(vi)(c): Requires investigators to sign Form 1572, committing to conduct trials in accordance with FDA regulations (21 CFR 50 & 56).

* The form includes commitments to personally supervise, obtain informed consent, maintain records, and permit FDA inspections. It does not include financial disclosures (covered under 21 CFR 54) or preclinical data (in the IB).

References: 21 CFR 312.53(c)(1)(vi)(c).

NEW QUESTION # 43

The sponsor withdrew an IND due to safety. Who must be notified promptly, in addition to FDA?

- **A. Reviewing IRBs/IECs**
- B. OHRP
- C. Site coordinator
- D. Investigational pharmacies

Answer: A

Explanation:

* 21 CFR 312.56(d): If an IND is withdrawn for safety, the sponsor must notify FDA and all participating investigators, who in turn notify IRBs.

* Ensures subjects are protected and sites stop enrollment.

References: 21 CFR 312.56(d).

NEW QUESTION # 44

For an investigational new drug study that has potential side effects of myalgia, arthralgia, and lethargy, which of the following could serve as an acceptable consent statement?

- A. You might develop symptoms of myalgia, arthralgia, and tiredness
- **B. You might have some muscle aches, joint pain, and tiredness**
- C. You might have some mild side effects while taking the investigational drug
- D. You might experience adverse events of myalgia, arthralgia, and lethargy

Answer: B

Explanation:

Consent forms must present information in language understandable to the subject, avoiding technical jargon.

* 21 CFR 50.20: "The information... shall be understandable to the subject... and not include any exculpatory language."

* ICH E6(R2) 4.8.6: Information should be presented in language non-technical and understandable to the subject.

Thus, while medical terms (myalgia, arthralgia) are precise, they may not be understandable to laypersons.

The correct format uses layman's terms: "muscle aches, joint pain, and tiredness" (B).

Correct answer: B.

References:

21 CFR 50.20.

ICH E6(R2), §4.8.6.

NEW QUESTION # 45

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