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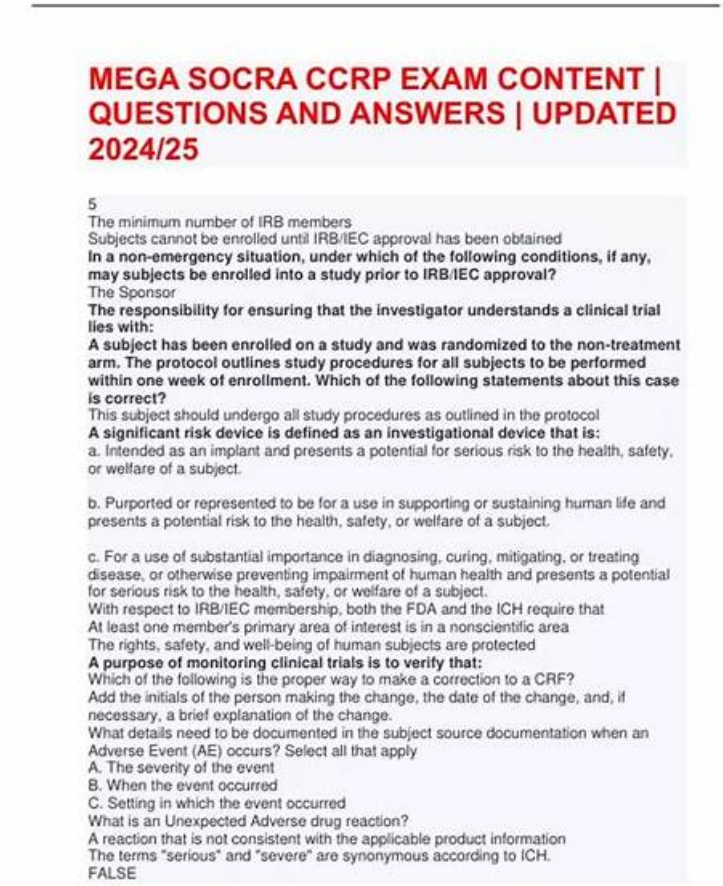
MEGA SOCRA CCRP EXAM CONTENT | QUESTIONS AND ANSWERS | UPDATED 2024/25

5
The minimum number of IRB members
Subjects cannot be enrolled until IRB/IEC approval has been obtained
In a non-emergency situation, under which of the following conditions, if any, may subjects be enrolled into a study prior to IRB/IEC approval?
The Sponsor
The responsibility for ensuring that the investigator understands a clinical trial lies with:
A subject has been enrolled on a study and was randomized to the non-treatment arm. The protocol outlines study procedures for all subjects to be performed within one week of enrollment. Which of the following statements about this case is correct?
This subject should undergo all study procedures as outlined in the protocol
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 of a subject.

b. Purported or represented to be for a use in supporting or sustaining human life and presents a potential risk to the health, safety, or welfare of a subject.

c. For a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.
With respect to IRB/IEC membership, both the FDA and the ICH require that
At least one member's primary area of interest is in a nonscientific area
The rights, safety, and well-being of human subjects are protected
A purpose of monitoring clinical trials is to verify that:
Which of the following is the proper way to make a correction to a CRF?
Add the initials of the person making the change, the date of the change, and, if necessary, a brief explanation of the change.
What details need to be documented in the subject source documentation when an Adverse Event (AE) occurs? Select all that apply
A. The severity of the event
B. When the event occurred
C. Setting in which the event occurred
What is an Unexpected Adverse drug reaction?
A reaction that is not consistent with the applicable product information
The terms "serious" and "severe" are synonymous according to ICH.
FALSE

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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.

SOCRA CCRP Testking Exam Questions Exam Latest Release | Updated CCRP: Certified Clinical Research Professional (CCRP)

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q122-Q127):

NEW QUESTION # 122
A sponsor is permitted to charge for an investigational drug but must provide what documentation?

- A. IRB attestation of institutional cost burden
- B. Orphan product evidence
- C. CMS approval letter
- D. Evidence of potential clinical benefit and significant advantage

Answer: D

Explanation:
* 21 CFR 312.8(b):Sponsors may charge for investigational drugs only if they demonstrate that the drug providespotential clinical benefitand asignificant advantageover existing therapy.
* FDA must approve charging requests.
References:21 CFR 312.8(b).

NEW QUESTION # 123
An unconscious patient experiencing life-threatening cardiac arrhythmias has been admitted to an emergency room. No FDA-

approved treatment is available, and no legal representative is present. The clinical investigator determined that the use of an investigational antiarrhythmic drug is required. In accordance with the CFR, who must certify the investigator's determination?

- A. An independent physician
- B. The sponsor's study monitor
- C. A sub-investigator
- D. The sponsor's medical monitor

Answer: A

Explanation:
This scenario falls underemergency use of investigational drugs without informed consent.
* 21 CFR 50.23(a):Allows waiver of informed consent if subject faces a life-threatening condition, available treatments are unproven, and immediate use is required.
* 21 CFR 50.23(a)(3):Requires that "the determination... be reviewed and concurred with by a physician who is not otherwise participating in the clinical investigation." Thus, anindependent physician(not part of the trial team) must certify the necessity of emergency investigational use.
Sponsors and monitors (C, D) are not authorized by regulation to make such determinations. Sub-investigators (A) lack independence and would be conflicted.
Correct answer:B (Independent physician).
References:
21 CFR 50.23(a)(3).

NEW QUESTION # 124
Which of the following should a clinical investigator include in a submission to an IRB/IEC for a Phase IV drug study?

- A. The amount of payments and compensation to subjects
- B. The investigator's clinical trial agreement with the sponsor
- C. The itemized study budget
- D. The drug development and marketing plan

Answer: A

Explanation:
For IRB/IEC submissions, investigators must disclose subject-related information that may impact voluntariness or fairness of participation.
* 21 CFR 56.111(a)(3):The IRB must ensure that subject selection is equitable.
* 21 CFR 50.25(a)(3):Requires disclosure of "any compensation and/or medical treatments available if injury occurs."
* ICH E6(R2) 4.8.10(n):Informed consent should describe "any compensation and/or reimbursement to subjects."
Thus,compensation amountsmust be reviewed by IRB/IEC to ensure they are not coercive or excessive.
Budgets (A), marketing plans (C), and contracts (D) are administrative and not part of IRB submission requirements.
Correct answer:B (The amount of payments and compensation to subjects).
References:
21 CFR 50.25(a)(3).
ICH E6(R2), §4.8.10(n).

NEW QUESTION # 125
In accordance with the CFR, clinical trial sponsors are required to retain records and reports after a marketing application is approved for at least:

- A. 5 years
- B. 2 years
- C. 15 years
- D. 3 years

Answer: B

Explanation:
TheFDA record retention requirementfor investigational drug studies is clearly outlined in21 CFR 312.57 (c)and21 CFR 312.62(c).

* 21 CFR 312.57(c):"A sponsor shall retain the records and reports... for2 years after a marketing application is approvedfor the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified."
* 21 CFR 312.62(c):Investigators also must retain study-related records for2 years following the date a marketing application is approvedor 2 years after the investigation is discontinued.
This requirement ensures FDA can audit investigational product data even after approval to confirm compliance and verify trial results. Longer retention (e.g., 15 years) may be institutional or sponsor policy but is not mandated by federal law.
Thus, the correct answer isA (2 years).
References:
21 CFR 312.57(c) (Sponsor record retention).
21 CFR 312.62(c) (Investigator record retention).

NEW QUESTION # 126
After randomization, investigational drug is shipped to site. Who is responsible for accountability?

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

Answer: C

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 # 127
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