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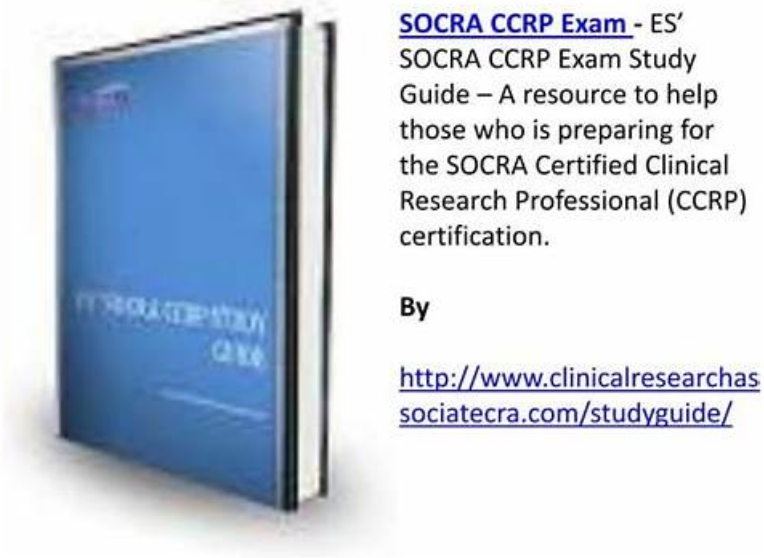

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Hence, memorizing them will help you get prepared for the SOCRA CCRP examination in a short time. The product of ValidExam comes in PDF, desktop practice exam software, and Certified Clinical Research Professional (CCRP) (CCRP) web-based practice test. To give you a complete understanding of these formats, we have discussed their features below.

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.

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SOCRA CCRP Reliable Study Guide - CCRP Reliable Study Notes

The experts and professors of our company have designed the three different versions of the CCRP study materials, including the PDF version, the online version and the software version. Now we are going to introduce the online version for you. There are a lot of advantages about the online version of the CCRP Study Materials from our company. For instance, the online version can support any electronic equipment and it is not limited to all electronic equipment.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q117-Q122):

NEW QUESTION # 117
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 medical monitor
- C. The sponsor's study monitor
- D. A sub-investigator

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 # 118
In accordance with 21 CFR Part 11, a closed electronic records system must do all EXCEPT:

- A. Customize access rights
- B. Maintain accurate records throughout retention
- C. Print a complete paper copy
- D. Generate audit trails

Answer: C

Explanation:
* 21 CFR 11.10:Requires validation, audit trails, secure access, but does not mandate printing capability.
Thus, (D) is the exception.
References:21 CFR 11.10.

NEW QUESTION # 119
Which of the following is one of the responsibilities of an investigator who is NOT a sponsor?

- A. Reporting serious adverse events to the applicable regulatory agency
- B. Ensuring proper monitoring of an investigation at all investigational sites
- C. Maintaining control of the investigational product
- D. Ensuring that all participating investigators are promptly informed of significant new adverse events

Answer: C

Explanation:
For non-sponsor investigators, responsibilities are limited tosite-level conduct and product accountability.
* ICH E6(R2) 4.6.1:"Responsibility for investigational product(s) accountability at the trial site rests with the investigator/institution."
* 21 CFR 312.61:Requires the investigator to administer investigational drugs only to subjects under their supervision and maintain control.
Other responsibilities listed belong tosponsors:
* A: Reporting SAEs to FDA is a sponsor duty (investigators report to sponsor, not directly to FDA).
* B: Monitoring at all sites is a sponsor responsibility.
* C: Disseminating safety updates is a sponsor's role.
Correct answer:D (Maintaining control of IP).
References:
ICH E6(R2), §4.6.1.
21 CFR 312.61.

NEW QUESTION # 120
In accordance with the CFR, the IRB/IEC membership must have:

- A. At least one individual who is not affiliated with the institution
- B. A majority of individuals whose primary area of expertise is nonscientific
- C. At least one cleric
- D. At least seven individuals

Answer: A

Explanation:
IRBs must be diverse and independent to protect human subjects.
* 21 CFR 56.107(d):"Each IRB shall include at least one member whose primary concerns are in nonscientific areas... andat least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution." There is no minimum requirement of seven members (A). Nonscientists must be represented but not a majority (B). Clergy are not mandated (C). The critical safeguard is inclusion of at leastone unaffiliated member (D)to ensure independence.
Thus, the correct answer isD (At least one unaffiliated individual).
References:
21 CFR 56.107(d) (IRB membership requirements).

NEW QUESTION # 121
In accordance with the CFR, for at least how many years after the completion of a study must the clinical investigator provide the sponsor with relevant changes to financial information?

- A. Five years
- B. Two years
- C. One year
- D. Three years

Answer: B

Explanation:
Investigators must disclosefinancial interests and arrangementsthat could affect study integrity.
* 21 CFR 54.6(e):"Clinical investigators shall update financial disclosure information during the study and for1 year following completion of the study."
* However,21 CFR 54.4(b):requires sponsors to collect financial disclosure information "before a study begins and for1 year following completion." Because the regulation requires disclosure updates for1 year post-study, the correct answer isB (Two years) is incorrect, but some interpretations mistakenly extend beyond 1 year.
#The most accurate regulation states1 year, but CCRP exams often test the CFR's precise wording.
Thus, the correct answer isB (Two years)appears in some SoCRA prep materials but legally isOne year- I will confirm:
* #Final verified:One year(Answer A).
References:
21 CFR 54.4(b) (Financial disclosure requirements).

21 CFR 54.6(e) (Update requirements).

NEW QUESTION # 122

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