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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.

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There is no shortcut to CCRP exam questions success except hard work. You cannot expect your dream of earning the SOCRA CERTIFICATION EXAM come true without using updated study material Certified Clinical Research Professional (CCRP) (CCRP) exam questions. Success in the CCRP exam adds more value to your resume and helps you land the best jobs in the

industry.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q74-Q79):

NEW QUESTION # 74
If a subject experiences a serious adverse event related to the study drug and only minimal information is available, the investigator must submit the information to the:

- A. Sponsor and IRB/IEC within five days
- B. Sponsor and IRB/IEC immediately, then update later
- C. IRB/IEC immediately, then sponsor when full details are available
- D. Sponsor and IRB/IEC within seven days

Answer: B

Explanation:
* ICH E6(R2) 4.11.1:Investigators must "immediately report all serious adverse events to the sponsor except for those the protocol identifies as not requiring immediate reporting."
* IRB must also be informed promptly per21 CFR 312.64(b).
* Follow-up information is submitted later as available.
References:ICH E6(R2), §4.11.1; 21 CFR 312.64(b).

NEW QUESTION # 75
For a Significant Risk device study, an investigator must report within 5 working days which event?

- A. Withdrawal of FDA approval
- B. Unanticipated adverse effect
- C. Completion of investigation
- D. Emergency deviation

Answer: D

Explanation:
* 21 CFR 812.150(a)(4):Any deviation from investigational plan made to protect the life or physical well- being of a subject in an emergency must be reported to the sponsor and IRBwithin 5 working days.
* Unanticipated adverse device effects have a 10-day reporting window.
References:21 CFR 812.150(a)(4).

NEW QUESTION # 76
A pharmaceutical company is developing a biologic study. In accordance with ICH, which of the following items should be included in an investigator's brochure (IB)?

- A. Lab draw requirements
- B. Results of recent nude mouse study
- C. Dispensing instructions
- D. Schedule of events

Answer: B

Explanation:
TheInvestigator's Brochure (IB)compilesclinical and nonclinical dataon an investigational product relevant to human study.
* ICH E6(R2) 7.2.3:The IB should summarizenonclinical pharmacology, toxicology, pharmacokinetics, and efficacy data, including results of animal studies.
* ICH E6(R2) 7.2.4:It should also includeavailable clinical trial dataand safety experience.
The "results of recent nude mouse study" (B) are nonclinical data, which appropriately belong in the IB. Lab draw requirements (A), dispensing instructions (C), and schedules of events (D) are operational/procedural and are found in theprotocol, not the IB.
Thus, the correct answer isB (Results of recent nude mouse study).
References:

ICH E6(R2), §7.2.3-7.2.4 (Contents of Investigator's Brochure).

NEW QUESTION # 77
A clinical investigator is developing the assent procedure for the enrollment of children into a new pediatric clinical trial. The ages of the children are described in the IRB/IEC submission. A description of which of the following must also be included in the submission?

- A. The economic status of the children
- B. The pediatrician (primary care provider notification process)
- C. The psychological status of the children
- D. The physiological status of the children

Answer: C

Explanation:
Children are avulnerable populationrequiring additional protections.
* 45 CFR 46.408(a):Requires "adequate provisions for soliciting the assent of the children, when in the judgment of the IRB, the children are capable of providing assent."
* 45 CFR 46.402:Defines "assent" as a child's affirmative agreement to participate.
* IRBs must consider theage, maturity, and psychological stateof the children when determining assent capability.
Economic status (B) is irrelevant to assent. Physiological status (C) pertains to eligibility, not assent. Provider notification (D) may be local practice but not required by regulation.
Correct answer:A (Psychological status).
References:
45 CFR 46.402-408.

NEW QUESTION # 78
Upon completion of a study, the investigator should do which of the following?

- A. Ensure that all payments from sponsor have been received
- B. Compile site data, publish the study results, and submit the publication to the IRB/IEC as the final report
- C. As soon as possible, provide the IRB/IEC with a final report that summarizes the trial's outcome
- D. Provide the IRB/IEC a final report, but only if the study has a positive outcome

Answer: C

Explanation:
Investigators must formally close out a trial with the IRB/IEC.
* ICH E6(R2) 4.13.2:"Upon completion of the trial, the investigator/institution should provide the IRB /IEC with a summary of the trial's outcome."
* 21 CFR 312.66:Reinforces investigator's duty to keep IRB informed throughout study lifecycle.
This applies regardless of whether outcomes were positive, negative, or inconclusive. IRBs are not concerned with sponsor payments (B) or publications (D).
Thus, the correct answer isA (Provide final report to IRB/IEC).
References:
ICH E6(R2), §4.13.2 (Final reporting requirement).

NEW QUESTION # 79
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