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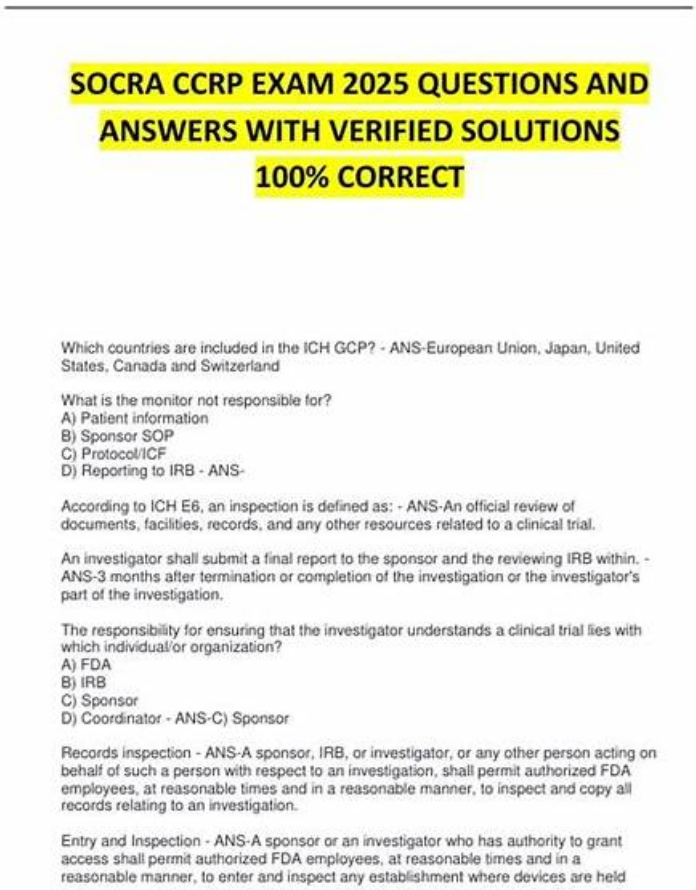

SOCRA CCRP EXAM 2025 QUESTIONS AND ANSWERS WITH VERIFIED SOLUTIONS 100% CORRECT

Which countries are included in the ICH GCP? - ANS-European Union, Japan, United States, Canada and Switzerland

What is the monitor not responsible for?
A) Patient information
B) Sponsor SOP
C) Protocol/ICF
D) Reporting to IRB - ANS-

According to ICH E6, an inspection is defined as: - ANS-An official review of documents, facilities, records, and any other resources related to a clinical trial.

An investigator shall submit a final report to the sponsor and the reviewing IRB within. - ANS-3 months after termination or completion of the investigation or the investigator's part of the investigation.

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 - ANS-C) Sponsor

Records inspection - ANS-A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, shall permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.

Entry and Inspection - ANS-A sponsor or an investigator who has authority to grant access shall permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held

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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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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q97-Q102):

NEW QUESTION # 97
For a Significant Risk device study, an investigator must report within 5 working days which event?

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

Answer: A

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 # 98
According to the CFR and the ICH GCP Guideline, which of the following must be submitted to the IRB after completion of the trial at the site?

- A. The final subject enrollment log
- B. The data safety monitoring summary
- C. The monitoring close-out visit report
- D. The final report

Answer: D

Explanation:
When a trial ends at a site, the investigator has an obligation to submit a final report to the IRB/IEC. This is outlined in both ICH and CFR:
ICH E6(R2) 4.13: "Upon completion of the trial, the investigator should provide the IRB/IEC with a summary of the trial's outcome."
21 CFR 312.66: Requires investigators to "report to the IRB all changes in the research activity and all unanticipated problems involving risk, and to provide reports at the end of the study." The final report provides closure and documentation that the study was conducted ethically and in compliance with regulatory standards. Other documents listed in the options (monitoring reports, DSMB summaries, subject logs) may be retained by the sponsor or site, but they are not mandated for IRB submission.
Thus, the correct answer is A (Final Report). This ensures the IRB/IEC has an accurate record of study completion, outcome, and compliance with ethical oversight.
References:
ICH E6(R2), §4.13 (Final reporting to IRB/IEC).
21 CFR 312.66 (IRB review and reporting).

NEW QUESTION # 99
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 the rationale for human testing and a description of the general investigational plan
- B. It is an application for the sponsor to sell the drug for profit
- C. It includes a disclosure of the financial interests and arrangements of clinical investigators
- D. It is an application to export the investigational drug

Answer: A

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 # 100
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 sponsor
- B. The Data Safety Monitoring Board
- C. The regulatory authority
- D. The IRB/IEC

Answer: A

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 # 101
According to the ICH GCP Guidelines, what is the purpose of source documents?

- A. To validate insurance reimbursement
- B. To validate reports submitted to the IRB/IEC
- C. To provide a record of subjects' investigational medical treatment
- D. To establish diverse subject enrollment

Answer: C

Explanation:
* ICH E6(R2) 1.52:Source documents are "original documents, data, and records... necessary for the reconstruction and evaluation of the trial."
* Their main role is to document treatment and verify CRFs.
References:ICH E6(R2), §1.52.

NEW QUESTION # 102
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