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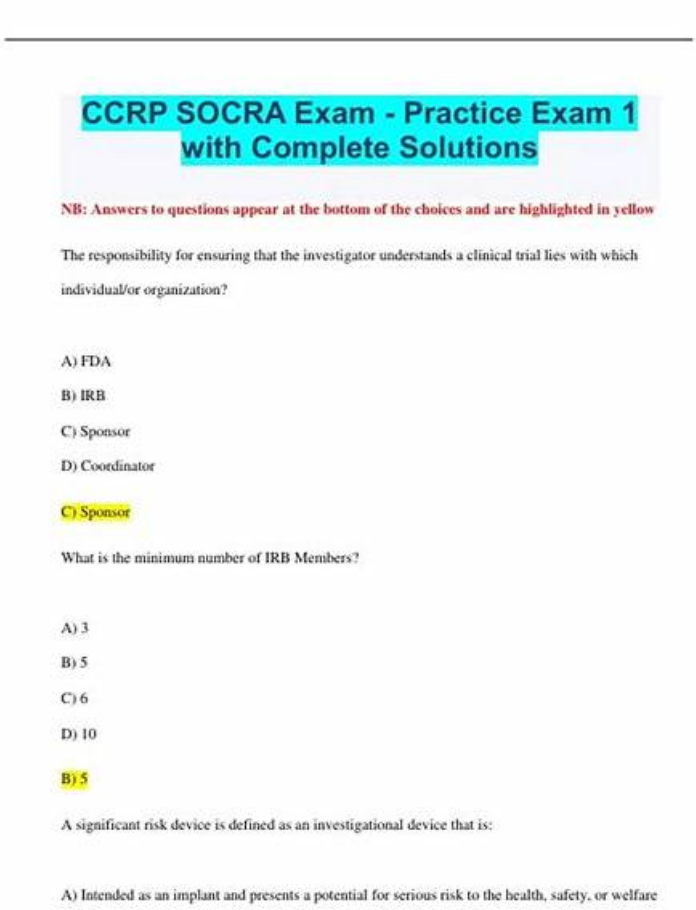

CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

NB: Answers to questions appear at the bottom of the choices and are highlighted in yellow

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

C) Sponsor

What is the minimum number of IRB Members?

A) 3
B) 5
C) 6
D) 10

B) 5

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

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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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q130-Q135):

NEW QUESTION # 130
A nonrandomized study of 30 subjects entitled "A study to evaluate the effectiveness of and to determine the common short-term side effects associated with the drug 'PainStop' for the treatment of subjects with chronic arthritis" is an example of a:

- A. Phase III
- B. Phase II
- C. Phase IV
- D. Phase I

Answer: B

Explanation:
Phase classification is based on study objectives, not just subject numbers.
* Phase I:Focuses on safety, pharmacokinetics, dose-ranging, usually in healthy volunteers or small patient groups.
* Phase II:Evaluateseffectiveness in patients with the conditionand monitors common short-term side effects.
* Phase III:Confirms effectiveness in larger populations, compares to standard therapy, gathers more safety data.
* Phase IV:Post-marketing studies exploring new indications, long-term safety, or special populations.
The given study aims toevaluate effectiveness and common short-term side effectsin 30 arthritis patients, which clearly aligns withPhase IIobjectives. It is not exploratory safety (Phase I), not confirmatory comparative (Phase III), nor post-marketing (Phase IV).
Thus, the correct answer isB (Phase II).
References:

FDA Guidance: The IND Application - §312.21 (Phases of an investigation).
ICH E8(R1), General Considerations for Clinical Studies.

NEW QUESTION # 131
Which of the following statements about the FDA's authority to inspect IRB/IEC records is correct?

- A. The FDA may inspect them only if the IRB/IEC formally requests inspection
- B. The FDA does not have regulatory authority to inspect them
- C. The FDA may inspect them at reasonable times, in a reasonable manner, but may not take copies unless requested with an affidavit
- D. The FDA may inspect them at reasonable times, in a reasonable manner, and may take copies of IRB /IEC records

Answer: D

Explanation:
The FDA has full regulatory authority to inspect IRB/IEC records.
* 21 CFR 56.115(b):"The IRB shall permit representatives of the Food and Drug Administration to inspect and copy all records maintained... at reasonable times and in a reasonable manner." Thus, FDA mayinspect and copyIRB/IEC records without requiring an affidavit or invitation. This ensures regulatory oversight and human subject protection.
Incorrect options:
* (A) limits authority incorrectly.
* (C) is false - FDA explicitly regulates IRBs.
* (D) is false - FDA does not need IRB invitation.
Correct answer:B.
References:
21 CFR 56.115(b).

NEW QUESTION # 132
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. IRB/IEC immediately, then sponsor when full details are available
- B. Sponsor and IRB/IEC within seven days
- C. Sponsor and IRB/IEC immediately, then update later
- D. Sponsor and IRB/IEC within five days

Answer: C

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 # 133
During an internal compliance review, the site study team identified that a protocol-required blood sample collection was not obtained for a majority of the subjects enrolled. In accordance with the ICH GCP Guideline, the clinical investigator should:

- A. Suspend all trial-related activities until the events of the deviation have been mitigated
- B. Document and explain the deviation from the protocol
- C. Assign another investigator to perform sample collections until an internal investigation is completed
- D. Immediately report the observation to the regulatory authority

Answer: B

Explanation:

ICH directs investigators todocument and explainany deviation, with prompt reporting to IRB/IEC only when deviations are implemented to eliminate immediate hazards or as required. Exact extracts:
* ICH E6(R2) 4.5.3: "The investigator should document and explain any deviationfrom the approved protocol."
* ICH E6(R2) 3.3.7 & 4.5.2 (paraphrased): deviations to eliminate immediate hazards must be reported as soon as possible.Here, absent immediate hazard, the required action is documentation and explanation (B).
References:
ICH E6(R2) Good Clinical Practice, §4.5.3 (Compliance with protocol; deviations).
ICH E6(R2) §3.3.7; §4.5.2 (Reporting deviations implemented to eliminate immediate hazards).

NEW QUESTION # 134
Upon completion of a study, the investigator should do which of the following?

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

Answer: B

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 # 135
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