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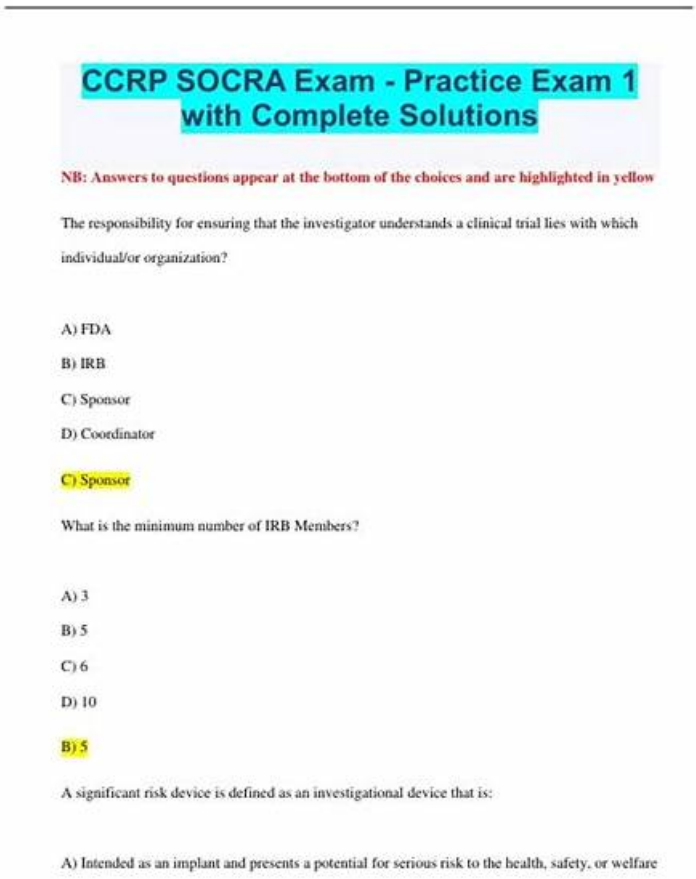

CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

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 Certified Clinical Research Professional (CCRP) Sample Questions (Q68-Q73):

NEW QUESTION # 68
Which of the following adverse events occurring during a study of an investigational new drug would require the sponsor to notify the FDA as soon as possible but in no case later than seven calendar days after the initial receipt of the information?

- A. Death due to disease progression, mentioned in the investigator's brochure
- B. Death as a result of arrhythmias (irregular heart rhythm), not mentioned in the investigator's brochure and thought to be related to the use of the drug
- C. An infection not related to the investigational drug requiring hospitalization for antibiotic therapy
- D. Aplastic anemia requiring hospitalization, mentioned in the investigator's brochure

Answer: B

Explanation:
Sponsors must reportserious, unexpected, and suspected adverse reactions (SUSARs)to the FDA.
* 21 CFR 312.32(c)(2):"Any adverse experience associated with the use of the drug that is bothserious and unexpectedshall be reported...as soon as possible but no later than 7 calendar daysafter the sponsor's initial receipt of the information, if it is fatal or life-threatening."
* ICH E2A 4.2:Requires expedited reporting oflife-threatening or fatal SUSARswithin 7 days.
Among the options, only (C) -death from arrhythmias not previously identified in the Investigator's Brochure and suspected to be drug-related- meets the definition of a SUSAR requiring7-day expedited reporting. Events already listed in the IB (A, D) or unrelated to the drug (B) do not trigger expedited reporting.
Thus, the correct answer isC.
References:
21 CFR 312.32(c)(2) (Expedited safety reporting).
ICH E2A, §4.2 (Expedited reporting of fatal/life-threatening adverse events).

NEW QUESTION # 69
Which of the following would be considered an addendum to an investigator's brochure for an unapproved Investigational Product?

- A. A Suspected Unexpected Serious Adverse Reaction (SUSAR) report
- B. A site-specific SAE report
- C. Revisions to the risk section of the informed consent form
- D. Product monograph updates

Answer: A

Explanation:
The IB must be updatedas new significant safety information emerges.
* ICH E6(R2) 7.3:"The sponsor should revise the IB as soon as new, significant information becomes available."
* ICH E2A:Requires sponsors to reportSuspected Unexpected Serious Adverse Reactions (SUSARs) in expedited reports and include them inIB updates or addenda.
A SUSAR report (B) represents new, unexpected, and serious safety information not previously documented, and therefore warrants inclusion as anIB addendumuntil the IB is formally updated.
Revised consent forms (A) are submitted to IRBs, not IBs. Site-specific SAE reports (C) remain at site /sponsor level, not in the IB. Product monograph updates (D) apply to approved products, not investigational ones.
Thus, the correct answer isB (SUSAR report).
References:
ICH E6(R2), §7.3 (Updating the Investigator's Brochure).
ICH E2A (Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

NEW QUESTION # 70
During the closeout visit, a monitor is completing the documentation of reconciliation of investigational product. All packaging, as well as the used and unused investigational product, are being returned to the sponsor for disposition. Which of the following documents wouldNOTbe required to be filed at the research site?

- A. A certificate of investigational product destruction
- B. Investigational product accountability forms
- C. Investigational product inventory forms
- D. Records of investigational product shipment

Answer: A

Explanation:
Investigators must document the receipt, use, return, or alternative disposition of investigational product (IP).
* ICH E6(R2) 4.6.3:Requires investigators to maintain records of IP delivery, inventory, use by subjects, and return/disposition.
* ICH E6(R2) 8.2.14-8.2.16:Essential documents include shipment records, accountability logs, and inventory records.
However,certificates of destructionare generated and retained by the sponsor (or authorized destruction facility), not required at the site unless the destruction occurred there. In this scenario, all IP was returned to the sponsor, so no destruction certificate would exist at the site.
Thus, the correct answer isD (Certificate of destruction).
References:
ICH E6(R2), §4.6.3 (Investigator product accountability).
ICH E6(R2), §8.2.14-8.2.16 (Essential documents).

NEW QUESTION # 71
A revised protocol added genomic testing to banked tissue samples. Before shipping samples, what must the site do?

- A. Ship under dangerous goods requirements
- B. Obtain IRB/IEC approval for revised protocol and ICF
- C. Execute material transfer agreement
- D. Notify enrolled subjects

Answer: B

Explanation:
* 21 CFR 56.109(a):IRB must review and approve any protocol amendments before implementation.
* ICH E6(R2) 4.5.2:Changes affecting subjects (e.g., genomic testing) require IRB/IEC approval and updated consent.
Thus, site must first obtainIRB approval for revised protocol and ICF.
References:21 CFR 56.109(a); ICH E6(R2) §4.5.2.

NEW QUESTION # 72
According to the ICH/GCP Guideline, which of the following should a sponsor provide to the clinical investigator before entering into a clinical trial agreement?

- A. The protocol
- B. Adequate resources
- C. Proper equipment
- D. Staff training

Answer: A

Explanation:
Before an investigator can commit to conducting a trial, they must review thestudy protocol.
* ICH E6(R2) 4.5.1:The investigator should conduct the trial in compliance with theprotocol approved by the IRB/IEC and sponsor.
* ICH E6(R2) 4.2.3:The investigator should be thoroughly familiar with the appropriate use of the investigational product as described in the investigator's brochure and the current approved protocol.
Although resources, training, and equipment are important, the fundamental step is provision of theprotocol, which forms the legal and ethical framework for study conduct. No trial agreement can be finalized until both parties agree on theprotocol details.

References:ICH E6(R2), §§4.2.3, 4.5.1.

NEW QUESTION # 73
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