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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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In today's global market, tens of thousands of companies and business people are involved in this line of CCRP exam. It is of utmost importance to inquire into the status of exam candidates' wills to figure out what are the CCRP practice materials you really needed. According to your requirements we made our CCRP Study Materials for your information, and for our pass rate of the CCRP exam questions is high as 98% to 100%, we can claim that you will pass the exam for sure.

SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q42-Q47):

NEW QUESTION # 42

A subject currently on a clinical trial was hospitalized for 2 days due to a SAE. The subject reported the hospitalization to the investigator at the next study visit. According to the ICH GCP Guideline, when should the investigator report the SAE to the sponsor?

- A. Within 7 working days
- **B. Immediately**
- C. Within 15 working days
- D. Within 10 working days

Answer: B

Explanation:

ICH requires immediate reporting of all SAEs to the sponsor (except those protocol-identified as not requiring immediate reporting).

Exact extract:

* ICH E6(R2) 4.11.1: "The investigator should report all serious adverse events immediately to the sponsor except for those SAEs that the protocol... identifies as not needing immediate reporting." Therefore, "Immediately" (A) is correct. The other timeframes are not aligned with ICH GCP for initial SAE notification from investigator to sponsor.

References:

ICH E6(R2) Good Clinical Practice, §4.11.1 (Safety reporting by investigators).=====

NEW QUESTION # 43

A coordinator for an ongoing industry-sponsored, multi-site Phase II clinical trial is taking an unexpected, long-term medical absence. The trial site retains coordinator services from an external source to support clinical trial activities. According to the ICH GCP Guideline, which of the following is responsible for implementing procedures to ensure the integrity of the clinical trial-related duties?

- A. The external source
- **B. The investigator/institution**

- C. The sponsor
- D. The IRB/IEC

Answer: B

Explanation:

The investigator/institution bears responsibility for site conduct, oversight of delegated tasks, and ensuring qualified, trained staff regardless of employment source. Exact extracts:

* ICH E6(R2) 4.1.1: "The investigator should be qualified... and have adequate resources to properly conduct the trial."

* ICH E6(R2) 4.1.5: "The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions."

* ICH E6(R2) 4.2.5: "The investigator may delegate... but retains responsibility for the conduct of the trial at the site." Therefore, the investigator/institution (B) must implement procedures and oversight to maintain integrity of trial duties.

References:

ICH E6(R2) Good Clinical Practice, §4.1.1; §4.1.5; §4.2.5 (Investigator responsibilities; delegation and oversight).=====

NEW QUESTION # 44

An investigator's responsibilities for conducting clinical trials include:

- A. Administering or overseeing investigational drug administration
- B. Maintaining financial documentation for study staff
- C. Observing preclinical drug effects
- D. Maintaining IRB meeting minutes

Answer: A

Explanation:

* ICH E6(R2) 4.6.1: The investigator is responsible for investigational product accountability at the site.

* 21 CFR 312.61: Investigators must administer the investigational drug only to subjects under their supervision.

The IRB maintains meeting minutes (A), preclinical studies are sponsor tasks (B), and financial interest documentation (C) is covered under sponsor reporting. Thus, D is correct.

References: ICH E6(R2) §4.6.1; 21 CFR 312.61.

NEW QUESTION # 45

In accordance with the ICH GCP Guideline, who is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the case report forms and in all required reports?

- A. The clinical investigator
- B. The quality control specialist
- C. The contract research organization monitor
- D. The IRB/IEC coordinator

Answer: A

Explanation:

The investigator holds ultimate responsibility for all data reported.

* ICH E6(R2) 4.9.1: "The investigator is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor on the CRFs and all required reports."

* Monitors (D) verify data accuracy but are not responsible for data quality. Quality specialists (B) and IRB staff (C) have no role in data entry.

Correct answer: A (The clinical investigator).

References:

ICH E6(R2), §4.9.1.

NEW QUESTION # 46

In accordance with the ICH GCP Guideline, at what intervals should the on-site study monitoring be performed?

- A. Every 4-6 weeks until study close-out

