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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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q10-Q15):

NEW QUESTION # 10

An approved investigational device exemption (IDE) permits a device to be:

- A. Shipped lawfully for the purpose of conducting a clinical study
- B. Marketed as a humanitarian device
- C. Used on a patient who is not enrolled on a clinical study
- D. Sold and marketed for profit

Answer: A

Explanation:

An Investigational Device Exemption (IDE) allows an unapproved medical device to be used in a clinical investigation.

* 21 CFR 812.1(a): "An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the Food, Drug, and Cosmetic Act that would otherwise apply." It does not allow commercial sale (B), non-study clinical use (C), or marketing as a humanitarian device (D).

Thus, the correct answer is A (Shipped lawfully for clinical study).

References:

21 CFR 812.1(a) (IDE exemption provisions).

NEW QUESTION # 11

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

Answer: C

Explanation:

ICH directs investigators to document and explain any 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 deviation from 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 # 12

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

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

Answer: D

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 obtain IRB approval for revised protocol and ICF.

References: 21 CFR 56.109(a); ICH E6(R2) §4.5.2.

NEW QUESTION # 13

On 15 May 2019, a sponsor announced that its investigational compound GHB331A will not be investigated any further and will not be pursued for a marketing approval. According to the CFR, what is the earliest date when the site may begin to destroy the study records?

- A. 15 May 2022
- B. 16 May 2022
- C. 15 May 2034
- D. 16 May 2021

Answer: B

Explanation:

Record retention requirements ensure regulatory access to data even after development is discontinued.

* 21 CFR 312.62(c): "An investigator shall retain records... for 2 years after the date a marketing application is withdrawn or discontinued and FDA is notified."

* In this case, development was terminated 15 May 2019. Therefore, the 2-year clock starts at discontinuation. Two years later is 15 May 2021, but FDA requires records to be maintained until after the 2-year period ends. The earliest permissible destruction date is 16 May 2022 (C).

Options A and B are premature; D (2034) is far beyond requirements.

Thus, the correct answer is C (16 May 2022).

References:

21 CFR 312.62(c) (Investigator record retention).

21 CFR 312.57(c) (Sponsor record retention).

NEW QUESTION # 14

In a Phase III cardiovascular trial, who is responsible for ongoing clinical trial safety evaluation?

- A. Sponsor
- B. FDA
- C. Pharmacist
- D. IRB/IEC

Answer: A

Explanation:

* ICH E6(R2) 5.16: Sponsors must implement ongoing safety evaluation, including expedited and periodic reporting. FDA and IRB review but do not conduct active monitoring.

References: ICH E6(R2), §5.16.

NEW QUESTION # 15

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With the unemployment rising, large numbers of people are forced to live their job. It is hard to find a high salary job than before. Many people are immersed in updating their knowledge. So people are keen on taking part in the CCRP exam. As you know, the competition between candidates is fierce. If you want to win out, you must master the knowledge excellently. Now our CCRP Study Materials are your best choice. With the assistance of our study materials, you will advance quickly.

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