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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 (Q70-Q75):

NEW QUESTION # 70

According to the CFR and ICH GCP, an IRB/IEC must retain all relevant records for how many years after project completion?

- A. One year
- B. Four years
- C. Two years
- **D. Three years**

Answer: D

Explanation:

Record retention is critical for regulatory inspection and subject protection.

* 21 CFR 56.115(b):IRBs must retain records for at least 3 years after completion of the research.

* ICH E6(R2) 3.4.3:Similarly requires retention of records for a minimum of 3 years after completion.

This allows audits, sponsor inspections, or regulatory reviews long after the study closes. Institutions may require longer retention, but federal minimum is 3 years.

References:21 CFR 56.115(b); ICH E6(R2) §3.4.3.

NEW QUESTION # 71

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

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

Answer: B

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 # 72

Why would a Phase IV study be conducted?

- A. Different dosage
- B. Different schedule of administration
- **C. Different off-label population**
- D. Different marketing strategy

Answer: C

Explanation:

Phase IV studies (post-marketing) examine real-world safety and effectiveness.

* ICH E8(R1):Describes Phase IV as "studies performed after drug approval to delineate additional information including the drug's risks, benefits, and optimal use."

* They often test drugs in new or broader populations beyond original approval.

While dosing and schedules are Phase I-III, Phase IV focuses on new patient populations or long-term outcomes.

References:ICH E8(R1).

NEW QUESTION # 73

In a completed multi-site Phase I drug study using remote EDC, who ensures the system complies with accuracy and reliability requirements?

- **A. Sponsor**
- B. Regulatory authority
- C. Institution
- D. Investigator

Answer: A

Explanation:

* ICH E6(R2) 5.5.3:Sponsors are responsible for validating computerized systems used in trials.

Investigators ensure proper data entry, but system compliance lies with sponsor.

References:ICH E6(R2), §5.5.3.

NEW QUESTION # 74

In accordance with the ICH GCP Guideline and the CFR, who is directly responsible for ensuring that an IRB /IEC will conduct the initial and continuing review of a study?

- **A. The investigator**
- B. The monitor
- C. The sponsor
- D. The study coordinator

Answer: A

Explanation:

The investigator is directly responsible for ensuring that the IRB/IEC reviews and approves the research both initially and on a continuing basis. This responsibility is not delegable to the sponsor or study staff.

* ICH E6(R2) 4.4.1:"Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, and any other written information to be provided to subjects."

* 21 CFR 312.66:"An investigator shall assure that an IRB that complies with the requirements... will be responsible for the initial and continuing review and approval of the proposed clinical study." This means that while the sponsor submits documents to the FDA and oversees general compliance, the investigator has the obligation to obtain and maintain IRB approval at their site. The monitor or study coordinator may assist in documentation, but legal responsibility rests with the investigator.

Thus, the correct answer is C (The investigator).

References:

ICH E6(R2), §4.4.1 (Investigator responsibility before initiation).

21 CFR 312.66 (IRB responsibility in clinical investigations).

NEW QUESTION # 75

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