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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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q128-Q133):

NEW QUESTION # 128
Which of the following statements about the initial IND application submission by a sponsor to the U.S. Food and Drug Administration is correct?

- A. It includes the rationale for human testing and a description of the general investigational plan
- B. It includes a disclosure of the financial interests and arrangements of clinical investigators
- C. It is an application for the sponsor to sell the drug for profit
- D. It is an application to export the investigational drug

Answer: A

Explanation:
AnInvestigational New Drug (IND) applicationprovides FDA with data to justify human testing.
* 21 CFR 312.23(a)(3):The IND must contain "a description of the general investigational plan, including the rationale for the drug or the research study."
* The IND also includes preclinical safety data, manufacturing details, investigator qualifications, and study protocols.
Financial disclosures (D) are reported separately under21 CFR Part 54, not as part of the initial IND. Export applications (A) are covered under21 CFR 312 Subpart E. Profit sales (C) are not permitted under INDs.
Thus, the correct answer isB (Rationale and plan for human testing).
References:
21 CFR 312.23(a)(3) (IND contents).
21 CFR 312.20 (General IND requirements).

NEW QUESTION # 129
According to the CFR and ICH GCP, an IRB/IEC must retain all relevant records for how many years after project completion?

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

Answer: A

Explanation:
Record retention is critical for regulatory inspection and subject protection.
* 21 CFR 56.115(b):IRBs must retain records forat least 3 yearsafter 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 is3 years.
References:21 CFR 56.115(b); ICH E6(R2) §3.4.3.

NEW QUESTION # 130
Which of the following is considered a source document?

- A. Standard operating procedures (SOPs)
- B. The subject instruction sheet
- C. Pharmacy dispensing records
- D. The protocol

Answer: C

Explanation:
Source documentsare the original records where trial data are first recorded, from which Case Report Form (CRF) entries are verified.
* ICH E6(R2) 1.52:Defines source documents as "original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, pharmacy dispensing records, recorded data from automated instruments, etc.)."
* ICH E6(R2) 8.3.13:Requires maintenance of "source documents" to verify data integrity and allow monitoring/audits.
Pharmacy dispensing records (D) fit this definition, as they show initial data on investigational product dispensing and accountability.
In contrast, subject instruction sheets (A) are communication tools, SOPs (B) are procedural guides, and the protocol (C) is a governing document, none of which qualify as original data records.
Therefore, the correct answer isD (Pharmacy dispensing records).
References:
ICH E6(R2), §1.52 (Definition of source documents).
ICH E6(R2), §8.3.13 (Source documents in essential documentation).

NEW QUESTION # 131
A research protocol requires patients to complete a patient reported outcome questionnaire in the sponsor's electronic data capture (EDC) system. What is the source data?

- A. A printout of the electronic medical record
- B. The EDC record
- C. The electronic medical record
- D. A printout of the EDC record

Answer: B

Explanation:
Source data areoriginal records where data are first recorded.
* ICH E6(R2) 1.51:Defines source data as "all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial." Since subjects directly enter responses into the EDC, theEDC record itself is the original source document.
EMRs (B, C) and printouts (D) are secondary records.
Correct answer:A (The EDC record).
References:
ICH E6(R2), §1.51 (Definition of source data).

NEW QUESTION # 132
An investigator received an updated informed consent form (ICF) from the sponsor for a study closed to enrollment. Subjects are

only in long-term follow-up. The change related to frequent radiation imaging at screening, with no change to drug safety profile. Who must the investigator notify first?

- A. Participants in long-term follow-up
- B. Sub-investigators
- C. No notification is required
- D. The IRB/IEC

Answer: D

Explanation:
* 21 CFR 56.109(a):IRBs must review all changes to informed consent before implementation.
* ICH E6(R2) 4.8.2:If new information could affect willingness to continue, consent forms must be revised and approved by the IRB.
Even though screening is closed, the IRB/IEC must review the updated form before any subject re-consenting.
References:21 CFR 56.109(a); ICH E6(R2) §4.8.2.

NEW QUESTION # 133
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