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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 (Q54-Q59):

NEW QUESTION # 54
Which of the following elements should NOT influence the investigator's ability to obtain endpoint data?

- A. Complexity of CRFs
- B. Length of study follow-up
- C. Complexity of study
- D. Participant compliance

Answer: A

Explanation:
* Endpoint data collection is based onprotocol designand subject compliance, not CRF formatting.
* ICH E6(R2) 4.9.0:Investigator responsible for data accuracy regardless of CRF complexity.
References:ICH E6(R2), §4.9.0.

NEW QUESTION # 55
A nonrandomized study of 30 subjects entitled "A study to evaluate the effectiveness of and to determine the common short-term side effects associated with the drug 'PainStop' for the treatment of subjects with chronic arthritis" is an example of a:

- A. Phase III
- B. Phase II
- C. Phase IV
- D. Phase I

Answer: B

Explanation:
Phase classification is based on study objectives, not just subject numbers.
* Phase I:Focuses on safety, pharmacokinetics, dose-ranging, usually in healthy volunteers or small patient groups.
* Phase II:Evaluateseffectiveness in patients with the conditionand monitors common short-term side effects.
* Phase III:Confirms effectiveness in larger populations, compares to standard therapy, gathers more safety data.
* Phase IV:Post-marketing studies exploring new indications, long-term safety, or special populations.
The given study aims toevaluate effectiveness and common short-term side effectsin 30 arthritis patients, which clearly aligns withPhase IIobjectives. It is not exploratory safety (Phase I), not confirmatory comparative (Phase III), nor post-marketing (Phase IV).
Thus, the correct answer isB (Phase II).
References:
FDA Guidance: The IND Application - §312.21 (Phases of an investigation).
ICH E8(R1), General Considerations for Clinical Studies.

NEW QUESTION # 56
Which of the following is one of the responsibilities of an investigator who is NOT a sponsor?

- A. Reporting serious adverse events to the applicable regulatory agency
- B. Ensuring that all participating investigators are promptly informed of significant new adverse events
- C. Maintaining control of the investigational product
- D. Ensuring proper monitoring of an investigation at all investigational sites

Answer: C

Explanation:
For non-sponsor investigators, responsibilities are limited tosite-level conduct and product accountability.
* ICH E6(R2) 4.6.1:"Responsibility for investigational product(s) accountability at the trial site rests with the investigator/institution."
* 21 CFR 312.61:Requires the investigator to administer investigational drugs only to subjects under their supervision and maintain control.
Other responsibilities listed belong tosponsors:
* A: Reporting SAEs to FDA is a sponsor duty (investigators report to sponsor, not directly to FDA).
* B: Monitoring at all sites is a sponsor responsibility.
* C: Disseminating safety updates is a sponsor's role.
Correct answer:D (Maintaining control of IP).
References:
ICH E6(R2), §4.6.1.
21 CFR 312.61.

NEW QUESTION # 57
In accordance with the CFR and the ICH GCP Guideline, which of the following is directly responsible for submitting protocols and amendments to the IRB/IEC for review?

- A. The sponsor
- B. The contract research organization
- C. The Food and Drug Administration
- D. The investigator

Answer: D

Explanation:
Theinvestigatorbears direct responsibility for ensuring IRB/IEC review and approval before initiating a study or implementing any amendments.
* 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, 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." While sponsors may provide protocol documents, the legal obligation to submit and maintain IRB/IEC approval rests with the investigator at each site. CROs act under sponsor delegation but cannot replace investigator accountability.
Thus, the correct answer isB (The investigator).
References:
ICH E6(R2), §4.4.1 (Investigator responsibilities).
21 CFR 312.66 (Investigator assurance of IRB oversight).

NEW QUESTION # 58
A sponsor received a report from an investigator regarding the investigator's use of an investigational device without having obtained informed consent. The sponsor must submit a copy of the report to the FDA within:

- A. 5 working days
- B. 1 day
- C. 30 working days
- D. 10 working days

Answer: A

Explanation:
Informed consent is a fundamental ethical requirement. If it is violated in a device trial, the FDA requires rapid reporting.
* 21 CFR 812.150(b)(5):States that a sponsor shall submit to FDA "any report of use of a device without obtaining informed consent, within5 working daysafter the sponsor first receives notice of such use."
* This expedited reporting ensures FDA oversight of serious violations and protection of human subjects.
Incorrect options:

* A (1 day) is overly strict and not codified.
* C (10 days) and D (30 days) are too delayed to meet regulatory intent of immediate oversight.
Thus, the correct timeline iswithin 5 working days.
References:
21 CFR 812.150(b)(5).

NEW QUESTION # 59
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