Certified Clinical Research Professional (CCRP) Exam Questions Can Help You Gain Massive Knowledge of CCRP Certification

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• 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.
Topic 2	• 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.

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your practice, which are interlinked and helpful for your exam. Unlike those untenable practice materials in the market, our CCRP practice materials are highly utilitarian for their accuracy of the real exam because all content are compiled by proficient experts who engaged in this area more than ten years. It is our unswerving will to help you pass the exam by CCRP study tool smoothly.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q16-Q21):

NEW QUESTION # 16
The sponsor discontinued the clinical development of an investigational product. In accordance with the ICH GCP Guidance, at least how long should the sponsor maintain all sponsor-specific essential documents?

- A. 3 years
- B. 15 years
- C. 5 years
- D. 2 years

Answer: D

Explanation:
Retention of essential documents ensures accountability and inspection readiness.
* ICH E6(R2) 5.5.12 & 8.1:Sponsors should retain essential documents "until at least2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applicationsor at least 2 years after formal discontinuation of clinical development of the investigational product." This standard balances subject protection with practical recordkeeping. Longer durations (B-D) may apply under institutional or national rules, but ICH establishes2 years minimum.
Correct answer:A (2 years).
References:
ICH E6(R2), §5.5.12, §8.1.

NEW QUESTION # 17
A study coordinator is developing an informed consent form for the first time. As per the CFR and ICH GCP Guideline, which of the following elements must be included?

- A. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- B. A statement confirming that the subject has received a copy of the signed consent document
- C. A note that the qualified investigator could be financially compensated by the sponsor to conduct the clinical trial
- D. An explanation of the person to contact at the sponsor for further information regarding research subjects' rights

Answer: A

Explanation:
Theinformed consent processmust include all basic elements listed in federal regulations.
* 21 CFR 50.25(a)(4):Requires "a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject."
* ICH E6(R2) 4.8.10(c):Mirrors this, requiring subjects to be informed of alternatives to participation, including available standard treatments.
This ensures the ethical principle ofRespect for Persons(Belmont Report), giving subjects the autonomy to choose among reasonable medical options.
Incorrect options:
* A: Contact information must be provided, but it is for the investigator (or IRB), not sponsor.
* B: Financial disclosures may be required for IRB review, not subject-facing.
* C: Subjects do receive a copy, but it is not a required consentelementin regulations.
Correct answer:D.
References:
21 CFR 50.25(a)(4).
ICH E6(R2), §4.8.10(c).

NEW QUESTION # 18

According to ICH GCP, an electronic data capture (EDC) system must:

- A. Limit remote access
- B. Limit file sharing
- C. Allow access across multiple platforms
- D. Allow for data changes and store audit trails

Answer: D

Explanation:
* ICH E6(R2) 5.5.3(g):Requires audit trails for any data changes, recording date, time, and person responsible.This ensures traceability and regulatory compliance.
Other restrictions (B-D) are not mandated under ICH.
References:ICH E6(R2), §5.5.3(g).

NEW QUESTION # 19
In accordance with the ICH GCP Guideline, who is responsible for ensuring that all study site personnel working on a clinical trial are qualified to conduct the trial?

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

Answer: C

Explanation:
The investigator has ultimate responsibility for site staff qualifications.
* ICH E6(R2) 4.2.4:"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product, and their trial-related duties and functions."
* ICH E6(R2) 4.1.5:Investigator must maintain current documentation of staff qualifications.
While sponsors and monitors oversee compliance, accountability rests with theclinical investigator.
Coordinators may implement duties, but do not hold legal responsibility.
Correct answer:B (The clinical investigator).
References:
ICH E6(R2), §4.2.4.
ICH E6(R2), §4.1.5.

NEW QUESTION # 20
A study coordinator is preparing an IRB submission for a Phase II oncology study. Which document must be included?

- A. Record storage plan
- B. Recruitment materials
- C. List of potential subjects
- D. Case report forms

Answer: B

Explanation:
* ICH E6(R2) 3.1.2 & FDA Recruitment Guidance (1998):Recruitment materials must be reviewed by IRB to ensure no coercion or misleading claims.
* CRFs and storage plans are sponsor/site tools, not IRB-reviewed documents.
References:ICH E6(R2) §3.1.2; FDA Recruitment Guidance, 1998.

NEW QUESTION # 21
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