Training CCRP Online, CCRP Study Plan

The language of our CCRP study materials is simple. The learners may come from many social positions and their abilities to master our CCRP study materials are varied. Based on this consideration we apply the most simple and easy-to-be-understood language to help the learners no matter he or she is the students or the in-service staff, the novice or the experienced employee which have worked for many years. CCRP Study Material use the simple language to explain the answers and detailed knowledge points and the concise words to show the complicated information about the CCRP study material.

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.

CCRP Study Plan - CCRP Exam Quiz

As we all know, office workers have very little time to prepare for examinations. It would be too painful to waste precious rest time on the subject. But if they have CCRP practice materials, things will become different. Our CCRP study materials not only include key core knowledge, but also allow you to use scattered time to learn, so that you can learn more easily and achieve a multiplier effect. And after you study with our CCRP Exam Questions for 20 to 30 hours, you will be able to pass the CCRP exam for sure.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q123-Q128):

NEW QUESTION # 123
An approved investigational device exemption (IDE) permits a device to be:

- A. Sold and marketed for profit
- 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. Marketed as a humanitarian device

Answer: B

Explanation:
AnInvestigational Device Exemption (IDE)allows an unapproved medical device to be used in aclinical 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 isA (Shipped lawfully for clinical study).
References:
21 CFR 812.1(a) (IDE exemption provisions).

NEW QUESTION # 124
Which countries have officially adopted ICH-GCP E6(R2) as a standard, in addition to U.S., EU, Japan, Canada, and Australia?

- A. China
- B. Brazil
- C. Switzerland
- D. India

Answer: D

Explanation:
India has aligned national regulations with ICH-GCP.
* DCGI/ICMR Guidelines (India):Explicitly adopt ICH E6(R2) as part of its Good Clinical Practice standards.China and Brazil are harmonizing, but full official adoption is noted in India.
References:Indian GCP Guidelines (2017 revision).

NEW QUESTION # 125
In a Phase III cardiovascular trial, who is responsible for ongoing clinical trial safety evaluation?

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

Answer: D

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 # 126
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. Sub-investigators
- B. Participants in long-term follow-up
- C. The IRB/IEC
- D. No notification is required

Answer: C

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 # 127
A physician wants to conduct research using an approved/marketed cardiac stent for use in the carotid artery, which is not an indication for which the device is approved. In this case, the physician must obtain which of the following?

- A. The Office for Human Research Protections (OHRP) and manufacturer approvals
- B. IRB/IEC and manufacturer approval
- C. IRB/IEC approval and an FDA IDE
- D. IRB/IEC approval and an FDA IND

Answer: C

Explanation:
When a physician investigates amedical device for a new use (off-label indication), FDA regulations classify this as aSignificant Risk Device Study, requiring anInvestigational Device Exemption (IDE)in addition to IRB approval.
* 21 CFR 812.20(a):"A sponsor shall submit an application to FDA for aninvestigational device exemption (IDE)if the device is to be used in a clinical investigation to determine safety and effectiveness."
* 21 CFR 812.2(b):Significant Risk device studies requireboth FDA and IRB approvalbefore initiation.
An IND (B) applies to drugs and biologics, not devices. Manufacturer permission (A, D) is not a regulatory requirement, although collaboration may be necessary. OHRP approval is not applicable.
Thus, the correct answer isC (IRB/IEC approval and an FDA IDE).
References:
21 CFR 812.20(a) (IDE submission requirements).
21 CFR 812.2(b) (Significant risk device studies).

NEW QUESTION # 128
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