

CCRP Zertifizierungsantworten & CCRP Lernhilfe



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SOCRA CCRP Prüfungsplan:

Thema	Einzelheiten
Thema 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.
Thema 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.

>> CCRP Zertifizierungsantworten <<

CCRP Lernhilfe, CCRP Übungsmaterialien

Nur kontinuierlich zu verbessern kann man immer an der führenden Stelle stehen. Und es ist auch unsere Firmenphilosophie. Deshalb prüfen wir regelmäßig nach, ob die SOCRA CCRP Prüfung aktualisiert hat. Wenn sie aktualisiert hat, informieren wir unsere Kunden sofort darüber. Dadurch lassen Sie die neueste Informationen über SOCRA CCRP Prüfung erfahren. Aller Kundendienst der Aktualisierung nach der Kauf der SOCRA CCRP Software ist kostenlos innerhalb einem Jahr.

SOCRA Certified Clinical Research Professional (CCRP) CCRP Prüfungsfragen mit Lösungen (Q38-Q43):

38. Frage

A subject on a multi-drug regimen could not tolerate a non-investigational drug. Can the investigational regimen continue?

- A. Yes, per protocol
- **B. Only after sponsor and IRB approval**
- C. Only for a short time, then change to placebo
- D. Only after medical monitor approval

Antwort: B

Begründung:

* ICH E6(R2) 4.5.1: Investigators must follow the protocol approved by the IRB/IEC.

* Any modification that is not pre-specified must be approved by sponsor and IRB before continuing.

Only deviations eliminating immediate hazard can be done without prior approval; in this case, continuation requires sponsor + IRB agreement.

References: ICH E6(R2) §4.5.1.

39. Frage

Which of the following entities, if any, must provide an approval before an investigator may enroll subjects in a quality-of-life research questionnaire study?

- **A. The IRB/IEC**
- B. The Department of Health and Human Services
- C. No approvals are necessary if no pharmaceutical drugs are involved
- D. The FDA or another regulatory authority

Antwort: A

Begründung:

Even if a study does not involve drugs, devices, or biologics, it still involves human subjects and therefore requires ethical review by an IRB/IEC.

* 45 CFR 46.109(a): "An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy."

* ICH E6(R2) 3.1.2: "The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects." Quality-of-life (QOL) studies may involve surveys, interviews, or questionnaires, but since they involve human participants, they are subject to human research protection regulations. FDA involvement is not required unless drugs or devices are tested. Similarly, HHS approval is not required unless the study is federally funded.

Thus, the correct answer is C (The IRB/IEC).

References:

45 CFR 46.109(a) (IRB review of research).

ICH E6(R2), §3.1.2 (IRB/IEC role in subject protection).

40. Frage

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

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

Antwort: B

Begründung:

* 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.

41. Frage

A sponsor is permitted to charge for an investigational drug but must provide what documentation?

- A. IRB attestation of institutional cost burden
- B. Orphan product evidence
- C. Evidence of potential clinical benefit and significant advantage
- D. CMS approval letter

Antwort: C

Begründung:

* 21 CFR 312.8(b): Sponsors may charge for investigational drugs only if they demonstrate that the drug provides potential clinical benefit and a significant advantage over existing therapy.

* FDA must approve charging requests.

References: 21 CFR 312.8(b).

42. Frage

Before approving a research protocol, an IRB/IEC must determine compliance with which of the following requirements?

- A. The investigator has adequate access to patients eligible for the trial
- B. The selection of subjects is equitable
- C. The sponsor is qualified to provide oversight of the trial
- D. A plan for the publication of study results is in place

Antwort: B

Begründung:

IRB/IEC review focuses on ethical protection of human subjects. Equitable subject selection is a cornerstone principle.

* 45 CFR 46.111(a)(3): "In order to approve research... the IRB shall determine that: Selection of subjects is equitable."

* ICH E6(R2) 3.1.2: "The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects... with particular attention to trials that may include vulnerable subjects." Publication plans (A) are not required by IRBs. Access to patients (C) and sponsor qualifications (D) are evaluated by sponsors, not IRBs. The IRB's role is ensuring fairness, minimizing coercion, and protecting vulnerable populations.

Thus, the correct answer is B (The selection of subjects is equitable).

References:

45 CFR 46.111(a)(3) (Equitable subject selection).

ICH E6(R2), §3.1.2 (IRB/IEC role).

43. Frage

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