

CCRP Prüfungsfrage & CCRP Fragen Antworten



Die Schulungsunterlagen zur SOCRA CCRP Zertifizierungsprüfung von ZertSoft sind unvergleichbar. Das hat nicht nur mit der Qualität zu tun. Am wichtigsten ist es, dass Die Schulungsunterlagen zur SOCRA CCRP Zertifizierungsprüfung von ZertSoft mit allen IT-Zertifizierungen im Einklang sind. So kümmern sich viele Kandidaten um uns. Sie glauben in uns und sind von uns abhängig. Das hat genau unsere Stärke reflektiert. Sie werden sicher Ihren Freuden nach dem Kauf unserer Produkte ZertSoft empfehlen. Denn es kann Ihnen wirklich sehr helfen.

SOCRA CCRP Prüfungsplan:

Thema	Einzelheiten
Thema 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.
Thema 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 Ressourcen Prüfung - CCRP Prüfungsguide & CCRP Beste Fragen

Unser ZertSoft verspricht, dass Sie die SOCRA CCRP Prüfung einmalig bestehen und das Zertifikat von den Experten bekommen können. Denn unser ZertSoft stellt Ihnen die besten Prüfungsfragen und Antworten zur SOCRA CCRP zur Verfügung. Und Sie können sich schrittweise auf die Prüfung gut vorbereiten. Unser ZertSoft verspricht, dass die Fragen und Antworten zur SOCRA CCRP Zertifizierungsprüfung von ZertSoft Ihren Erfolg garantiert.

SOCRA Certified Clinical Research Professional (CCRP) CCRP Prüfungsfragen mit Lösungen (Q94-Q99):

94. Frage

During an audit for a Phase II IND study, the auditor identified unreported serious protocol deviations. Which party must take prompt action to ensure compliance?

- A. The IRB/IEC chair
- B. The CRO
- C. The investigator
- **D. The sponsor**

Antwort: D

Begründung:

The sponsor holds ultimate responsibility for trial oversight and compliance.

* ICH E6(R2) 5.20.1: If noncompliance is discovered, the sponsor must "take prompt action to secure compliance" and, if necessary, terminate participation of the investigator/institution.

* 21 CFR 312.56(b): Sponsors must ensure proper conduct and report investigators who fail to comply to the FDA and IRB.

While investigators commit to protocol adherence, once deviations are identified, the sponsor must act to safeguard subjects and trial validity.

References: ICH E6(R2) §5.20.1; 21 CFR 312.56(b).

95. Frage

The sponsor withdrew an IND due to safety. Who must be notified promptly, in addition to FDA?

- **A. Reviewing IRBs/IECs**
- B. Site coordinator
- C. Investigational pharmacies
- D. OHRP

Antwort: A

Begründung:

* 21 CFR 312.56(d): If an IND is withdrawn for safety, the sponsor must notify FDA and all participating investigators, who in turn notify IRBs.

* Ensures subjects are protected and sites stop enrollment.

References: 21 CFR 312.56(d).

96. Frage

Which of the following is one of the responsibilities of an investigator?

- **A. Maintaining accurate and current case histories of study subjects**
- B. Selecting qualified monitors on the basis of training, experience, and expertise
- C. Participating in the IRB/IEC voting process for approval of their protocol
- D. Updating the investigator brochure with new safety information

Antwort: A

Begründung:

Investigators are required to maintain accurate subject records, often referred to as case histories.

* 21 CFR 312.62(b): "An investigator shall prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation."

* ICH E6(R2) 4.9.0: Reinforces that investigators are responsible for recording, handling, and storing clinical trial data.

Incorrect options:

* B: Investigators may present protocols but cannot vote on IRB approval.

* C: Sponsor responsibility (ICH E6 §5.18).

* D: Sponsors are responsible for IB updates (ICH E6 §7.3.1).

Correct answer: A.

References:

21 CFR 312.62(b).

ICH E6(R2), §4.9.0.

97. Frage

A clinical investigator received an honorarium from the sponsor of a covered study. At what payment value must this be reported?

- **A. \$10,000**
- B. Any amount
- C. \$5,000
- D. >\$25,000

Antwort: A

Begründung:

* 21 CFR 54.2(f) & 54.4(a): Requires disclosure of "significant payments of other sorts" (SPOOS) that exceed \$25,000 or equity interests exceeding \$50,000.

* However, honoraria or consulting exceeding \$10,000 annually also trigger disclosure.

Thus, the reporting threshold is \$10,000.

References: 21 CFR 54.2(f), 54.4(a).

98. Frage

According to the ICH GCP Guidelines, what is the purpose of source documents?

- A. To validate reports submitted to the IRB/IEC
- **B. To provide a record of subjects' investigational medical treatment**
- C. To establish diverse subject enrollment
- D. To validate insurance reimbursement

Antwort: B

Begründung:

* ICH E6(R2) 1.52: Source documents are "original documents, data, and records... necessary for the reconstruction and evaluation of the trial."

* Their main role is to document treatment and verify CRFs.

References: ICH E6(R2), §1.52.

99. Frage

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IT-Zertifizierungsprüfungen haben hohe Konjunktur in heutiger Gesellschaft, besonders in IT-Industrie. Die IT-Zertifizierung ist auch international anerkannt. Die IT-Zertifizierungsprüfungen sind Ihre beste Chance, wenn Sie beförderten Arbeitsplatz und höheres Gehalt oder nur Ihre Arbeitsfähigkeit erhöhen wollen. Und SOCRA CCRP ist jetzt sehr populär. Wollen Sie daran teilnehmen? Falls Sie nicht wissen, wie Sie sich auf CCRP Prüfung vorzubereiten, bietet ZertSoft Ihnen die Weise. Sie können alle nützlichen Prüfungsmaterialien zur SOCRA CCRP Zertifizierungsprüfung auf ZertSoft.de finden.

CCRP Fragen Antworten: <https://www.zertsoft.com/CCRP-pruefungsfragen.html>

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