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SOCRA CCRP Prüfungsplan:

Thema	Einzelheiten
Thema 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.
Thema 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.

>> CCRP Antworten <<

CCRP echter Test & CCRP sicherlich-zu-bestehen & CCRP Testguide

Die echten und originalen Prüfungsfragen und Antworten zu CCRP Zertifizierung (Certified Clinical Research Professional (CCRP)) bei ZertSoft wurden verfasst von unseren IT-Experten mit den Informationen von CCRP Prüfungen (Certified Clinical Research Professional (CCRP)) aus dem Testcenter wie PROMETRIC oder VUE.

SOCRA Certified Clinical Research Professional (CCRP) CCRP Prüfungsfragen mit Lösungen (Q130-Q135):

130. Frage
The study coordinator for a new Phase III vaccine study is preparing documents for IRB/IEC submission.
According to the ICH GCP Guidelines, which of the following documents should be included in the submission?

- A. The investigators' CVs
- B. Local lab normal ranges
- C. Recruitment materials
- D. Case report forms

Antwort: C

Begründung:
IRBs/IECs are responsible for ensuring that subject recruitment is ethical and not coercive.
* ICH E6(R2) 3.1.2:The IRB/IEC safeguards subjects by reviewing recruitment procedures and materials.
* 21 CFR 56.111(a)(3):Requires equitable subject selection, which extends to advertisements and recruitment.
* FDA Guidance on Recruiting Study Subjects (1998):States that "advertisements and recruitment materials must be reviewed and approved by the IRB prior to use." While CVs (D) and lab ranges (A) are essential documents for study feasibility and quality, they are not mandatory for IRB approval package. CRFs (B) are sponsor tools for data collection, not subject-facing, and thus not reviewed by IRBs.
Correct answer:C (Recruitment materials).
References:
ICH E6(R2), §3.1.2.
FDA Recruitment Guidance, 1998.

131. Frage
A research protocol requires patients to complete a patient reported outcome questionnaire in the sponsor's electronic data capture (EDC) system. What is the source data?

- A. A printout of the EDC record
- B. The electronic medical record
- C. The EDC record
- D. A printout of the electronic medical record

Antwort: C

Begründung:
Source data areoriginal records where data are first recorded.
* ICH E6(R2) 1.51:Defines source data as "all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial." Since subjects directly enter responses into the EDC, theEDC record itself is the original source document.
EMRs (B, C) and printouts (D) are secondary records.
Correct answer:A (The EDC record).
References:
ICH E6(R2), §1.51 (Definition of source data).

132. Frage
In accordance with 21 CFR Part 11, in order for an electronic record to be equivalent to a paper record the electronic record must be:

- A. Managed within a validated computer system
- B. Entered into an electronic case report form

- C. Restricted to authorized clinical trial personnel
- D. Printed, signed, and dated

Antwort: A

Begründung:
21 CFR Part 11governs the use of electronic records and electronic signatures in FDA-regulated research.
* 21 CFR 11.10(a):Requires "validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records."
* Validated systems ensure equivalency between electronic and paper records.
While access controls (D) are also mandated, they arepart of system validation, not the defining requirement. Printing/signing paper copies (A) is unnecessary under Part 11. Entry into an eCRF (C) is just one function, not sufficient for compliance.
Thus, the correct answer isB (Managed within a validated computer system).
References:
21 CFR 11.10(a) (System validation requirement).

133. Frage
A clinical investigator is developing the assent procedure for the enrollment of children into a new pediatric clinical trial. The ages of the children are described in the IRB/IEC submission. A description of which of the following must also be included in the submission?

- A. The pediatrician (primary care provider notification process)
- B. The psychological status of the children
- C. The physiological status of the children
- D. The economic status of the children

Antwort: B

Begründung:
Children are avulnerable populationrequiring additional protections.
* 45 CFR 46.408(a):Requires "adequate provisions for soliciting the assent of the children, when in the judgment of the IRB, the children are capable of providing assent."
* 45 CFR 46.402:Defines "assent" as a child's affirmative agreement to participate.
* IRBs must consider theage, maturity, and psychological stateof the children when determining assent capability.
Economic status (B) is irrelevant to assent. Physiological status (C) pertains to eligibility, not assent. Provider notification (D) may be local practice but not required by regulation.
Correct answer:A (Psychological status).
References:
45 CFR 46.402-408.

134. Frage
In order to meet recruitment goals, a sponsor is adding a new site to a multi-center study. Which of the following documents should the sponsor obtain from a new site prior to starting research at the site?

- A. The delegation of duties log
- B. The site's SOPs
- C. The site's accreditation certificate
- D. The IRB/IEC trial approval documentation

Antwort: D

Begründung:
* 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."
* Sponsors must confirm IRB approval before authorizing initiation.
References:ICH E6(R2), §4.4.1.

135. Frage

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