CCRP최신버전공부문제, CCRP적중율높은덤프

그리고 Itcertkr CCRP 시험 문제집의 전체 버전을 클라우드 저장소에서 다운로드할 수 있습니다: https://drive.google.com/open?id=18EusFpQOpo9O46xpYsw8NvyS0xG1QKmi

SOCRA인증 CCRP시험을 어떻게 공부하면 패스할수 있을지 고민중이시면 근심걱정 버리시고Itcertkr 의 SOCRA인증 CCRP덤프로 가보세요. 문항수가 적고 적중율이 높은 세련된SOCRA인증 CCRP시험준비 공부자료는Itcertkr제품이 최고입니다.

SOCRA CCRP 시험요강:

주제	소개

주제 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.
주제 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.

최신 Clinical Research Professional CCRP 무료샘플문제 (Q73-Q78):

질문 # 73
In accordance with the CFR, the sponsor (who is not a sponsor-investigator) is responsible for which of the following?

- A. Submitting progress reports to the reviewing IRB/IEC
- B. Overseeing the administration of the investigational drug to the subjects
- C. Ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug
- D. Maintaining case histories that record all observations and other data pertinent to the investigation

정답：C

설명：
Sponsors are responsible for distributing safety updates across all investigators and the FDA.
* 21 CFR 312.55(b):"The sponsor shall promptly notify all participating investigators, and the FDA, of new significant adverse effects or risks with respect to the drug." Other responsibilities fall elsewhere:
* Case histories (C) are maintained by investigators (21 CFR 312.62(b)).
* Progress reports to IRBs (D) are the investigator's duty (21 CFR 312.66).
* Administration of investigational drug (A) is managed by the investigator at site level.
Thus, the correct answer isB (Ensuring FDA and investigators are promptly informed).
References:
21 CFR 312.55(b) (Sponsor notification requirements).

질문 # 74
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 IRB/IEC trial approval documentation
- B. The site's accreditation certificate
- C. The delegation of duties log
- D. The site's SOPs

정답：A

설명：
* 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.

질문 # 75
A revised protocol added genomic testing to banked tissue samples. Before shipping samples, what must the site do?

- A. Obtain IRB/IEC approval for revised protocol and ICF
- B. Notify enrolled subjects
- C. Execute material transfer agreement
- D. Ship under dangerous goods requirements

정답：A

설명：
* 21 CFR 56.109(a):IRB must review and approve any protocol amendments before implementation.
* ICH E6(R2) 4.5.2:Changes affecting subjects (e.g., genomic testing) require IRB/IEC approval and updated consent.
Thus, site must first obtainIRB approval for revised protocol and ICF.
References:21 CFR 56.109(a); ICH E6(R2) §4.5.2.

질문 # 76
Sponsor must maintain drug disposition records for how long after marketing approval?

- A. 2 years
- B. 1 year
- C. 3 years
- D. 5 years

정답：A

설명：
* 21 CFR 312.57(c):"Sponsors shall retain records for2 years after a marketing application is approvedor if not approved, 2 years after shipment and delivery of investigational drug for investigation." References:21 CFR 312.57(c).

질문 # 77
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 investigator
- B. The clinical research coordinator
- C. The study monitor
- D. The sponsor

정답：A

설명：
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.

질문 # 78
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