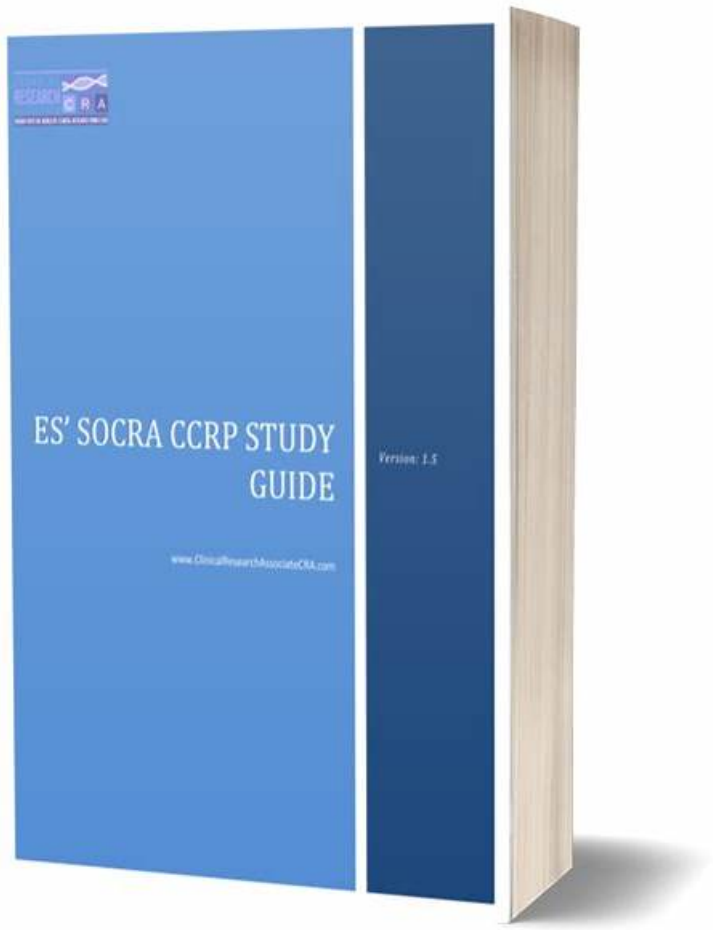
SOCRA CCRP최고기출문제 - CCRP최신업데이트버전 인증시험자료



BONUS!!! KoreaDumps CCRP 시험 문제집 전체 버전을 무료로 다운로드하세요: https://drive.google.com/open?id=1UFvRtJ7syP-pIpeRAZ90x2gjenLAoQ29

IT자격증을 많이 취득하여 IT업계에서 자신만의 단단한 자리를 보장하는것이 여러분들의 로망이 아닐가 싶습니다. KoreaDumps의 완벽한 SOCRA인증 CCRP덤프는 IT전문가들이 자신만의 노하우와 경험으로 실제SOCRA인증 CCRP시험문제에 대비하여 연구제작한 완벽한 작품으로서 100%시험통과율을 보장합니다.

인재가 넘치는 IT업계에서 자기의 자리를 지켜나가려면 학력보다 능력이 더욱 중요합니다.고객님의 능력을 증명해주는 수단은 국제적으로 승인받은 IT인증자격증이 아니겠습니까? SOCRA인증 CCRP시험이 어렵다고 하여 두려워 하지 마세요. IT자격증을 취득하려는 분들의 곁에는KoreaDumps가 있습니다. KoreaDumps의SOCRA인증 CCRP 시험준비를 하시고 시험패스하여 자격증을 취득하세요. 국제승인 자격증이라 고객님의 경쟁율을 업그레이드 시켜드립니다.

>> SOCRA CCRP최고기출문제 <<

CCRP최신 업데이트버전 인증시험자료, CCRP완벽한 덤프공부자료

여러분은 먼저 우리 KoreaDumps사이트에서 제공되는SOCRA인증CCRP시험덤프의 일부분인 데모를 다운받으셔서 체험해보세요. KoreaDumps는 여러분이 한번에SOCRA인증CCRP시험을 패스하도록 하겠습니다. 만약SOCRA인증CCRP시험에서 떨어지셨다고 하면 우리는 덤프비용전액 환불입니다.

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 (Q35-Q40):

질문 # 35
According to the ICH/GCP Guideline, which of the following should a sponsor provide to the clinical investigator before entering into a clinical trial agreement?

- A. Adequate resources
- B. The protocol
- C. Proper equipment
- D. Staff training

정답： B

설명：
Before an investigator can commit to conducting a trial, they must review thestudy protocol.
* ICH E6(R2) 4.5.1:The investigator should conduct the trial in compliance with theprotocol approved by the IRB/IEC and sponsor.
* ICH E6(R2) 4.2.3:The investigator should be thoroughly familiar with the appropriate use of the investigational product as described in the investigator's brochure and the current approved protocol.
Although resources, training, and equipment are important, the fundamental step is provision of theprotocol, which forms the legal and ethical framework for study conduct. No trial agreement can be finalized until both parties agree on theprotocol details.
References:ICH E6(R2), §§4.2.3, 4.5.1.

질문 # 36
In accordance with the CFR, which body must determine that a study meets the criteria for minimal risk?

- A. The medical monitor
- B. A data safety monitoring board
- C. The clinical investigator
- D. The reviewing IRB/IEC

정답： D

설명：
Minimal risk determination is a regulatory function of the IRB/IEC.

* 45 CFR 46.102(j):Defines minimal risk as harm or discomfort not greater than those ordinarily encountered in daily life.
* 45 CFR 46.109(a):The IRB has authority to approve, require modifications, or disapprove research, including assessment ofrisk level.
* Investigators may propose a study as minimal risk, but only theIRB/IEC can formally classify it.
This ensures independent, unbiased evaluation of risk, protecting participants from investigator or sponsor bias.
References:45 CFR 46.102(j), 46.109(a).

질문 # 37
In accordance with the CFR and the ICH GCP Guideline, which of the following is directly responsible for submitting protocols and amendments to the IRB/IEC for review?

- A. The investigator
- B. The sponsor
- C. The contract research organization
- D. The Food and Drug Administration

정답： A

설명：
Theinvestigatorbears direct responsibility for ensuring IRB/IEC review and approval before initiating a study or implementing any amendments.
* 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 for the trial protocol, written informed consent form, and any other written information to be provided to subjects."
* 21 CFR 312.66:"An investigator shall assure that an IRB that complies with the requirements... will be responsible for the initial and continuing review and approval of the proposed clinical study." While sponsors may provide protocol documents, the legal obligation to submit and maintain IRB/IEC approval rests with the investigator at each site. CROs act under sponsor delegation but cannot replace investigator accountability.
Thus, the correct answer isB (The investigator).
References:
ICH E6(R2), §4.4.1 (Investigator responsibilities).
21 CFR 312.66 (Investigator assurance of IRB oversight).

질문 # 38
A subject enrolled in a drug clinical trial has withdrawn from the study. In accordance with ICH GCP, which of the following documents should be consulted to determine whether the participant should be replaced?

- A. The protocol
- B. The data safety monitoring plan
- C. The Investigator's Brochure
- D. The informed consent document

정답： A

설명：
Theprotocolgoverns all trial conduct, including whether subjects should be replaced when they withdraw.
* ICH E6(R2) 6.0:The protocol must contain "detailed information on trial design, methodology, statistical considerations, and the organization of the trial."
* ICH E6(R2) 6.9.2:The section on "Subject withdrawal or discontinuation" specifies "whether and under what conditions subjects may be replaced." Other documents serve different functions: the DSM plan (A) manages safety oversight, the IB (C) summarizes product background, and the consent form (D) explains subject rights but does not guide study conduct. Only theprotocolprovides the operational answer regarding replacement.
Thus, the correct answer isB (The protocol).
References:
ICH E6(R2), §6.0 (Protocol content).
ICH E6(R2), §6.9.2 (Subject withdrawal/discontinuation).

질문 # 39
A pharmaceutical company is developing a biologic study. In accordance with ICH, which of the following items should be included in an investigator's brochure (IB)?

- A. Lab draw requirements
- B. Dispensing instructions
- C. Schedule of events
- D. Results of recent nude mouse study

정답：D

설명：
TheInvestigator's Brochure (IB)compilesclinical and nonclinical dataon an investigational product relevant to human study.
* ICH E6(R2) 7.2.3:The IB should summarizenonclinical pharmacology, toxicology, pharmacokinetics, and efficacy data, including results of animal studies.
* ICH E6(R2) 7.2.4:It should also includeavailable clinical trial dataand safety experience.
The "results of recent nude mouse study" (B) are nonclinical data, which appropriately belong in the IB. Lab draw requirements (A), dispensing instructions (C), and schedules of events (D) are operational/procedural and are found in theprotocol, not the IB.
Thus, the correct answer isB (Results of recent nude mouse study).
References:
ICH E6(R2), §7.2.3-7.2.4 (Contents of Investigator's Brochure).

질문 # 40
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