시험패스에유효한CCRP덤프최신버전인증시험기출자료

참고: Pass4Test에서 Google Drive로 공유하는 무료, 최신 CCRP 시험 문제집이 있습니다: https://drive.google.com/open?id=121N8a4Qzddn0yQOKWnyAsMi_5XPKgBHs

Pass4Test에서 출시한 SOCRA인증 CCRP덤프는 실제시험문제 커버율이 높아 시험패스율이 가장 높습니다. SOCRA인증 CCRP시험을 통과하여 자격증을 취득하면 여러방면에서 도움이 됩니다. Pass4Test에서 출시한 SOCRA인증 CCRP덤프를 구매하여SOCRA인증 CCRP시험을 완벽하게 준비하지 않으실래요? Pass4Test의 실력을 증명해드릴게요.

SOCRA CCRP 시험요강:

주제	소개
주제 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.

주제 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.

최신 Clinical Research Professional CCRP 무료샘플문제 (Q16-Q21):

질문 # 16
For a study with a significant risk investigational medical device that could optimize the effects of radiation therapy on cancer tumors, the investigational plan states mild burns are an anticipated effect. One subject developed severe burns with blistering. In accordance with the CFR, this effect must be reported to the sponsor and the IRB/IEC as soon as possible and at most how long after the investigator first learns of the effect?

- A. 5 working days
- B. 10 working days
- C. 7 working days
- D. 2 working days

정답：B

설명：
In device trials,unanticipated adverse device effects (UADEs)must be promptly reported.
* 21 CFR 812.150(a)(1):"An investigator shall submit to the sponsor and the reviewing IRB a report of anyunanticipated adverse device effectas soon as possible, but in no event later than10 working days after the investigator first learns of the effect." In this case,severe burns with blisteringgo beyond the anticipated effect of mild burns listed in the investigational plan. Therefore, it qualifies as aUADEand triggers expedited reporting. Options A, B, and C are too short; the regulation specifically mandates a10 working day maximumtimeframe.
Thus, the correct answer isD (10 working days).
References:
21 CFR 812.150(a)(1) (Reporting requirements for investigators).

질문 # 17
Which of the following adverse events occurring during a study of an investigational new drug would require the sponsor to notify the FDA as soon as possible but in no case later than seven calendar days after the initial receipt of the information?

- A. Aplastic anemia requiring hospitalization, mentioned in the investigator's brochure

- B. Death due to disease progression, mentioned in the investigator's brochure
- C. An infection not related to the investigational drug requiring hospitalization for antibiotic therapy
- D. Death as a result of arrhythmias (irregular heart rhythm), not mentioned in the investigator's brochure and thought to be related to the use of the drug

정답：D

설명：
Sponsors must reportserious, unexpected, and suspected adverse reactions (SUSARs)to the FDA.
* 21 CFR 312.32(c)(2):"Any adverse experience associated with the use of the drug that is bothserious and unexpectedshall be reported...as soon as possible but no later than 7 calendar daysafter the sponsor's initial receipt of the information, if it is fatal or life-threatening."
* ICH E2A 4.2:Requires expedited reporting oflife-threatening or fatal SUSARswithin 7 days.
Among the options, only (C) -death from arrhythmias not previously identified in the Investigator's Brochure and suspected to be drug-related- meets the definition of a SUSAR requiring7-day expedited reporting. Events already listed in the IB (A, D) or unrelated to the drug (B) do not trigger expedited reporting.
Thus, the correct answer isC.
References:
21 CFR 312.32(c)(2) (Expedited safety reporting).
ICH E2A, §4.2 (Expedited reporting of fatal/life-threatening adverse events).

질문 # 18
An unconscious patient experiencing life-threatening cardiac arrhythmias has been admitted to an emergency room. No FDA-approved treatment is available, and no legal representative is present. The clinical investigator determined that the use of an investigational antiarrhythmic drug is required. In accordance with the CFR, who must certify the investigator's determination?

- A. The sponsor's medical monitor
- B. A sub-investigator
- C. An independent physician
- D. The sponsor's study monitor

정답：C

설명：
This scenario falls underemergency use of investigational drugs without informed consent.
* 21 CFR 50.23(a):Allows waiver of informed consent if subject faces a life-threatening condition, available treatments are unproven, and immediate use is required.
* 21 CFR 50.23(a)(3):Requires that "the determination... be reviewed and concurred with by a physician who is not otherwise participating in the clinical investigation." Thus, anindependent physician(not part of the trial team) must certify the necessity of emergency investigational use.
Sponsors and monitors (C, D) are not authorized by regulation to make such determinations. Sub-investigators (A) lack independence and would be conflicted.
Correct answer:B (Independent physician).
References:
21 CFR 50.23(a)(3).

질문 # 19
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 site's SOPs
- B. The site's accreditation certificate
- C. The delegation of duties log
- D. The IRB/IEC trial approval documentation

정답：D

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 # 20
The sponsor discontinued the clinical development of an investigational product. In accordance with the ICH GCP Guidance, at least how long should the sponsor maintain all sponsor-specific essential documents?

- A. 3 years
- B. 2 years
- C. 15 years
- D. 5 years

정답：B

설명：
Retention of essential documents ensures accountability and inspection readiness.
* ICH E6(R2) 5.5.12 & 8.1:Sponsors should retain essential documents "until at least2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applicationsor at least 2 years after formal discontinuation of clinical development of the investigational product." This standard balances subject protection with practical recordkeeping. Longer durations (B-D) may apply under institutional or national rules, but ICH establishes2 years minimum.
Correct answer:A (2 years).
References:
ICH E6(R2), §5.5.12, §8.1.

질문 # 21
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- www.stes.tyc.edu.tw, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, ncon.edu.sa, jptsexams1.com, www.stes.tyc.edu.tw, www.stes.tyc.edu.tw, myportal.utt.edu.tt, courses.beinspired.co.za, Disposable vapes

참고: Pass4Test에서 Google Drive로 공유하는 무료, 최신 CCRP 시험 문제집이 있습니다: https://drive.google.com/open?id=121N8a4Qzddn0yQOKWnyAsMi_5XPKgBHs