CCRP參考資料 & CCRP最新題庫

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NewDumps提供的SOCRA CCRP 認證考試測試練習題和真實的考試題目很相似。如果你選擇了NewDumps提供的測試練習題和答案，我們會給你提供一年的免費線上更新服務。NewDumps可以100%保證你通過考試，如果你的考試未通過，我們將全額退款給你。

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>> CCRP參考資料 <<

CCRP參考資料 |高通過率| 100％通過Certified Clinical Research Professional (CCRP)考試

當前 SOCRA 作爲企業資訊解決方案的重要性及緊要性與日俱增，相關的工作機會將會越來越多，對技術能力的要求也越來越被企業作爲面試的一個標準，所以不管在哪個行業，SOCRA 工作者都必須不斷自我學習、接受訓練課程或是參加各式的專業認證來充實自己，使自己在工作上可以更加得心應手。而通過了SOCRA CCRP 認證考試，證明你的IT專業知識很強，有很強的能力，可以勝任一份很好的工作。

SOCRA CCRP 考試大綱：

主題	簡介
主題 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.

主題 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.

最新的 Clinical Research Professional CCRP 免費考試真題 (Q73-Q78):

問題 #73
After the sponsor's auditor completes the final audit report for a Phase II trial with an investigational new drug, which of the following is responsible for providing the audit certificate to the clinical site?

- A. The Data Safety Monitoring Board
- B. The IRB/IEC
- C. The sponsor
- D. The regulatory authority

答案：C

解題說明：
Audits are part of sponsor quality assurance to ensure trial compliance.
* ICH E6(R2) 5.19.3:"The sponsor's auditing procedures should include the provision of anaudit certificatewhere required."
* ICH E6(R2) 8.2.20:Audit certificates are essential documents generated and retained by the sponsor.
IRBs (A), regulators (B), and DSMBs (C) are not responsible for audit documentation. Therefore, only the sponsorissues and maintains audit certificates, providing them to sites when appropriate.
Correct answer:D.
References:
ICH E6(R2), §5.19.3.
ICH E6(R2), §8.2.20.

問題 #74
In accordance with the CFR, a sponsor must submit a protocol amendment to the FDA for which of the following?

- A. The addition of a new test that is intended to improve monitoring the subject for an adverse effect
- B. The addition of a sub-investigator with the scientific training and expertise to conduct the investigation
- C. A change in the manufacturing site for the investigational product
- D. A significant change in an investigator's financial interest in the investigational product

答案：C

解題說明：
The U.S. Code of Federal Regulations (CFR) specifies when sponsors must notify FDA of changes to investigational drug studies under 21 CFR 312.30. A protocol amendment is required if there is:
A change to the protocol (e.g., objectives, design, subject population, dosing, or procedures).
The addition of a new investigator.
A change in the chemistry, manufacturing, or controls (CMC) that could significantly affect product quality or safety.
Among the listed options, a change in the manufacturing site (D) directly falls under significant manufacturing changes, requiring FDA submission. Changes in investigator financial interests (B) are covered under 21 CFR 54 and reported separately, not as protocol

amendments. Addition of a sub-investigator (C) does not require a formal amendment, only site-level documentation and delegation log update. Addition of a monitoring test (A) may affect the protocol, but not necessarily mandate an amendment unless it changes objectives or subject safety endpoints.
Therefore, the correct answer is D. This ensures FDA oversight of product safety, efficacy, and compliance with CMC standards before investigational use.
References:
21 CFR 312.30 (Protocol amendments).
21 CFR 312.23(a)(7) (Chemistry, manufacturing, and controls information).

問題 #75
The sponsor of a multi-institutional clinical trial provided a site with information regarding a newly identified unanticipated adverse event attributed to study drug administration. The site's investigator has a subject actively receiving this study drug. Which of the following is the site investigator's responsibility to the subject?

- A. To discontinue the subject's study drug
- B. To provide the subject with information regarding the significant new findings
- C. To submit this safety update to the regulatory authority
- D. To give the subject's contact information to the sponsor in order to allow the sponsor to contact the subject

答案：B

解題說明：
Investigators are obligated to inform subjects ofnew informationthat may affect their willingness to continue.
* ICH E6(R2) 4.8.2:"If new information becomes available that may be relevant to a subject's willingness to continue participation, the informed consent document should be revised, and the subject should be informed in a timely manner."
* 21 CFR 50.25(b)(5):Consent must include a statement that "significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided." Thus, the investigator mustcommunicate new risk information to the subject.
Discontinuation (A) may not be warranted unless medically indicated. Reporting to FDA (B) is the sponsor's role. Sharing subject contact with sponsor (D) would violate confidentiality.
Correct answer:C.
References:
ICH E6(R2), §4.8.2.
21 CFR 50.25(b)(5).

問題 #76
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

答案：B

解題說明：
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.

問題 #77
A nonrandomized study of 30 subjects entitled "A study to evaluate the effectiveness of and to determine the common short-term side effects associated with the drug 'PainStop' for the treatment of subjects with chronic arthritis" is an example of a:

- A. Phase I
- B. Phase III
- C. Phase IV
- D. Phase II

答案：D

解題說明：
Phase classification is based on study objectives, not just subject numbers.
* Phase I:Focuses on safety, pharmacokinetics, dose-ranging, usually in healthy volunteers or small patient groups.
* Phase II:Evaluateseffectiveness in patients with the conditionand monitors common short-term side effects.
* Phase III:Confirms effectiveness in larger populations, compares to standard therapy, gathers more safety data.
* Phase IV:Post-marketing studies exploring new indications, long-term safety, or special populations.
The given study aims toevaluate effectiveness and common short-term side effectsin 30 arthritis patients, which clearly aligns withPhase IIobjectives. It is not exploratory safety (Phase I), not confirmatory comparative (Phase III), nor post-marketing (Phase IV).
Thus, the correct answer isB (Phase II).
References:
FDA Guidance: The IND Application - §312.21 (Phases of an investigation).
ICH E8(R1), General Considerations for Clinical Studies.

問題 #78
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