

素晴らしいCCRP | 最高のCCRP関連問題資料試験 | 試験の準備方法Certified Clinical Research Professional (CCRP)受験対策



P.S. It-PassportsがGoogle Driveで共有している無料かつ新しいCCRPダンプ: <https://drive.google.com/open?id=1Tgu4QkJPcUW4050yGHuf5g0NhOulivu4>

我々のSOCRAのCCRPソフトはあなたのすべての需要を満たすのを希望します。問題集の全面性と権威性、SOCRAのCCRPソフトがPDF版、オンライン版とソフト版があるという資料のバージョンの多様性、購入の前にデモの無料ダウンロード、購入の後でSOCRAのCCRPソフトの一年間の無料更新、これ全部は我々の誠の心を示しています。

It-PassportsのCCRP試験トレントの合格率は、効果的で有用を証明する唯一の基準であるというのは常識です。CCRP試験問題の利点についての一般的な考えは既にお持ちのことと思いますが、CCRPガイドトレントの最大の強みである最高の合格率をお見せしたいと思います。SOCRA統計によると、CCRPガイドトレントのガイダンスに従って試験を準備したお客様の合格率は、98~100%に達し、CCRP試験トレントを20~30時間しか練習していません。

>> CCRP関連問題資料 <<

CCRP受験対策、CCRP合格問題

当社SOCRAには多くの専門家や教授がいます。当社のすべてのCCRP研究トレントは、It-Passportsさまざまな分野のこれらの優秀な専門家および教授によって設計されています。CCRPテストトレントが他の学習教材よりも高い品質を持っていることを確認できます。私たちのデザインの目的は、学習を改善し、最短時間でCCRP認定を取得できるようにすることです。認定資格を取得したい場合は、Certified Clinical Research Professional (CCRP)ガイド急流が最適です。

SOCRA CCRP 認定試験の出題範囲:

トピック	出題範囲
トピック 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.

トピック 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.
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SOCRA Certified Clinical Research Professional (CCRP) 認定 CCRP 試験 問題 (Q33-Q38):

質問 # 33

While reviewing site records during a monitoring visit, a monitor can cite which of the following as a site violation of informed consent regulations?

- A. A copy of the consent document was not provided to a subject
- B. A subject's signature is missing on the copy of the summary of the short form consent
- C. Only the signatures of the person obtaining consent and the witness appear on the copy of the summary of the short form consent
- D. The sponsor-generated informed consent template is missing required elements

正解: A

解説:

Providing a copy of the signed consent form to subjects is a mandatory requirement.

* 21 CFR 50.27(a): "A copy shall be given to the person signing the form."

* ICH E6(R2) 4.8.11: Reinforces that "a copy of the signed and dated written informed consent form should be given to the subject."

Failure to provide this copy constitutes a direct violation of informed consent regulations.

Other issues:

* A & C concern proper short form process but do not invalidate informed consent if a copy was provided.

* D concerns sponsor template, but the site's responsibility is ensuring use of IRB-approved version.

Correct answer: B.

References:

21 CFR 50.27(a).

ICH E6(R2), §4.8.11.

質問 # 34

A clinical investigator wants to publish a subject's unique results. The consent form did not mention publication. What is required?

- A. Approval from monitor
- B. Nothing further
- C. IRB chair approval
- D. Consent from subject

正解: D

解説:

* ICH E6(R2) 4.8.10(n): Consent must include explanation about confidentiality and possible publication.

* If not included, specific subject consent must be obtained before publishing identifiable results.

Thus, subject's explicit permission is required.

References:ICH E6(R2) §4.8.10(n).

質問 # 35

If a subject experiences a serious adverse event related to the study drug and only minimal information is available, the investigator must submit the information to the:

- A. Sponsor and IRB/IEC within five days
- B. IRB/IEC immediately, then sponsor when full details are available
- C. Sponsor and IRB/IEC within seven days
- **D. Sponsor and IRB/IEC immediately, then update later**

正解: **D**

解説:

* ICH E6(R2) 4.11.1: Investigators must "immediately report all serious adverse events to the sponsor except for those the protocol identifies as not requiring immediate reporting."

* IRB must also be informed promptly per 21 CFR 312.64(b).

* Follow-up information is submitted later as available.

References: ICH E6(R2), §4.11.1; 21 CFR 312.64(b).

質問 # 36

According to ICH GCP, an electronic data capture (EDC) system must:

- A. Limit file sharing
- **B. Allow for data changes and store audit trails**
- C. Allow access across multiple platforms
- D. Limit remote access

正解: **B**

解説:

* ICH E6(R2) 5.5.3(g): Requires audit trails for any data changes, recording date, time, and person responsible. This ensures traceability and regulatory compliance.

Other restrictions (B-D) are not mandated under ICH.

References: ICH E6(R2), §5.5.3(g).

質問 # 37

After randomization, investigational drug is shipped to site. Who is responsible for accountability?

- A. Investigational pharmacist
- **B. Investigator**
- C. Sponsor
- D. Research coordinator

正解: **B**

解説:

* ICH E6(R2) 4.6.1: "Responsibility for investigational product accountability at the trial site rests with the investigator."

* May delegate to pharmacist or coordinator, but ultimate responsibility lies with investigator.

References: ICH E6(R2) §4.6.1.

質問 # 38

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CCRP試験に実際に参加して資料を選択する前に、このような証明書を保持することの重要性を思い出してください。このようなCCRP証明書を取得することで、昇給、昇進の機会、上司や同僚からの信頼など、将来の多く

BONUS!!! It-Passports CCRPダンプの一部を無料でダウンロード: <https://drive.google.com/open?id=1Tgu4QkJPcUW4050yGHuf5g0NhOulivu4>