

# SOCRA CCRPダウンロード & CCRP日本語サンプル



**SOCRA CCRP Exam - ES'**  
SOCRA CCRP Exam Study  
Guide – A resource to help  
those who is preparing for  
the SOCRA Certified Clinical  
Research Professional (CCRP)  
certification.

By

<http://www.clinicalresearchasociatecra.com/studyguide/>

ちなみに、JPTestKing CCRPの一部をクラウドストレージからダウンロードできます：  
<https://drive.google.com/open?id=1gkU4JVBZ8S69edA43rQyVJTqAFpK6jUU>

この知識が支配的な世界では、知識と実用的な作業能力の組み合わせが非常に重要視されています。JPTestKing 実際の能力を向上させたい場合は、CCRP認定試験に参加できます。CCRP認定に合格すると、実践能力と知識の両方を高めることができます。また、CCRPの最新の質問を購入すると、CCRP試験にスムーズに合格します。

## SOCRA CCRP 認定試験の出題範囲：

| トピック   | 出題範囲                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| トピック 1 | <ul style="list-style-type: none"><li>研究終了：この試験セクションでは、臨床研究コーディネーターのスキルを評価し、臨床試験を適切に終了するために必要な活動について学びます。試験終了時の訪問に参加し、文書の確認や治験薬の記録確認を行います。また、IRB、治験依頼者、規制当局、および <a href="http://clinicaltrials.gov">clinicaltrials.gov</a> への最終終了報告書の作成と提出も含まれます。さらに、試験記録のアーカイブ化手順についても学びます。</li></ul>                                                                                                                                                                                                                                                                                                                                                                            |
| トピック 2 | <ul style="list-style-type: none"><li>研究調査の立ち上げ：このセクションでは、臨床研究コーディネーターのスキルを評価し、臨床試験の初期計画と準備について学びます。試験プロトコルの開発を調整し、倫理ガイドラインやIND（治験実施計画）やIDE（治験薬承認申請）などの規制当局の承認を確実に取得することが含まれます。また、インフォームド・コンセント用紙や症例報告書などの重要な研究文書の作成も含まれます。この領域では、IRB（治験審査委員会）やスポンサーなどの利害関係者からの必要な承認の取得、試験実施施設の選定、スタッフのトレーニング、そして試験が各種法令を遵守していることの確保も含まれます。さらに、研究製品の入手、試験開始に必要なすべてのツールと文書の準備も含まれます。<br/>研究調査の実施：このセクションでは、臨床研究アソシエイトのスキルを評価し、臨床試験の積極的な管理と実施について学びます。試験プロトコルと標準操作手順の遵守、治験薬の管理、そして継続的な規制遵守の確保に重点が置かれます。この領域では、有害事象やプロトコルからの逸脱などの試験の異常を特定、記録、報告することも含まれます。さらに、被験者の募集、同意取得、維持管理、そしてすべての試験記録と重要な文書の維持管理も含まれます。さらに、品質と規制の遵守を確保するために、すべての研究関係者とコミュニケーションを取り、研究監査に参加することも含まれます。</li></ul> |

## CCRP認定試験、CCRP練習問題、CCRP有効な練習資料

SOCRA CCRP「Certified Clinical Research Professional (CCRP)」認証試験に合格することが簡単ではなくて、SOCRA CCRP証明書は君にとってはIT業界に入るの一つの手づるになるかもしれません。しかし必ずしも大量の時間とエネルギーで復習しなくて、弊社が丹精にできあがった問題集を使って、試験なんて問題ではありません。

### SOCRA Certified Clinical Research Professional (CCRP) 認定 CCRP 試験問題 (Q74-Q79):

#### 質問 # 74

Which of the following would be considered an addendum to an investigator's brochure for an unapproved Investigational Product?

- A. A Suspected Unexpected Serious Adverse Reaction (SUSAR) report
- B. Revisions to the risk section of the informed consent form
- C. A site-specific SAE report
- D. Product monograph updates

正解: A

解説:

The IB must be updated as new significant safety information emerges.

\* ICH E6(R2) 7.3: "The sponsor should revise the IB as soon as new, significant information becomes available."

\* ICH E2A: Requires sponsors to report Suspected Unexpected Serious Adverse Reactions (SUSARs) in expedited reports and include them in IB updates or addenda.

A SUSAR report (B) represents new, unexpected, and serious safety information not previously documented, and therefore warrants inclusion as an IB addendum until the IB is formally updated.

Revised consent forms (A) are submitted to IRBs, not IBs. Site-specific SAE reports (C) remain at site / sponsor level, not in the IB. Product monograph updates (D) apply to approved products, not investigational ones.

Thus, the correct answer is B (SUSAR report).

References:

ICH E6(R2), §7.3 (Updating the Investigator's Brochure).

ICH E2A (Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

#### 質問 # 75

An investigator received \$60,000 equity interest three years after study completion. What is the financial reporting requirement?

- A. Report to FDA
- B. None
- C. Report to OHRP
- D. Report to sponsor

正解: B

解説:

\* 21 CFR 54.4(b): Requires disclosure during the study and for 1 year after completion.

\* After three years, no disclosure is required.

References: 21 CFR 54.4(b).

#### 質問 # 76

When can the IRB/IEC require that additional information be given to subjects as part of informed consent?

- A. At any time, but only if the sponsor agrees that the information is essential
- B. At any time, but only if the investigator agrees that the information is essential
- C. At any time, but only if the sponsor and investigator agree that the information is essential
- D. At any time, at the discretion of the IRB/IEC

正解: D

解説:

The IRB/IEC is empowered to protect subjects and ensure informed consent remains accurate, complete, and understandable.

\* ICH E6(R2) 3.1.2: "The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid... when considering the adequacy and completeness of the written information to be provided to the subjects."

\* 21 CFR 56.109(b): "The IRB shall require that information given to subjects as part of informed consent is in accordance with §50.25. The IRB may require that information, in addition to that specifically mentioned in §50.25, be given to the subjects when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects." This confirms that the IRB/IEC has unilateral authority to request additional information at any time, regardless of sponsor or investigator agreement. Thus, the correct answer is A (At any time, at the discretion of the IRB/IEC).

References:

ICH E6(R2), §3.1.2 (IRB responsibilities).

21 CFR 56.109(b) (IRB review of informed consent).

#### 質問 # 77

Why would a Phase IV study be conducted?

- A. Different off-label population
- B. Different marketing strategy
- C. Different dosage
- D. Different schedule of administration

正解: A

解説:

Phase IV studies (post-marketing) examine real-world safety and effectiveness.

\* ICH E8(R1): Describes Phase IV as "studies performed after drug approval to delineate additional information including the drug's risks, benefits, and optimal use."

\* They often test drugs in new or broader populations beyond original approval.

While dosing and schedules are Phase I-III, Phase IV focuses on new patient populations or long-term outcomes.

References: ICH E8(R1).

#### 質問 # 78

A subject currently on a clinical trial was hospitalized for 2 days due to a SAE. The subject reported the hospitalization to the investigator at the next study visit. According to the ICH GCP Guideline, when should the investigator report the SAE to the sponsor?

- A. Within 7 working days
- B. Within 15 working days
- C. Within 10 working days
- D. Immediately

正解: D

解説:

ICH requires immediate reporting of all SAEs to the sponsor (except those protocol-identified as not requiring immediate reporting).

Exact extract:

\* ICH E6(R2) 4.11.1: "The investigator should report all serious adverse events immediately to the sponsor except for those SAEs that the protocol... identifies as not needing immediate reporting." Therefore, "Immediately" (A) is correct. The other timeframes are not aligned with ICH GCP for initial SAE notification from investigator to sponsor.

References:

ICH E6(R2) Good Clinical Practice, §4.11.1 (Safety reporting by investigators).=====

#### 質問 # 79

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難しいIT認証試験に受かることを選んだら、頑張って準備すべきです。JPTestKingのSOCRAのCCRP試験トレーニング資料はIT認証試験に受かる最高の資料で、手に入れたら成功への鍵を持つようになります。JPTestKingの

CCRP日本語サンプル: <https://www.jp-testking.com/CCRP-exam.html>

- 2026年JPTestKingの最新CCRP PDFダンプおよびCCRP試験エンジンの無料共有: <https://drive.google.com/open?id=1gkU4JVBZ8S69edA43rQyVJTqAFpK6jUU>