

有用的なCCRP試験対応 & 資格試験におけるリーダー オファース & 唯一無二なCCRP: Certified Clinical Research Professional (CCRP)

Materials Provided



1. Canine CRP kit should be stored between 1 to 30°C (33.8-86 °F).
2. Expiration date of this kit is 24 months after its manufacture date.

1. Test devices individually foil-pouched with a desiccant

2. Assay solution in tube(1ul/tube): 10units

3. EDTA Tube:10units

4. Disposable dropper: 10units

5. 5ul capillary pipette (for serum or plasma): 10units

6. 10ul capillary pipette(for whole blood):10units

7. Instruction manual for use: 1 sheet

8. Easy Test Color Index : 1 sheet

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>

SOCRA資格試験はそんなに難しいのですか? 弊社の資料を利用したら、CCRP試験は簡単になります。お客様に最高のSOCRA問題集を入手させるために、我々は常に問題集の質を改善し、ずっと最新の試験のシラバスに応じて問題集を更新しています。我々のCCRP問題集の解答を暗記すれば、お客様は必ずこの試験に合格することができます。

IT業界での競争がますます激しくなるうちに、あなたの能力をどのように証明しますか。SOCRAのCCRP試験に合格するのは説得力を持っています。我々ができるのはあなたにより速くSOCRAのCCRP試験に合格させます。数年間の発展で我々JPTestKingはもっと多くの資源と経験を得ています。改善されているソフトはあなたのSOCRAのCCRP試験の復習の効率を高めることができます。

>> CCRP試験対応 <<

CCRPコンポーネント & CCRP復習解答例

あなたの目標はとても高いですから、あなたに色々なヘルプをあげられる資料が必要です。JPTestKing SOCRAのCCRP試験問題集はあなたが自分の目標を達成することを助けられます。JPTestKing SOCRAのCCRP問題資料は高度に認証されたIT領域の専門家の経験と創造を含めているものです。当社の製品は、すべての可能性のある問題を試させられます。受験生の皆様に問題の100パーセント真実な解答を提供することを保証します。

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

質問 # 74

Which of the following statements about the initial IND application submission by a sponsor to the U.S. Food and Drug

Administration is correct?

- A. It includes a disclosure of the financial interests and arrangements of clinical investigators
- B. It is an application to export the investigational drug
- **C. It includes the rationale for human testing and a description of the general investigational plan**
- D. It is an application for the sponsor to sell the drug for profit

正解: C

解説:

An Investigational New Drug (IND) application provides FDA with data to justify human testing.

* 21 CFR 312.23(a)(3): The IND must contain "a description of the general investigational plan, including the rationale for the drug or the research study."

* The IND also includes preclinical safety data, manufacturing details, investigator qualifications, and study protocols.

Financial disclosures (D) are reported separately under 21 CFR Part 54, not as part of the initial IND. Export applications (A) are covered under 21 CFR 312 Subpart E. Profit sales (C) are not permitted under INDs.

Thus, the correct answer is B (Rationale and plan for human testing).

References:

21 CFR 312.23(a)(3) (IND contents).

21 CFR 312.20 (General IND requirements).

質問 # 75

In determining the classification of risk for a study involving a medical device, it is necessary to consider the:

- A. Investigators' prior training and experience
- B. Number of patients to be treated with the device
- C. Cost of device
- **D. Use of the device in the particular study**

正解: D

解説:

FDA regulations for investigational devices are found under 21 CFR 812. Risk classification determines whether a device is considered Significant Risk (SR) or Non-Significant Risk (NSR). The critical factor is how the device will be used in the specific study.

21 CFR 812.3(m): Defines a "significant risk device study" as one that "is intended as an implant, is purported or represented to be for a use in supporting or sustaining human life, or otherwise presents a potential for serious risk to the health, safety, or welfare of a subject." Risk is judged within the context of the protocol - i.e., use of the device in that particular study (D).

Number of patients (A), device cost (B), or investigator experience (C) are irrelevant to FDA's risk classification. For example, a stent used in an approved indication may be NSR, but if used in a new anatomical location, it may be SR.

Therefore, the correct answer is D. This ensures ethical review bodies and FDA assess safety in the intended clinical context rather than device attributes alone.

References:

21 CFR 812.3(m) (Definition of significant risk device).

FDA Guidance on Significant Risk and Nonsignificant Risk Medical Device Studies.

質問 # 76

Upon completion of a study, the investigator should do which of the following?

- A. Compile site data, publish the study results, and submit the publication to the IRB/IEC as the final report
- B. Ensure that all payments from sponsor have been received
- **C. As soon as possible, provide the IRB/IEC with a final report that summarizes the trial's outcome**
- D. Provide the IRB/IEC a final report, but only if the study has a positive outcome

正解: C

解説:

Investigators must formally close out a trial with the IRB/IEC.

* ICH E6(R2) 4.13.2: "Upon completion of the trial, the investigator/institution should provide the IRB

/IEC with a summary of the trial's outcome."

* 21 CFR 312.66: Reinforces investigator's duty to keep IRB informed throughout study lifecycle.

This applies regardless of whether outcomes were positive, negative, or inconclusive. IRBs are not concerned with sponsor payments (B) or publications (D).

Thus, the correct answer is A (Provide final report to IRB/IEC).

References:

ICH E6(R2), §4.13.2 (Final reporting requirement).

質問 # 77

A research protocol requires patients to complete a patient reported outcome questionnaire in the sponsor's electronic data capture (EDC) system. What is the source data?

- A. A printout of the EDC record
- B. A printout of the electronic medical record
- C. The electronic medical record
- **D. The EDC record**

正解: **D**

解説:

Source data are original records where data are first recorded.

* ICH E6(R2) 1.51: Defines source data as "all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial." Since subjects directly enter responses into the EDC, the EDC record itself is the original source document.

EMRs (B, C) and printouts (D) are secondary records.

Correct answer: A (The EDC record).

References:

ICH E6(R2), §1.51 (Definition of source data).

質問 # 78

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

正解: **B**

解説:

This scenario falls under emergency 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, an independent 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).

質問 # 79

.....

