CCRP無料問題 & CCRP模擬試験最新版

BONUS！！！ GoShiken CCRPダンプの一部を無料でダウンロード：https://drive.google.com/open?id=1Sr9yo_XJ9BOMNds2JxfW44nvXfthLb4k

当社GoShikenのCCRP認定ファイルは、代表的な傑作であり、品質、サービス、革新をリードしています。テストCCRP認定に関する最も重要な情報を収集し、業界の上級専門家および認定講師および著者によって作成およびコンパイルされた新しい知識ポイントを補足します。クライアントがCCRPクイズ教材を効率的に学習し、CCRP試験に合格できるように、実際の試験を刺激する機能などの補助機能を提供します。

SOCRA CCRP 認定試験の出題範囲：

トピック	出題範囲
トピック 1	• 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.
トピック 2	• 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.

>> CCRP無料問題 <<

CCRP試験の準備方法｜効率的なCCRP無料問題試験｜素晴らしい

Certified Clinical Research Professional (CCRP)模擬試験最新版

私たちは皆、ほとんどの候補者が製品の品質を心配することを知っていました。CCRP学習教材の品質を保証するために、会社のすべての労働者は、共通の目標のために、;CCRP試験問題です。 CCRPガイドトレントを購入すると、高品質の製品、リーズナブルな価格、アフターサービスを提供することが保証されます。私たちのCCRPテストトレントは、他の学習教材よりもあなたにとってより良い選択だと思います。

SOCRA Certified Clinical Research Professional (CCRP) 認定 CCRP 試験問題 (Q106-Q111):

質問 # 106
An investigator reports a serious adverse event suspected to be drug-related. By CFR, the sponsor must notify FDA no later than:

- A. 7 days
- B. 10 days
- C. 1 day
- D. 15 days

正解：A

解説：
* 21 CFR 312.32(c)(2):Life-threatening or fatal unexpected adverse events must be reported within7 calendar days.Other serious unexpected events are reported within 15 days.
References:21 CFR 312.32(c)(2).

質問 # 107
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. The electronic medical record
- C. The EDC record
- D. A printout of the electronic medical record

正解：C

解説：
Source data areoriginal 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, theEDC 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 # 108
A subject has creatinine 1.6 mg/dL, slightly above eligibility (#1.5). Investigator believes this is normal for size. When can subject be enrolled?

- A. After sponsor revises eligibility and IRB approves amendment
- B. After investigator documents explanation in chart
- C. After monitor approves deviation
- D. After repeat test confirms 1.6

正解：A

解説：

* ICH E6(R2) 4.5.1:"The investigator should conduct the trial in compliance with the protocol approved by IRB/IEC."
* Deviations must not occur unless to eliminate hazard. Eligibility criteria cannot be overridden by investigator opinion.
Thus, enrollment requires protocol amendment and IRB approval.
References:ICH E6(R2), §4.5.1.

質問 # 109
The study coordinator for a new Phase III vaccine study is preparing documents for IRB/IEC submission.
According to the ICH GCP Guidelines, which of the following documents should be included in the submission?

- A. Case report forms
- B. The investigators' CVs
- C. Recruitment materials
- D. Local lab normal ranges

正解：C

解説：
IRBs/IECs are responsible for ensuring that subject recruitment is ethical and not coercive.
* ICH E6(R2) 3.1.2:The IRB/IEC safeguards subjects by reviewing recruitment procedures and materials.
* 21 CFR 56.111(a)(3):Requires equitable subject selection, which extends to advertisements and recruitment.
* FDA Guidance on Recruiting Study Subjects (1998):States that "advertisements and recruitment materials must be reviewed and approved by the IRB prior to use." While CVs (D) and lab ranges (A) are essential documents for study feasibility and quality, they are not mandatory for IRB approval package. CRFs (B) are sponsor tools for data collection, not subject-facing, and thus not reviewed by IRBs.
Correct answer:C (Recruitment materials).
References:
ICH E6(R2), §3.1.2.
FDA Recruitment Guidance, 1998.

質問 # 110
An IND application must contain all EXCEPT:

- A. Chemistry, manufacturing, and control information
- B. Financial disclosure information
- C. Investigator's brochure
- D. A cover sheet

正解：B

解説：
* 21 CFR 312.23(a):Requires cover sheet, CMC information, and IB.
* Financial disclosureis required separately under21 CFR 54, not part of IND content.
References:21 CFR 312.23(a); 21 CFR 54.

質問 # 111
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ルは《 jp.fast2test.com 》にて検索CCRP再テスト

- CCRPキャリアパス □ CCRP合格内容 □ CCRP技術内容 □ 検索するだけで□ www.goshiken.com □から“ CCRP ”を無料でダウンロードCCRP技術内容
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