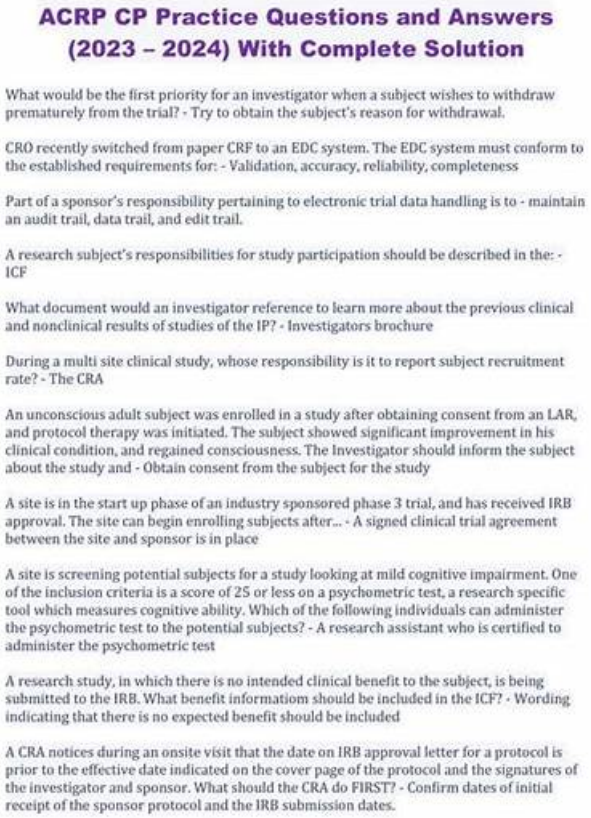
ACRP-CP최신버전시험덤프공부최신덤프샘플문제다운



ACRP CP Practice Questions and Answers (2023 – 2024) With Complete Solution

What would be the first priority for an investigator when a subject wishes to withdraw prematurely from the trial? - Try to obtain the subject's reason for withdrawal.

CRO recently switched from paper CRF to an EDC system. The EDC system must conform to the established requirements for: - Validation, accuracy, reliability, completeness

Part of a sponsor's responsibility pertaining to electronic trial data handling is to - maintain an audit trail, data trail, and edit trail.

A research subject's responsibilities for study participation should be described in the: - ICF

What document would an investigator reference to learn more about the previous clinical and nonclinical results of studies of the IP? - Investigators brochure

During a multi site clinical study, whose responsibility is it to report subject recruitment rate? - The CRA

An unconscious adult subject was enrolled in a study after obtaining consent from an LAR, and protocol therapy was initiated. The subject showed significant improvement in his clinical condition, and regained consciousness. The Investigator should inform the subject about the study and - Obtain consent from the subject for the study

A site is in the start up phase of an industry sponsored phase 3 trial, and has received IRB approval. The site can begin enrolling subjects after... - A signed clinical trial agreement between the site and sponsor is in place

A site is screening potential subjects for a study looking at mild cognitive impairment. One of the inclusion criteria is a score of 25 or less on a psychometric test, a research specific tool which measures cognitive ability. Which of the following individuals can administer the psychometric test to the potential subjects? - A research assistant who is certified to administer the psychometric test

A research study, in which there is no intended clinical benefit to the subject, is being submitted to the IRB. What benefit informatiom should be included in the ICF? - Wording indicating that there is no expected benefit should be included

A CRA notices during an onsite visit that the date on IRB approval letter for a protocol is prior to the effective date indicated on the cover page of the protocol and the signatures of the investigator and sponsor. What should the CRA do FIRST? - Confirm dates of initial receipt of the sponsor protocol and the IRB submission dates.

그리고 Pass4Test ACRP-CP 시험 문제집의 전체 버전을 클라우드 저장소에서 다운로드할 수 있습니다: https://drive.google.com/open?id=1fwVVRI4r6r8ol1FFWZGzjrSkyFqWLnwG

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>> ACRP-CP최신버전 시험덤프공부 <<

ACRP-CP최신버전 시험덤프공부 인기덤프

요즘같이 시간인즉 금이라는 시대에 시간도 절약하고 빠른 시일 내에 학습할 수 있는 Pass4Test의 덤프를 추천합니다. 귀중한 시간절약은 물론이고 한번에ACRP ACRP-CP인증시험을 패스함으로 여러분의 발전공간을 넓혀줍니다.

최신 ACRP Certified Professional ACRP-CP 무료샘플문제 (Q70-Q75):

질문 # 70
One key attribute for good study documentation is that the data are contemporaneous, which refers to the practice of:

- A. Recording the date and time each data element is entered onto the source document.
- B. Comparing source document data to other data recorded in the same study time period.
- C. Allowing real-time access for data review in the eCRF.
- D. Recording data on source documents at the time the data are collected during the conduct of the study.

정답：D

설명：
Contemporaneous data means that data entries are made at the time of the event or as soon as possible after the event occurs. This practice ensures that the recorded data accurately reflect the participant's condition and study procedures, minimizing recall bias and errors. Maintaining contemporaneous records is a fundamental requirement for ensuring the accuracy and reliability of clinical trial data.
GCP guidelines specify that data should be recorded as close to the time of the event as possible to ensure accuracy and reliability. "Data must be contemporaneously recorded, meaning they are documented at the time of the occurrence to accurately reflect the study conduct." Objectives:
* Ensure accurate and real-time data capture.
* Maintain data integrity by minimizing recall bias.

질문 # 71
A study to determine the effective dose and regimen of a new IP for the treatment of hypothyroidism is considered to be:

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

정답：B

설명：
A Phase II clinical trial is typically conducted to evaluate the efficacy of a drug, determine the optimal dosing regimen, and further assess its safety profile. Since the objective is to establish the effective dose and regimen for hypothyroidism treatment, this clearly falls under Phase II.
GCP guidelines categorize Phase II trials as those aimed at determining efficacy and optimal dosing of investigational products. "Phase II trials focus on determining the therapeutic efficacy, optimal dosage, and further evaluating the safety of the investigational product." Objectives:
* Identify effective dosing regimens.
* Evaluate therapeutic efficacy for targeted conditions.

질문 # 72
When assessing the monitoring needs for a study, sponsors should:

- A. Permit PIs to select a monitor for their site as long as they are independent of the PI.
- B. Ensure monitoring visits are conducted at periodic intervals with a minimum of monthly monitoring visits.
- C. Ensure monitors have the scientific and/or clinical knowledge needed to monitor the trial adequately.
- D. Use central monitoring instead of conducting physical monitoring visits at sites.

정답：C

설명：
Sponsors must ensure that monitors are adequately qualified, possessing the necessary scientific and clinical knowledge to effectively oversee the trial. This ensures that monitors can accurately assess protocol compliance, data integrity, and participant safety. The quality of monitoring directly impacts the credibility of the trial outcomes.
GCP guidelines specify that monitors must be adequately trained and knowledgeable about the trial protocol, investigational product (IP), and clinical research standards.
"The sponsor must ensure that monitors have appropriate qualifications and training to conduct effective trial monitoring." Objectives:
* Maintain data integrity through skilled monitoring.

* Ensure patient safety and protocol compliance.

질문 # 73
The investigator/institution should permit:

- A. Monitoring and auditing by the appropriate regulatory authority(ies), and inspection by the sponsor.
- B. Monitoring and inspection by the sponsor, and auditing by the appropriate regulatory authority(ies).
- C. Monitoring and inspection by the appropriate regulatory authority(ies), and auditing by the sponsor.
- D. Monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).

정답：C

설명：
The investigator and institution must allow both monitoring and inspection by the appropriate regulatory authorities and auditing by the sponsor. This dual oversight ensures that the trial complies with regulatory standards and sponsor requirements, thereby maintaining the integrity and validity of the data.
GCP guidelines specify that regulatory authorities have the right to inspect, while sponsors typically conduct audits to verify compliance and data quality.
"The institution should permit monitoring and inspection by regulatory authorities and auditing by the sponsor to ensure compliance with GCP and protocol adherence." Objectives:
* Facilitate monitoring and inspection for compliance.
* Ensure trial data integrity and quality assurance.

질문 # 74
Upon receiving their first dose of study drug in the clinic, the subject exhibits an immediately life-threatening reaction. The protocol prohibits any concomitant medications. What should be the investigator's IMMEDIATE response?

- A. Report the AE to the sponsor.
- B. Administer rescue medication.
- C. Consult the IB.
- D. Call the medical monitor.

정답：B

설명：
In a life-threatening situation, the investigator's first priority is the safety and well-being of the participant.
Administering rescue medication immediately is critical to stabilize the patient, regardless of protocol restrictions. Ethical considerations and patient safety always take precedence over protocol compliance.
GCP guidelines emphasize that subject safety is the primary concern, and appropriate medical care must be administered in emergencies.
"In cases of life-threatening events, the investigator should administer necessary medical interventions to safeguard the subject's health." Objectives:
* Prioritize patient safety in emergency situations.
* Make decisions based on medical necessity rather than protocol restrictions.

질문 # 75
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시험준비에 가장 좋은 ACRP-CP최신버전 시험덤프공부 인증공부

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