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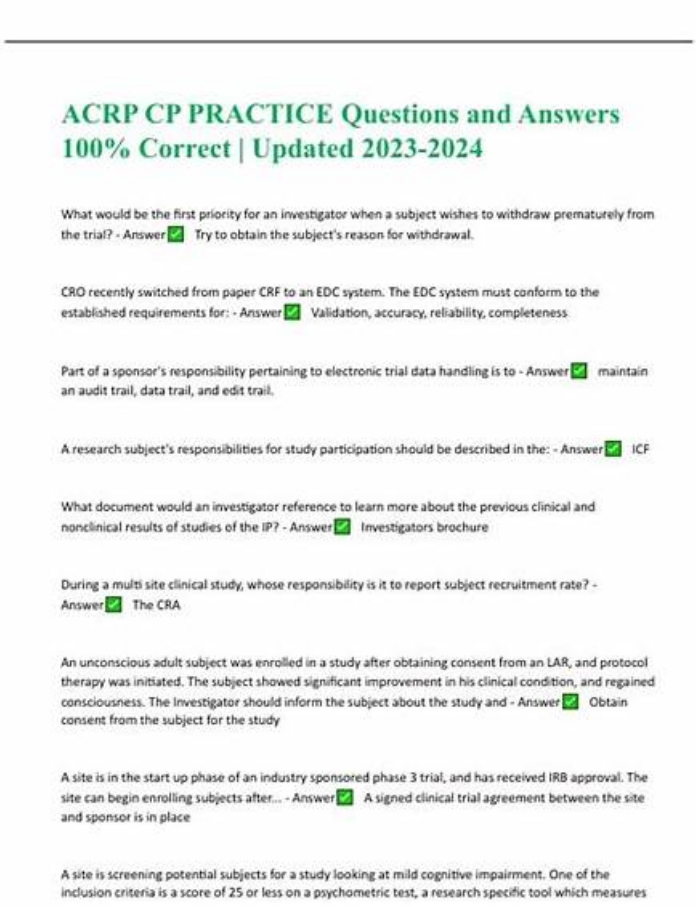

ACRP CP PRACTICE Questions and Answers
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What would be the first priority for an investigator when a subject wishes to withdraw prematurely from the trial? - Answer✅ Try to obtain the subject's reason for withdrawal.

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

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

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

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

During a multi site clinical study, whose responsibility is it to report subject recruitment rate? - Answer✅ 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 - Answer✅ 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... - Answer✅ 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

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問題 #100
All of the following are steps to assure an effective risk management approach while conducting a clinical study EXCEPT:

- A. Controlling risk by setting thresholds of risk acceptability.
- B. Assessing risk based on study impact.
- C. Identifying potential study risks.
- D. Documenting all possible risk scenarios.

答案：D

解題說明：
While identifying potential risks, assessing them based on their impact, and setting risk acceptability thresholds are integral parts of a risk management approach, documenting every possible risk scenario is impractical and unnecessary. Instead, focus should be on identifying and managing the most significant and likely risks that could affect the study's quality and safety.
GCP guidelines emphasize identifying, assessing, and controlling critical risks rather than exhaustively documenting all hypothetical scenarios.
"Effective risk management involves identifying key risks, evaluating their impact, and setting control measures, rather than documenting every possible risk." Objectives:
* Implement practical and targeted risk management strategies.
* Focus on significant and likely risks rather than hypothetical ones.

問題 #101
A study protocol must contain which of the following elements?

- A. Participant reimbursement details
- B. Chemical structure of the IP
- C. Data management plan
- D. Description of statistical methods

答案：D

解題說明：
A clinical study protocol must include a clear description of the statistical methods to be used in analyzing the collected data. This ensures that the analysis plan is predefined, unbiased, and statistically sound. The statistical methodology must address how the primary and secondary endpoints will be evaluated.
GCP guidelines require that the protocol clearly outlines statistical methods to ensure accurate and unbiased analysis of trial data.
"The protocol should include a detailed description of the statistical methods employed to ensure the validity of the trial results."
Objectives:
* Maintain transparency in data analysis.
* Ensure scientific rigor in evaluating study outcomes.

問題 #102
A serious unexpected ADR is one:

- A. That results in the death of the subject.
- B. Where the severity of the reaction is not consistent with IB.
- C. Severity and nature of the reaction is consistent with protocol.
- D. That does not need to be reported to the IRB/IEC.

答案：B

解題說明：
A serious unexpected adverse drug reaction (ADR) is characterized by an event that is not consistent with the information provided in the Investigator's Brochure (IB). Such reactions may indicate new risks associated with the investigational product and warrant immediate reporting to the sponsor and regulatory authorities.
This answer follows the ICH E6(R2) GCP guidelines, which specify the criteria for reporting serious and unexpected adverse events.
"An unexpected adverse drug reaction is one whose nature or severity is not consistent with the applicable product information (e.g.,

IB)." Objectives:
* Understanding classification of ADRs
* Ensuring timely and accurate reporting of unexpected events

問題 #103
Who is responsible for securing agreement from all involved parties to ensure direct access of all trial-related source documents?

- A. CRO
- B. Investigator
- C. CRC
- D. Sponsor

答案：D

解題說明：
The sponsor is responsible for ensuring that agreements are in place with all involved parties (including investigators and institutions) to grant direct access to trial-related source documents. This is crucial for monitoring, auditing, and inspection purposes, ensuring transparency and compliance with regulatory requirements.
According to GCP guidelines, the sponsor must establish agreements to secure direct access to trial data for verification and compliance checks.
"The sponsor should ensure that agreements are in place to permit direct access to source data and documents for monitoring and inspection." Objectives:
* Maintain compliance with regulatory requirements.
* Facilitate data verification and quality assurance.

問題 #104
The process of ensuring and documenting that an electronic data processing system conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance is called:

- A. Programming
- B. Validation
- C. Quality Control
- D. Quality Assurance

答案：B

解題說明：
Validation is the process of ensuring that an electronic data processing system meets the sponsor's specifications for completeness, accuracy, reliability, and consistent performance. It involves systematic testing and documentation to demonstrate that the system functions as intended, especially in the context of capturing, processing, and managing clinical trial data.
GCP guidelines specify that validation of electronic systems is crucial to maintain data integrity and compliance with regulatory standards.
"Validation ensures that electronic data systems function according to the sponsor's requirements, maintaining data accuracy and reliability." Objectives:
Maintain data integrity and reliability.
Demonstrate system compliance with regulatory requirements.

問題 #105
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