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ACRP-CP Exam With Latest Updated Answers 2025

What is an ADR? - correct answer.Adverse drug reaction (ADR)

1.Pre-approval clinical experience with a new medicinal product or its new usages: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

2. Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function.

What is an AE? - correct answer.Adverse event (AE)

1. Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

What is an SAE? - correct answer.Serious adverse event (SAE)

1. Results in death
2. Is life-threatening
3. Requires inpatient hospitalization or prolongation of existing hospitalization
4. Results in persistent or significant disability/incapacity
5. Is a congenital anomaly/birth defect

What is an UADR? - correct answer.Unexpected adverse drug reaction (UADR)

1. An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., IB for an unapproved IP or package insert/summary of product characteristics for an approved product)

Who constitutes a vulnerable subject? - correct answer.Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits

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ACRP Certified Professional Exam Sample Questions (Q49-Q54):

NEW QUESTION # 49
Who is responsible for securing agreement from all involved parties to ensure direct access of all trial-related source documents?

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

Answer: D

Explanation:
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.

NEW QUESTION # 50
Who determines what criteria and procedures should be followed if a subject discontinues/withdraws their consent?

- A. Subject
- B. CRO
- C. PI
- D. Sponsor

Answer: D

Explanation:
The sponsor is responsible for defining the criteria and procedures for subject withdrawal or discontinuation of consent. This includes specifying how data already collected will be handled and whether any follow-up is required. The procedures must be clearly outlined in the study protocol and communicated to the research team.
This answer follows GCP guidelines, which state that the sponsor must ensure that procedures for subject withdrawal are clearly defined and documented.
"The sponsor is responsible for defining procedures to be followed if a subject discontinues participation or withdraws consent, including handling of data collected prior to withdrawal." Objectives:
* Ensure transparent procedures for participant withdrawal.
* Maintain data integrity while respecting participant autonomy.

NEW QUESTION # 51
The coding system for a double-blind clinical trial is accessible by the:

- A. PI
- B. Regulatory authority
- C. IRB/IEC
- D. Sponsor

Answer: D

Explanation:
The sponsor is typically responsible for maintaining the code that links the treatment assignment to participants in a double-blind clinical trial. The code is securely maintained and is only accessible in cases where unblinding is necessary for safety reasons. This process helps to preserve the integrity of the study while allowing for emergency unblinding if needed.
GCP guidelines state that the sponsor should maintain the blind unless unblinding is necessary due to safety concerns or regulatory requirements.
"The sponsor maintains the randomization code and ensures that unblinding occurs only when necessary, to protect the study's integrity." Objectives:
* Maintain the integrity of double-blind trials.
* Allow controlled access to randomization codes.

NEW QUESTION # 52

A study protocol must contain which of the following elements?

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

Answer: B

Explanation:
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.

NEW QUESTION # 53

Which statement does NOT represent a study monitor's responsibilities?

- A. Verify that the PI has adequate qualifications and resources to conduct the study.
- B. Provide communication between the sponsor and the PI.
- C. Check the accuracy and completeness of case report forms with source documents.
- D. Report serious adverse events to the IRB/IEC.

Answer: D

Explanation:
It is not the monitor's responsibility to report serious adverse events (SAEs) to the IRB/IEC. This responsibility typically falls on the PI or the sponsor. Monitors focus on data accuracy, protocol compliance, and communication between the site and the sponsor.
The answer follows GCP standards where the monitor's role is clearly defined, excluding SAE reporting to IRB/IEC.
"Monitors are responsible for verifying data accuracy and communicating with the sponsor but not for direct reporting of SAEs to the IRB/IEC." Objectives:
* Distinguish between the responsibilities of monitors and investigators
* Clarify SAE reporting protocols

NEW QUESTION # 54

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