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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 (Q47-Q52):

NEW QUESTION # 47

The IB contains which of the following sections?

- A. Participant dosing schedule
- **B. Known pharmacokinetic effects**
- C. Participant eligibility criteria
- D. IP preparation instructions

Answer: B

Explanation:

The Investigator's Brochure (IB) contains comprehensive information about the investigational product (IP), including its pharmacokinetic and pharmacodynamic properties, preclinical and clinical trial data, and any known side effects. The IB provides a scientific basis for the study protocol and helps investigators understand the potential risks and benefits.

GCP guidelines state that the IB must include relevant scientific data, including pharmacokinetic and pharmacodynamic profiles.

"The IB should provide data on the pharmacokinetics and pharmacodynamics of the investigational product to inform clinical practice." Objectives:

- * Provide comprehensive data on investigational products.
- * Support safe and informed clinical decision-making.

NEW QUESTION # 48

After enrolling and treating a few subjects on an investigator-initiated trial, the PI would like to include a subject diary for each trial subject to capture their activities and experiences on the trial regimen. After the PI has generated a diary, what should the PI do next?

- A. No approval is necessary: give the diary to each subject.
- **B. Submit the diary to the IRB/IEC for approval.**
- C. Submit the diary to the sponsor for approval.
- D. Submit the diary to the regulatory authority for approval.

Answer: B

Explanation:

Any new data collection tool introduced during a clinical trial, including subject diaries, must be reviewed and approved by the IRB/IEC before implementation. This ensures that the new tool is ethically appropriate, respects subject privacy, and aligns with the approved protocol.

This answer aligns with ICH E6(R2) GCP guidelines, which mandate IRB/IEC approval for any new or modified subject-related documents introduced during a trial.

"All changes in study documents, including subject diaries, must be submitted for IRB/IEC review to ensure compliance with ethical standards." Objectives:

- * Maintain compliance with IRB/IEC requirements.
- * Ensure ethical handling of subject data.

NEW QUESTION # 49

The sponsor should supply a PI with the IP after:

- A. Approval of protocol by the sponsor.
- **B. Approval/favorable opinion from IRB/IEC and regulatory authority.**
- C. Submission of documents to IRB/IEC and regulatory authority for review.
- D. Approval of protocol by the PI.

Answer: B

Explanation:

The sponsor may only provide the investigational product (IP) after the IRB/IEC and relevant regulatory authorities have approved

the protocol. This ensures that the trial complies with ethical and legal standards before initiating IP administration. According to GCP guidelines, sponsors must wait for all necessary approvals before distributing IP to the trial site. "The investigational product may only be supplied after obtaining regulatory and IRB/IEC approval to ensure ethical conduct of the trial." Objectives:

- * Ensure regulatory compliance before initiating IP distribution.
- * Protect participant safety and ethical standards.

NEW QUESTION # 50

Which document confirms the PI's agreement to permit auditing at the study site?

- A. IB
- B. Delegation Log
- C. Protocol
- **D. ICF**

Answer: D

Explanation:

The Informed Consent Form (ICF) typically includes a statement indicating that the participant's records may be reviewed by monitors, auditors, and regulatory authorities. This ensures transparency and compliance with regulatory requirements, allowing for audits and inspections when necessary.

This answer follows GCP guidelines which specify that the ICF should include consent for audits and inspections to protect subject confidentiality while ensuring data integrity.

"The ICF must include a statement allowing access to trial data for monitoring, auditing, and regulatory inspection purposes."

Objectives:

- * Ensure informed consent for data access.
- * Facilitate compliance with auditing requirements.

NEW QUESTION # 51

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. Identifying potential study risks.
- **C. Documenting all possible risk scenarios.**
- D. Assessing risk based on study impact.

Answer: C

Explanation:

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.

NEW QUESTION # 52

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