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ACRP Certified Professional Exam Sample Questions (Q13-Q18):

NEW QUESTION # 13
Who is responsible for defining, establishing, and allocating all trial-related duties and functions prior to initiating a trial?

- A. IRB/IEC
- B. CRO
- C. Investigator
- D. Sponsor

Answer: D

Explanation:
The sponsor is responsible for defining, establishing, and allocating all trial-related duties and functions before the trial begins. This includes outlining roles and responsibilities in collaboration with investigators, CROs, and other stakeholders. Proper delegation ensures the trial is conducted according to protocol and regulatory requirements.
This answer is verified based on GCP guidelines, which clearly state that sponsors are responsible for the organization and management of trial-related tasks.
"The sponsor is responsible for allocating duties and functions related to the conduct of the trial, ensuring compliance with regulatory and ethical standards." Objectives:
* Clarify the sponsor's role in clinical trial management
* Define responsibilities in trial planning

NEW QUESTION # 14
An impartial witness should be present during the entire informed consent discussion when:

- A. A subject has been determined to be vulnerable.
- B. An interpreter is translating the consent form for a subject.
- C. A parent/guardian is consenting for a minor subject.
- D. A legally acceptable representative is unable to read.

Answer: D

Explanation:
An impartial witness is required when a legally acceptable representative (LAR) or the subject themselves cannot read. The witness ensures that the information is presented accurately and that the consent process is conducted ethically. The witness also signs the consent form to confirm that the subject or representative understands the study details.
GCP guidelines require an impartial witness to be present to confirm that the consent information is correctly conveyed and understood when the subject or LAR cannot read.
"An impartial witness is required when the subject or legally acceptable representative is unable to read, ensuring the consent process is transparent and ethically sound." Objectives:
* Protect the rights of individuals with literacy challenges.
* Maintain ethical standards in the consent process.

NEW QUESTION # 15
A protocol requires participants to take IP for 6 months. The protocol allows for any participants who are noncompliant to be replaced by enrolling additional participants, except if it is due to an AE. The investigator has enrolled 12 participants.
The status of the enrolled participants is as follows:
* 3 participants were withdrawn due to noncompliance
* 1 participant withdrew consent after experiencing severe nausea
* 1 participant had to discontinue IP for an unscheduled hospitalization
* 1 participant who is not returning for visits
* 2 participants completed the 6 months of treatment
* 4 participants currently on IP
How many participants should be replaced?

- A. 3 participants
- B. 4 participants
- C. 6 participants

- D. 5 participants

Answer: A

Explanation:
Since the protocol specifies that participants withdrawn due to an Adverse Event (AE) should not be replaced, only the participants withdrawn for noncompliance (3 in total) should be replaced. The participant who withdrew consent due to severe nausea (an AE) and the one who discontinued IP due to hospitalization should not be replaced.
GCP guidelines specify that replacement of subjects should follow the protocol criteria, particularly when AEs are involved.
"Participants withdrawn due to AEs should not be replaced if the protocol stipulates this condition, while noncompliant participants may be replaced." Objectives:
* Follow protocol guidelines for participant replacement.
* Ensure compliance with study criteria.

NEW QUESTION # 16
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 III
- C. Phase I
- D. Phase II

Answer: D

Explanation:
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.

NEW QUESTION # 17
A written description of a trial in which the clinical and statistical description, presentations, and analyses are fully integrated into a single document is called a:

- A. Clinical Study Report
- B. Investigator Brochure
- C. IDMC/DSMB Report
- D. Clinical Study Protocol

Answer: A

Explanation:
A Clinical Study Report (CSR) is a comprehensive document that integrates clinical and statistical data from a clinical trial. It provides a complete and detailed account of the study's methods, results, and conclusions, including safety and efficacy analyses.
The CSR is prepared at the end of the trial to summarize the data for regulatory submission and scientific publication.
GCP guidelines state that the CSR should integrate both clinical and statistical information to provide a comprehensive overview of the trial's outcomes.
"The Clinical Study Report contains a complete and integrated presentation of clinical and statistical findings from a clinical trial."
Objectives:
* Document trial outcomes comprehensively.
* Facilitate regulatory review and scientific dissemination.

NEW QUESTION # 18
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