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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q100-Q105):

NEW QUESTION # 100

A nonrandomized study of 30 subjects entitled "A study to evaluate the effectiveness of and to determine the common short-term side effects associated with the drug 'PainStop' for the treatment of subjects with chronic arthritis" is an example of a:

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

Answer: C

Explanation:

Phase classification is based on study objectives, not just subject numbers.

* Phase I: Focuses on safety, pharmacokinetics, dose-ranging, usually in healthy volunteers or small patient groups.

* Phase II: Evaluates effectiveness in patients with the condition and monitors common short-term side effects.

* Phase III: Confirms effectiveness in larger populations, compares to standard therapy, gathers more safety data.

* Phase IV: Post-marketing studies exploring new indications, long-term safety, or special populations.

The given study aims to evaluate effectiveness and common short-term side effects in 30 arthritis patients, which clearly aligns with Phase II objectives. It is not exploratory safety (Phase I), not confirmatory comparative (Phase III), nor post-marketing (Phase IV).

Thus, the correct answer is B (Phase II).

References:

FDA Guidance: The IND Application - §312.21 (Phases of an investigation).

ICH E8(R1), General Considerations for Clinical Studies.

NEW QUESTION # 101

Protocol increases drug dose by 20%. Baseline: 370 mg/m². New dose = ?

- A. 492 mg/m²
- B. 420 mg/m²
- C. 444 mg/m²
- D. 400 mg/m²

Answer: C

Explanation:

$370 \times 1.20 = 444 \text{ mg/m}^2$.

Accurate dosing calculations are critical for protocol adherence and patient safety.

References: Standard pharmacology dose adjustment principles; ICH E6(R2) §4.5.1.

NEW QUESTION # 102

In accordance with the ICH GCP Guideline, who is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the case report forms and in all required reports?

- A. The quality control specialist
- B. The contract research organization monitor
- C. The clinical investigator
- D. The IRB/IEC coordinator

Answer: C

Explanation:

The investigator holds ultimate responsibility for all data reported.

* ICH E6(R2) 4.9.1: "The investigator is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor on the CRFs and all required reports."

* Monitors (D) verify data accuracy but are not responsible for data quality. Quality specialists (B) and IRB staff (C) have no role in data entry.

Correct answer: A (The clinical investigator).

References:

ICH E6(R2), §4.9.1.

NEW QUESTION # 103

A subject currently on a clinical trial was hospitalized for 2 days due to a SAE. The subject reported the hospitalization to the investigator at the next study visit. According to the ICH GCP Guideline, when should the investigator report the SAE to the sponsor?

- A. Immediately
- B. Within 10 working days
- C. Within 15 working days
- D. Within 7 working days

Answer: A

Explanation:

ICH requires immediate reporting of all SAEs to the sponsor (except those protocol-identified as not requiring immediate reporting).

Exact extract:

* ICH E6(R2) 4.11.1: "The investigator should report all serious adverse events immediately to the sponsor except for those SAEs that the protocol... identifies as not needing immediate reporting." Therefore, "Immediately" (A) is correct. The other timeframes are not aligned with ICH GCP for initial SAE notification from investigator to sponsor.

References:

ICH E6(R2) Good Clinical Practice, §4.11.1 (Safety reporting by investigators).=====

NEW QUESTION # 104

A Phase I study of a new blood pressure medication has been submitted for initial approval to an IRB/IEC. In accordance with the CFR, the IRB/IEC must consider which of the following criteria when determining whether to approve the study?

- **A. The equitability of the selection of subjects**
- B. The availability of the patient population
- C. The educational background of the study team
- D. The funding source for the trial

Answer: A

Explanation:

When reviewing protocols, IRBs/IECs are primarily responsible for safeguarding human subjects by evaluating risks, benefits, and fairness in subject selection.

* 21 CFR 56.111(a)(3): "In making its determination the IRB shall determine that... selection of subjects is equitable."

* 45 CFR 46.111(a)(3): Repeats this requirement, emphasizing fairness across gender, race, age, and socioeconomic status.

Other options:

* Patient population availability (A) is a feasibility issue, addressed by investigators and sponsors, not IRBs.

* Education of the study team (C) is confirmed by the sponsor and investigator, not IRB.

* Funding sources (D) may raise conflict of interest concerns, but they are not IRB approval criteria per federal regulations.

Thus, IRBs focus on justice and fairness in subject selection as part of the Belmont Report principles.

References:

21 CFR 56.111(a)(3).

Belmont Report (Justice principle).

NEW QUESTION # 105

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