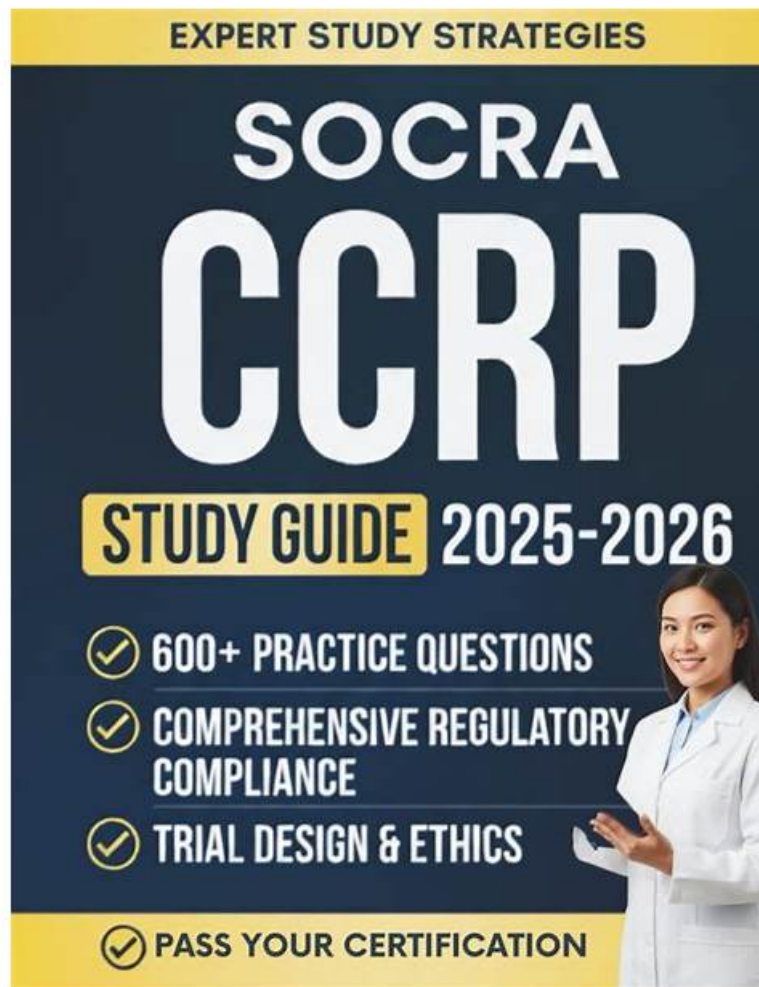


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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q54-Q59):

NEW QUESTION # 54

Which of the following statements about the investigator's brochure is correct?

- A. It includes financial disclosure information from investigators
- B. It consists of the instructions for the investigator to conduct the study
- C. It provides documents that permit the evaluation of the conduct of the study and the quality of the data
- **D. It contains a summary of the pharmacological and toxicological effects of the drug in animals, and to the extent known, in humans**

Answer: D

Explanation:

The Investigator's Brochure (IB) is a critical regulatory document designed to provide investigators with comprehensive knowledge about an investigational product.

* ICH E6(R2) 7.1: Defines the IB as "a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects."

* ICH E6(R2) 7.2.2: Specifies the IB should contain a summary of pharmacological, toxicological, pharmacokinetic, and metabolic studies in animals, as well as results from previous human experience.

* The purpose is to allow investigators to make risk-benefit assessments, support protocol design, and ensure subject safety.

Incorrect options:

* A (instructions to conduct study) describes the protocol, not the IB.

* C (financial disclosures) are required under 21 CFR 54, not part of the IB.

* D refers to trial master file/essential documents, not the IB.

Therefore, the IB's defining function is to provide a scientific summary of preclinical and clinical data supporting safe human use.

References:

ICH E6(R2), §7.1, §7.2.2.

NEW QUESTION # 55

For a study with a significant risk investigational medical device that could optimize the effects of radiation therapy on cancer tumors, the investigational plan states mild burns are an anticipated effect. One subject developed severe burns with blistering. In accordance with the CFR, this effect must be reported to the sponsor and the IRB/IEC as soon as possible and at most how long after the investigator first learns of the effect?

- A. 2 working days
- B. 7 working days
- **C. 10 working days**
- D. 5 working days

Answer: C

Explanation:

In device trials, unanticipated adverse device effects (UADEs) must be promptly reported.

* 21 CFR 812.150(a)(1): "An investigator shall submit to the sponsor and the reviewing IRB a report of any unanticipated adverse device effect as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect." In this case, severe burns with blistering go beyond the anticipated effect of mild burns listed in the investigational plan. Therefore, it qualifies as a UADE and triggers expedited reporting. Options A, B, and C are too short; the regulation specifically mandates a 10 working day maximum timeframe.

Thus, the correct answer is D (10 working days).

References:

21 CFR 812.150(a)(1) (Reporting requirements for investigators).

NEW QUESTION # 56

For a Significant Risk device study, an investigator must report within 5 working days which event?

- A. Completion of investigation

- B. Withdrawal of FDA approval
- C. Unanticipated adverse effect
- **D. Emergency deviation**

Answer: D

Explanation:

* 21 CFR 812.150(a)(4): Any deviation from investigational plan made to protect the life or physical well-being of a subject in an emergency must be reported to the sponsor and IRB within 5 working days.

* Unanticipated adverse device effects have a 10-day reporting window.

References: 21 CFR 812.150(a)(4).

NEW QUESTION # 57

According to the CFR, which of the following is a complete and accurate list of the signatures required on the short form consent document?

- A. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee; the witness
- **B. The subject or else the subject's legally authorized representative; the witness**
- C. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee
- D. The subject or else the subject's legally authorized representative

Answer: B

Explanation:

The short form consent process is permitted when the subject is presented with a brief written statement that they were informed of the study, supplemented by an oral presentation.

* 21 CFR 50.27(b)(2): Requires the short form to be signed by the subject (or legally authorized representative) and a witness.

* The witness ensures that oral consent was properly conveyed and understood.

* The person obtaining consent must sign a separate written summary, but not the short form itself.

Thus, the accurate answer is A: subject (or LAR) + witness.

References:

21 CFR 50.27(b)(2).

NEW QUESTION # 58

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

- A. 400 mg/m²
- B. 420 mg/m²
- **C. 444 mg/m²**
- D. 492 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 # 59

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