



SOCRA CCRP Practice Questions

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Question 1

Question Type: MultipleChoice

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

Options:

- A- 400 mg/m
- B- 420 mg/m
- C- 444 mg/m
- D- 492 mg/m

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Answer:

C

Explanation:

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

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

Question 2

Question Type: MultipleChoice

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?

Options:

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

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Answer:

A

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).

ICH E6(R2), 4.9.1.

Question 3

Question Type: MultipleChoice

An investigator received \$60,000 equity interest three years after study completion. What is the financial reporting requirement?

Options:

- A- None
- B- Report to FDA
- C- Report to OHRP
- D- Report to sponsor

Answer:

A

Explanation:

21 CFR 54.4(b): Requires disclosure during the study and for 1 year after completion.

After three years, no disclosure is required.

Question 4

Question Type: MultipleChoice

On 15 May 2019, a sponsor announced that its investigational compound GHB33IA will not be investigated any further and will not be pursued for a marketing approval. Based on the CFR, what is the earliest date when the site may begin to destroy the study records?

Options:

- A- 16 May 2021
- B- 15 May 2022
- C- 16 May 2022
- D- 15 May 2034

Answer:

C

Explanation:

Record retention requirements ensure regulatory access to data even after development is discontinued.

21 CFR 312.62(c): "An investigator shall retain records... for 2 years after the date a marketing application is withdrawn or discontinued and FDA is notified."

In this case, development was terminated 15 May 2019. Therefore, the 2-year clock starts at discontinuation. Two years later is 15 May 2021, but FDA requires records to be maintained until after the 2-year period ends. The earliest permissible destruction date is 16 May 2022 (C).

Options A and B are premature; D (2034) is far beyond requirements.

Thus, the correct answer is C (16 May 2022).

21 CFR 312.62(c) (Investigator record retention).

21 CFR 312.57(c) (Sponsor record retention).

Question 5

Question Type: MultipleChoice

An investigator reports a serious adverse event suspected to be drug-related. By CFR, the sponsor must notify FDA no later than:

Options:

- A- 1 day
- B- 7 days
- C- 10 days
- D- 15 days

Answer:

B

Explanation:

21 CFR 312.32(c)(2): Life-threatening or fatal unexpected adverse events must be reported within 7 calendar days.

Other serious unexpected events are reported within 15 days.

Question 6

Question Type: MultipleChoice

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

Options:

- A- Unanticipated adverse effect
- B- Completion of investigation
- C- Withdrawal of FDA approval
- 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.



Question 7

Question Type: MultipleChoice

Which option best is considered a source document?

Options:

- A- The subject instruction sheet
- B- Standard operating procedures (SOPs)
- C- The protocol
- D- Pharmacy dispensing records

Answer:

D



Explanation:

Source documents are the original records where trial data are first recorded, from which Case Report Form (CRF) entries are verified.

ICH E6(R2) 1.52: Defines source documents as "original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, pharmacy dispensing records, recorded data from automated instruments, etc.)."

ICH E6(R2) 8.3.13: Requires maintenance of "source documents" to verify data integrity and allow monitoring/audits.

Pharmacy dispensing records (D) fit this definition, as they show initial data on investigational

product dispensing and accountability. In contrast, subject instruction sheets (A) are communication tools, SOPs (B) are procedural guides, and the protocol (C) is a governing document, none of which qualify as original data records.

Therefore, the correct answer is D (Pharmacy dispensing records).

ICH E6(R2), 1.52 (Definition of source documents).

ICH E6(R2), 8.3.13 (Source documents in essential documentation).

Question 8

Question Type: MultipleChoice

Which document was created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and summarizes the basic ethical principles and guidelines for the conduct of research involving human subjects?

Options:

- A- The Nuremberg Code
- B- The Declaration of Helsinki
- C- The ICH Guidelines
- D- The Belmont Report

Answer:

D

Explanation:

The Belmont Report (1979), issued by the U.S. National Commission, identifies three core ethical principles guiding human subject research:

Respect for Persons (informed consent, autonomy, protection of vulnerable populations).

Beneficence (maximize benefits, minimize harms).

Justice (fairness in subject selection and treatment).

The Nuremberg Code (1947) was developed post-WWII to prevent unethical experiments.

The Declaration of Helsinki (1964, updated) is a World Medical Association document guiding

international physician research ethics.

The ICH Guidelines (1996) outline harmonized regulatory requirements for good clinical practice.

Only the Belmont Report fits the description of a U.S.-based, principle-driven framework for human research ethics.

Thus, the correct answer is D (The Belmont Report).

The Belmont Report (1979), National Commission for the Protection of Human Subjects.

45 CFR 46 (Human Subject Protections).



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