

SCDM Practice Test Questions and Answers

1. In SDTM, what is a 'domain'?

- A) A standardized dataset containing related observations of a specific type (e.g., demographics, adverse events)
- B) A geographic region grouping clinical trial sites
- C) A category of edit checks applied to a specific CRF module
- D) A type of electronic signature used in regulatory submissions

2. What is 'eCOA' in clinical data collection?

- A) Electronic Clinical Outcome Assessment — collecting patient or clinician outcomes via electronic devices
- B) Electronic Certificate of Authorization for site access
- C) An EDC module for centralized lab data integration
- D) An electronic SAE reporting portal

3. In MedDRA, what is a 'Preferred Term' (PT)?

- A) A distinct descriptor for a symptom, sign, disease, diagnosis, or therapeutic indication at a specific level of the hierarchy
- B) The highest-level grouping of related medical concepts in MedDRA
- C) A synonym for a verbatim term entered by site staff
- D) The lowest-level code assigned to an individual patient's event

4. In clinical coding, what is a 'synonym list'?

- A) A pre-approved list mapping specific verbatim terms to their corresponding dictionary codes to enable autocoding
- B) A list of acceptable alternative terms for CRF field labels
- C) A glossary of MedDRA terms and their definitions
- D) A catalog of WHO-DD drug names and their generic equivalents

Answers: 1-A 2-A 3-A 4-A

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