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SCDM Certified Clinical Data Manager Sample Questions (Q11-Q16):

NEW QUESTION # 11
During an inspection to determine appropriate documentation for use of a computerized system, what SOP might the inspector expect to find?

- A. Data backup plan
- B. Edit specifications
- C. Statistical analysis plan

- D. Data management plan

Answer: A

Explanation:

During a regulatory inspection, inspectors expect to find documented Standard Operating Procedures (SOPs) governing the use, validation, and maintenance of computerized systems, including data backup and recovery procedures.

According to the GCDMP (Chapter: Computerized Systems and Compliance) and FDA 21 CFR Part 11, organizations must maintain an SOP that ensures data protection against loss, corruption, or unauthorized access. The SOP should describe backup frequency, secure storage, verification of backup integrity, and procedures for data restoration.

While the Data Management Plan (A) and Edit Specifications (D) are study-level documents, and the Statistical Analysis Plan (C) focuses on analysis procedures, only a Data Backup Plan (B) constitutes a required system-level SOP ensuring compliance and data continuity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 5.2 - Data Security, Backup, and Recovery SOPs FDA 21 CFR Part 11 - Subpart B, Controls for Closed Systems ICH E6(R2) GCP, Section 5.5.3 - System Security, Data Backup, and Recovery Requirements

NEW QUESTION # 12
A Data Manager is designing a CRF for a study for which the efficacy data are not covered by the current SDTM domains. Which search should the Data Manager do?

- A. Search for relevant data element standards
- B. Work with the study team to define new data elements
- C. Use controlled terminology covering the needed concepts
- D. Advise the study team not to collect the data

Answer: A

Explanation:

When existing SDTM (Study Data Tabulation Model) domains do not cover specific efficacy data, the best practice is to first search for relevant data element standards that may be available through CDISC CDASH (Clinical Data Acquisition Standards Harmonization) or other recognized industry standards.

Per GCDMP (Chapter: Standards and Data Integration), Data Managers must ensure that new CRF elements are consistent with standardized definitions, controlled terminology, and data models to support interoperability, future analysis, and regulatory submission.

If no existing standards exist, only then should the Data Manager collaborate with the study team to define new elements - but standard searches always come first.

Thus, option C is correct - search for relevant data element standards ensures alignment with CDISC best practices and regulatory expectations.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.1 - Use of CDISC Standards in CRF Design CDISC CDASH Implementation Guide, Section 4.1 - Standardization of Data Collection Fields FDA Study Data Technical Conformance Guide (SDTCG), Section 2.4 - Use of Standard and Custom Domains

NEW QUESTION # 13
A study collects blood pressure. Which is the best way to collect the data?

- A. Check boxes for twenty-point increments
- B. High/Low radio button
- C. Two continuous variables
- D. Coding a verbatim field with a MedDRA diagnosis

Answer: C

Explanation:

Blood pressure is a quantitative physiological measurement, typically consisting of two continuous numeric values: systolic and diastolic pressure. Therefore, the most appropriate and scientifically valid method of data collection is to use two continuous variables (e.g., systolic = 120 mmHg, diastolic = 80 mmHg).

According to the GCDMP (Chapter: CRF Design and Data Collection), data fields must be designed to capture the most precise, accurate, and analyzable form of clinical data. Numeric data should be collected using numeric data types to allow for range checks, calculations (e.g., mean arterial pressure), and statistical analysis.

Options such as categorical representations (radio buttons or check boxes) introduce rounding, data loss, and analytic limitations. Coding a verbatim diagnosis (option A) is inappropriate for numeric vital sign data and violates the principle of capturing data at the most granular level.

Thus, the correct and validated method per CCDM standards is two continuous variables, ensuring accuracy, traceability, and analytical flexibility.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.2 - Best Practices for Quantitative Data Capture ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Accuracy and Collection Standards FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Data Format and Structure Requirements

NEW QUESTION # 14

When reviewing local lab data from a paper study, a Data Manager notices there are lab values not entered. What should the Data Manager request data-entry personnel do?

- A. Call the patient to verify the information
- B. Flag the module for review
- C. Issue a query
- D. Nothing

Answer: C

Explanation:

When laboratory data are missing from a paper-based clinical study, the Data Manager should direct data-entry personnel to issue a query to the investigative site for clarification or correction.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), every missing, inconsistent, or out-of-range data point must be reviewed and, if necessary, resolved through the formal query management process. This ensures that all discrepancies between the source documents and database entries are properly documented, traceable, and auditable.

Data-entry staff are not authorized to infer or fill in missing information. They must escalate such discrepancies to the site via query, preserving data integrity and regulatory compliance with ICH E6 (R2) and FDA 21 CFR Part 11. Calling the patient directly (option B) would violate confidentiality and site communication protocol, while simply flagging or ignoring the issue (options A and D) would not meet GCDMP query resolution standards.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.2 - Query Management and Resolution ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication of Data Discrepancies FDA 21 CFR Part 11 - Electronic Records; Query Audit Trails Requirements

NEW QUESTION # 15

Which statement is true regarding User Acceptance Testing (UAT) in an EDC application?

- A. System tools in EDC do not remove the need for UAT
- B. Every rule should be tested with at least one "pass" and one "fail" scenario
- C. The extent of UAT (i.e., the number of test cases and rules) cannot be risk-based
- D. Data should not be collected in a production environment until UAT is completed

Answer: D

Explanation:

In Electronic Data Capture (EDC) system validation, User Acceptance Testing (UAT) is a mandatory phase that must be completed before data collection begins in the production environment.

According to the GCDMP (Chapter: Database Design, Validation, and Testing) and FDA 21 CFR Part 11, UAT ensures that the EDC system meets all protocol-specific, functional, and regulatory requirements before it is deployed for live use. The goal is to verify that the system performs exactly as intended by simulating real-world user interactions with test data in a validated test environment.

Data collection prior to UAT completion would violate validation requirements and risk noncompliance with ICH E6 (R2) GCP

Section 5.5.3, which mandates that all computerized systems be validated and tested before use.
While options A and C describe correct components of testing strategy, the key regulatory requirement is that UAT must be completed and approved before live data entry begins. Option D is incorrect - risk-based UAT is an accepted modern validation approach under both FDA and GAMP5 principles.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Validation, Section 5.3 - User Acceptance Testing FDA 21 CFR Part 11 - Validation of Electronic Systems (Section 11.10(a)) ICH E6 (R2) GCP, Section 5.5.3 - Validation Before Use in Production Environment

NEW QUESTION # 16

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Of course, at Hogwarts School of Witchcraft and Wizardry, potion making CCDM relies on magic, Notations as more important than methods—As already stated, the notation is the means of communication in a design.

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