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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• Coordination and Project Management Tasks: This domain evaluates the skills of a Clinical Systems Analyst in coordinating data management workload, vendor selection, scheduling, cross-team communication, project timeline management, risk handling, metric tracking, and preparing for audits.
Topic 2	• Testing Tasks: This section measures the skills of Data Managers and involves creating test plans, generating test data, executing validation and user acceptance testing, and documenting results to ensure systems and processes perform reliably and according to specifications.
Topic 3	• Data Processing Tasks: This section measures skills of Clinical Systems Analysts and focuses on handling, transforming, integrating, reconciling, coding, querying, updating, and archiving study data while maintaining quality, consistency, and proper privileges over the data lifecycle.

Topic 4	• Review Tasks: This section measures the skills of Data Managers and involves reviewing protocols, CRFs, data tables, listings, figures, and clinical study reports (CSRs) for consistency, accuracy, and alignment with data handling definitions and regulatory requirements.
Topic 5	• Design Tasks: This section of the CCDM Exam measures skills of Data Managers and covers how to design and document data collection instruments, develop workflows and data flows, specify data elements, CRF forms, edit checks, reports, database structure, and define standards and procedures for traceability and auditability.

SCDM Certified Clinical Data Manager Sample Questions (Q134-Q139):

NEW QUESTION # 134

A relational database has tables for PATIENT_DEMOGRAPHY and VITAL_SIGNS data collected during a visit. The primary key for the VITAL_SIGNS table is a composite key that includes the unique patient identifier, visit number, and vital signs parameter name. The two tables are joined on the patient identifier. What will be the number of records in the result set?

- A. One record per visit
- B. One record per patient
- C. One record per patient per visit per vital sign parameter
- D. One record per patient per visit

Answer: C

Explanation:

In a relational database structure, each record in a table is uniquely identified by a primary key. In this case, the VITAL_SIGNS table uses a composite primary key consisting of:

Patient Identifier,

Visit Number, and

Vital Signs Parameter Name.

This means each record represents a unique measurement of a specific parameter (e.g., blood pressure, pulse) for a patient at a specific visit.

When joining PATIENT_DEMOGRAPHY and VITAL_SIGNS tables on the patient identifier, the result set will include one record for every combination of patient, visit, and parameter - i.e., one record per patient per visit per vital sign parameter.

Therefore, option C correctly describes the expected number of records.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Primary and Foreign Key Relationships in Relational Models

CDISC SDTM Implementation Guide, Section 5.3 - Observation-Level Data Structures ICH E6(R2) GCP, Section 5.5.3 - Data Organization and Integration Principles

NEW QUESTION # 135

Which of the following SOPs are required for management of an EDC system?

- A. Measurement of data quality
- B. Change control
- C. Maintenance of coding dictionaries
- D. Management of vendors

Answer: B

Explanation:

The most essential Standard Operating Procedure (SOP) for management of an Electronic Data Capture (EDC) system is Change Control.

Per GCDMP (Chapter: Computerized Systems and Compliance) and FDA 21 CFR Part 11, any changes made to an EDC system-whether to software configuration, study database design, or system functionality-must follow a documented, validated, and auditable change control process. This ensures that:

Modifications are properly authorized, tested, and approved before implementation.

System validation remains intact.

Data integrity, traceability, and regulatory compliance are maintained.

While vendor management (A) and coding maintenance (C) have supporting SOPs, change control (D) is mandatory for any system handling regulated clinical data. Measurement of data quality (B) is important but not specifically tied to system management procedures.

Thus, option D (Change control) is the correct answer.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 5.3 - Change Control and System Maintenance FDA 21 CFR Part 11 - Electronic Records and Electronic Signatures, Section 11.10(a-k) ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation and Change Documentation

NEW QUESTION # 136

What additional task does the site study coordinator role perform when utilizing an EDC application compared to paper CRF?

- A. Resolving queries
- B. Medical record abstraction
- C. Data curation
- D. Data entry

Answer: D

Explanation:

In paper-based trials, site staff (e.g., study coordinators) record data manually on paper Case Report Forms (CRFs), which are later transcribed by data entry personnel into an electronic database.

However, in EDC-based studies, the site coordinator is directly responsible for entering data into the EDC system. This eliminates the need for centralized double data entry and shortens data cleaning timelines.

The GCDMP (Chapter: Electronic Data Capture Systems) states that EDC systems shift certain tasks, including data entry, initial query response, and source verification preparation, to the site level. Yet, data entry remains the most significant additional responsibility compared to paper-based studies.

Option A (Query resolution) is performed in both EDC and paper-based systems.

Option C (Data curation) is typically a Data Management function.

Option D (Medical record abstraction) is part of source documentation, not specific to EDC.

Thus, option B (Data entry) is correct - it is the additional site coordinator duty unique to EDC environments.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.3 - Site Responsibilities and Workflow Changes ICH E6(R2) GCP, Section 5.5.3 - Data Entry and Role Delegation in Computerized Systems FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.2 - Site-Level Data Entry Controls

NEW QUESTION # 137

Which of the following data verification checks would most likely be included in a manual or visual data review step?

- A. Checking adverse event treatments against concomitant medications
- B. Checking a value against a reference range
- C. Checking an entered value against a valid list of values
- D. Checking mandatory fields for missing values

Answer: A

Explanation:

Manual or visual data review is used to identify complex clinical relationships and contextual inconsistencies that cannot be detected by automated edit checks.

According to the GCDMP (Chapter: Data Validation and Cleaning), automated edit checks are ideal for structured validations, such as missing fields (option C), reference ranges (option D), or predefined value lists (option A). However, certain clinical cross-checks-such as verifying adverse event treatments against concomitant medication records-require clinical judgment and contextual understanding.

For example, if an adverse event of "severe headache" was reported but no analgesic appears in the concomitant medication log, the data may warrant manual review and query generation. These context-based checks are best performed by trained data reviewers or medical data managers during manual data review cycles.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.3 - Manual

Review and Clinical Data Consistency Checks ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Clinical Data Review Responsibilities FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Verification Principles

NEW QUESTION # 138
For clinical investigational sites on an EDC trial, which of the following archival options allows traceability of changes made to data?

- A. Storing the computer used at the clinical investigational site
- B. ASCII files of the site's data and related audit trails
- C. PDF images of the final eCRF screens for each patient
- D. Paper copies of the source documents

Answer: B

Explanation:
Regulatory agencies such as the FDA and ICH require that electronic data be retained in a format that preserves audit trails and traceability.
While PDF images (option C) provide a static representation of data, they do not preserve the underlying audit trail (i.e., who changed what, when, and why). The ASCII data files with corresponding audit trails (option D) provide complete transparency and comply with 21 CFR Part 11 and GCDMP archival standards.
Option A (storing computers) is unnecessary and impractical, and Option B (paper source documents) are site records, not system archives.
Hence, option D is correct - ASCII data files with audit trails meet traceability and compliance standards.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.4 - Archival Formats and Audit Trail Retention ICH E6(R2) GCP, Section 5.5.3 - Data Integrity, Audit Trails, and Record Retention FDA 21 CFR Part 11 - Electronic Records; Audit Trail and Retention Requirements

NEW QUESTION # 139
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