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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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.
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	• 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.

SCDM Certified Clinical Data Manager Sample Questions (Q36-Q41):

NEW QUESTION # 36
Which competency is necessary for EDC system use in a study using the medical record as the source?

- A. Resolving discrepant data
- B. Screening study subjects
- C. Training on how to log into Medical Records system
- D. Using ePRO devices

Answer: C

Explanation:
In studies where the medical record serves as the source document, the Electronic Data Capture (EDC) system users (typically study coordinators or site personnel) must have appropriate training on how to access and log into the medical record system. This competency ensures that data abstracted from the electronic medical record (EMR) are complete, accurate, and verifiable in compliance with Good Clinical Practice (GCP) and Good Clinical Data Management Practices (GCDMP).
According to the GCDMP (Chapter: EDC Systems and Data Capture) and ICH E6(R2), all personnel involved in data entry and verification must be trained in both the EDC and the primary source systems (e.g., EMR). This ensures that the integrity of data flow-from source to EDC-is maintained, and that personnel understand system access controls, audit trails, and proper documentation of source verification.
While resolving discrepant data (C) and screening subjects (A) are part of study operations, the competency directly related to EDC system use in EMR-based studies is the ability to properly log into and navigate the medical records system to extract source data.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Electronic Data Capture (EDC), Section 5.1 - Source Data and System Access Requirements ICH E6(R2) Good Clinical Practice, Section 4.9 - Source Documents and Data Handling FDA Guidance: Use of Electronic Health Record Data in Clinical Investigations, Section 3 - Investigator Responsibilities

NEW QUESTION # 37
Which action has the most impact on the performance of a relational database system?

- A. Executing a properly designed database query
- B. Entering data into the database from CRFs
- C. Making updates to data previously entered into the database
- D. Loading a large lab data file into the database

Answer: D

Explanation:
In a relational database system used in clinical data management, performance refers to how efficiently the system processes transactions, retrieves data, and handles large volumes of information without delay or data integrity issues. Among the listed options,

loading a large lab data file into the database (Option B) has the most significant impact on database performance.
According to the Good Clinical Data Management Practices (GCDMP, Chapter on Database Design and Build), the bulk data load process - such as importing large external datasets (e.g., central lab data, ECG results, or imaging metadata) - can be computationally intensive. This process engages the database's input/output (I/O) subsystem, indexing mechanisms, and transaction logs simultaneously, often locking tables temporarily and consuming significant memory and processing resources.
Unlike standard CRF data entry (Option A) or record updates (Option D), which are incremental and typically processed in smaller transactional batches, bulk loading operations handle thousands or millions of rows at once. If not optimized (e.g., via staging tables, indexing strategies, or commit frequency control), such operations can degrade system performance, slow down concurrent user access, and increase the risk of transaction failure.
Executing a properly designed query (Option C) can also be resource-intensive depending on data volume and join complexity, but when queries are properly optimized (using indexed keys, efficient SQL joins, and selective retrieval), their impact is generally controlled and transient compared to large data imports.
Therefore, as outlined in the GCDMP Database Design and Build and FDA Computerized Systems Guidance, the most performance-impacting activity in a relational database is bulk loading large external datasets, making Option B the correct answer.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Build, Section 6.7 - Database Performance and Optimization FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - System Performance and Data Handling Efficiency ICH E6 (R2) Good Clinical Practice, Section 5.5 - Data Handling and Record Integrity CDISC Operational Data Model (ODM) Implementation Guide - Bulk Data Transfer and Validation Considerations

NEW QUESTION # 38
Which of the following factors can be tested through a second test transfer?

- A. Transfer frequency
- B. File format
- C. Change management
- D. Transfer method

Answer: B

Explanation:
In the context of database design and external data management, a test data transfer (or trial data load) is performed to ensure the proper configuration, structure, and integrity of data imported from an external vendor or system. The second test transfer is specifically useful to confirm that data structures and formats are consistently aligned between the sending and receiving systems after initial adjustments have been made from the first test.
According to the Good Clinical Data Management Practices (GCDMP), the file format - including variables, data types, field lengths, delimiters, and encoding - must be validated during test transfers to confirm compatibility and ensure accurate loading into the target database. Once the initial test identifies and corrects errors (e.g., mismatched variable names or data types), the second transfer verifies that the corrections have been implemented correctly and that the file structure functions as intended.
Testing change management (A) involves procedural controls, not data transfers. The transfer method (C) and transfer frequency (D) are validated during initial process setup, not during subsequent test transfers.
Therefore, option B (File format) is correct, as the second test transfer verifies the technical integrity of the file structure before live production transfers begin.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers and Data Integration, Section 5.2 - Test Transfers and File Validation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Data Import and Validation Controls

NEW QUESTION # 39
A study team member suggests that data for a small, 50-patient, 2-year study can be entered and cleaned in two weeks before lock. Which are important other considerations?

- A. Processing the data in two weeks after the study is over would save money because the data manager would not be involved until the end
- B. Processing the data in two weeks after the study is over would save money because the EDC system would only be needed for a month
- C. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study

- D. It would take more than two weeks to get second iteration queries generated and resolved

Answer: D

Explanation:
The most critical consideration is that data cleaning is an iterative process, and completing all necessary steps - including query generation, site resolution, and second-pass validation - cannot realistically be accomplished within two weeks after study close.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), data cleaning must occur continuously throughout the study, not only at the end. Post-database lock activities typically include running final validation checks, resolving outstanding queries, performing reconciliation (e.g., SAEs, labs, coding), and conducting final quality review.
Even in small studies, query turnaround and response cycles from sites take time - typically 2-4 weeks per iteration - making a two-week total cleaning period unrealistic.
Therefore, Option D is correct: it would take more than two weeks to handle second-round (follow-up) queries and confirm final resolutions prior to database lock.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.4 - Ongoing vs. End-of-Study Data Cleaning ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Quality and Timeliness FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Management and Cleaning

NEW QUESTION # 40
What additional task does the site study coordinator role perform when utilizing an EDC application compared to paper CRF?

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

Answer: B

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 # 41
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