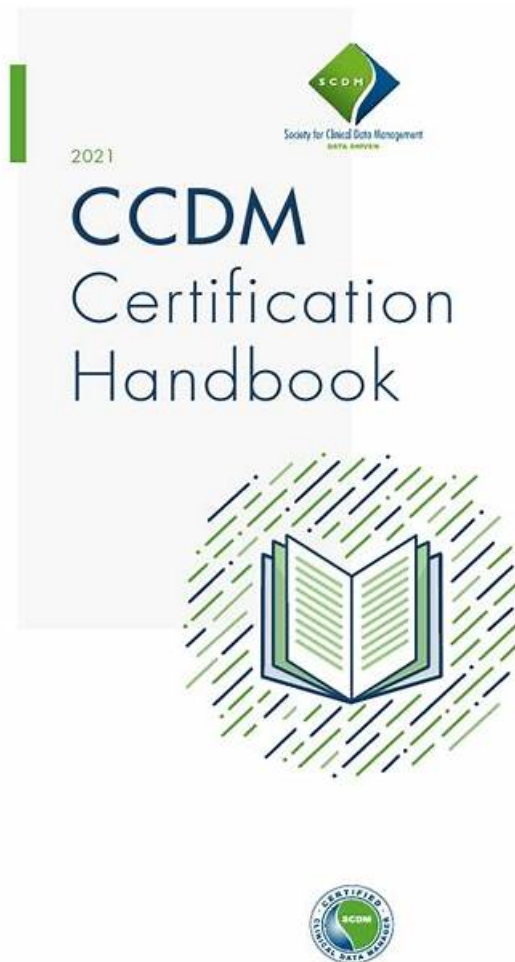# Reliable SCDM CCDM Practice Materials | New CCDM Dumps Book

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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	• 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 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	• 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 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.

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With the ever-increasing competition, people take SCDM CCDMcertification to exhibit their experience, skills, and abilities in a better way. Having Certified Clinical Data Manager CCDM certificate shows that you have better exposure than others. So, CCDM Certification also gives you an advantage in the industry when employers seek candidates for job opportunities. However, preparing for the SCDM CCDM exam can be a difficult and time-consuming process.

SCDM Certified Clinical Data Manager Sample Questions (Q116-Q121):

NEW QUESTION # 116
A Clinical Data Manager reads a protocol for a clinical trial to test the efficacy of an antiviral to counteract a new epidemic. The stated primary efficacy endpoint is 3-month survival. Which data element is needed for the primary efficacy endpoint?

- A. Cause of death
- B. Birth date
- C. Date of autopsy
- D. Death date

Answer: D

Explanation:
When the primary efficacy endpoint in a clinical trial is 3-month survival, the key data element required is the death date. This is because the survival endpoint is determined by calculating whether the subject lived or died within a defined time frame from study enrollment or randomization.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the Clinical Data Manager (CDM) must identify and ensure the capture of all critical data elements necessary to evaluate the study endpoints. For time-to-event analyses (e.g., survival studies), accurate event dates (death date) are essential for endpoint derivation and statistical analysis.
Other data elements such as cause of death or date of autopsy (options B and C) may support secondary analyses or safety reviews but are not necessary to determine the survival endpoint itself. Similarly, birth date (option D) contributes to demographic data but is unrelated to the primary efficacy outcome.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.4 - Critical Data Identification for Endpoints ICH E9 - Statistical Principles for Clinical Trials, Section 2.2.3 - Time-to-Event Data Considerations FDA Guidance for Industry: Clinical Trial Endpoints for Drug Development

NEW QUESTION # 117
Which action has the most impact on the performance of a relational database system?

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

Answer: A

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 # 118

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

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

Answer: A

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 # 119

An external organization has been hired to manage SAE follow-up for a large study. Which of the following would be used as guidance for exchange of the SAE data between the EDC system and the vendor's safety management system?

- A. Submission Data Tabulation Model
- B. Biomedical Research Domain Model
- C. Individual Case Safety Report
- D. Medical Document for Regulatory Activities

Answer: C

Explanation:
The Individual Case Safety Report (ICSR) is the standard format used globally for the exchange of Serious Adverse Event (SAE) data between clinical data management systems (EDC) and safety management systems.
According to ICH E2B(R3) and Good Clinical Data Management Practices (GCDMP, Chapter: Safety Data Management and SAE Reconciliation), the ICSR provides the data structure and content standards for electronic transmission of safety data, including patient demographics, event details, outcomes, and product information. It ensures interoperability between systems by defining standardized message elements and controlled terminologies.
Other options are not applicable:
A . Medical Document for Regulatory Activities (MDRA) is not a recognized standard.
B . Biomedical Research Domain Model (BRIDG) provides conceptual modeling but not data exchange guidance.
D . SDTM is used for regulatory submission datasets, not real-time SAE exchange.
Thus, option C (Individual Case Safety Report) is correct, as it defines the internationally accepted electronic format for SAE data exchange between safety and clinical databases.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Safety Data Management and SAE Reconciliation, Section 4.3 - SAE Data Exchange and Standards
ICH E2B(R3): Electronic Transmission of Individual Case Safety Reports FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Postmarketing ICSRs (2014)

NEW QUESTION # 120
What action should be taken regarding the clinical database when MedDRA releases a new version of its dictionary?

- A. Identify an alternative dictionary.
- B. Evaluate the extent and impact of the changes.
- C. Upgrade the version immediately and recode.
- D. Continue using the existing version to code.

Answer: B

Explanation:
When a new version of MedDRA (Medical Dictionary for Regulatory Activities) is released, the correct action is to evaluate the extent and impact of the changes before implementation.
According to the GCDMP (Chapter: Medical Coding and Dictionaries), MedDRA updates are published twice yearly (March and September). Each release may introduce new terms, modify hierarchies, or retire old ones. Prior to adopting a new version, the Data Manager and Medical Coder must:
Assess the number and type of term changes,
Determine the potential effect on ongoing coding consistency, and
Decide whether migration to the new version is warranted mid-study or deferred until database lock.
Immediate recoding (option C) without evaluation may cause inconsistencies and require additional validation. Continuing with the existing version (option B) may be acceptable short-term but must be justified. Using an alternative dictionary (option D) is noncompliant, as MedDRA is the regulatory standard for safety reporting.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Medical Coding and Dictionaries, Section 6.3 - Version Control and Impact Assessment MedDRA Term Selection: Points to Consider (MSSO, Latest Version), Section 3 - Versioning and Maintenance ICH E2B(R3) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

NEW QUESTION # 121
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