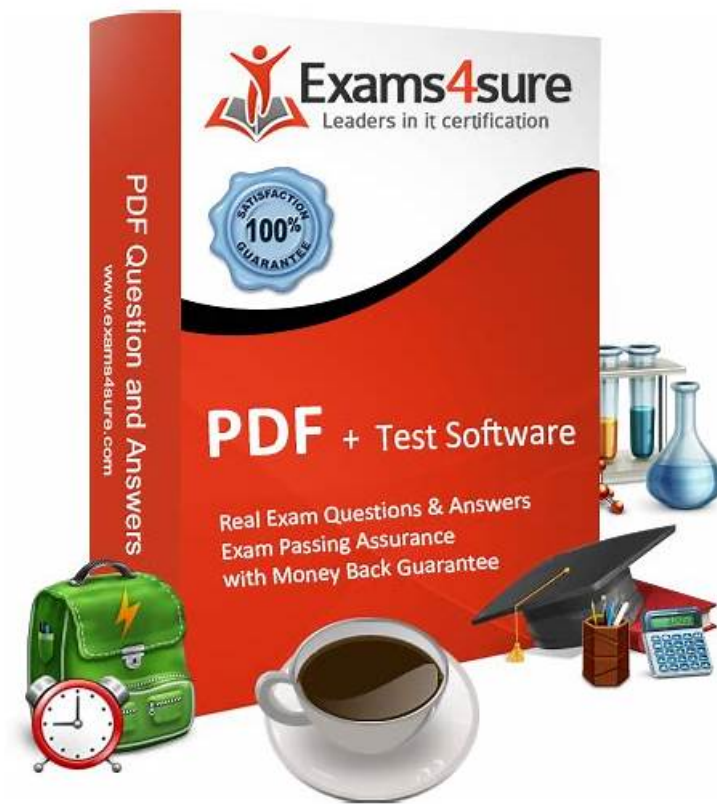# Enhance Your Preparation with the SCDM CCDM Online Practice Test Engine

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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	• 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 4	• 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 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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SCDM Certified Clinical Data Manager Sample Questions (Q46-Q51):

NEW QUESTION # 46
ACME Intervention Co. is testing a new carotid artery stent in patients with coronary artery disease, in hopes of proving superiority over the current standard of care. After a subject signs consent, the surgeon enrolls the patient and retrieves information on which stent to use, but the surgeon does not share this information with the subject. Yesterday, the surgeon was instructed to use the control stent. Today, the surgeon has completed two surgeries: the first one the surgeon was instructed to use the control stent; the second one the surgeon was instructed to use the test stent. In what type of trial is the surgeon participating?

- A. Open label
- B. Cross-over
- C. Double-blind
- D. Single-blind

Answer: D

Explanation:
This scenario describes a single-blind trial, in which only one party-typically the subject-is unaware of the treatment assignment, while the investigator or surgeon knows which intervention is being administered.
In this case, the surgeon receives instructions on which stent (test or control) to use, meaning they are aware of treatment allocation. However, the subject is blinded to which device is being implanted. This setup minimizes subject bias while maintaining procedural safety since the surgeon must know which product to use.
Double-blind (A): Neither subject nor investigator knows the treatment.
Open-label (B): Both subject and investigator know the treatment.
Cross-over (D): Each subject receives both treatments in different periods.
Thus, the correct answer is C. Single-blind, as only the participant remains blinded in this surgical device trial design.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Clinical Trial Phases and Protocols, Section 3.2 - Study Blinding and Randomization Concepts ICH E6(R2) GCP, Section 1.10 - Definition of Blinding/Masking FDA Guidance for Industry: Design Considerations for Pivotal Clinical Investigations for Medical Devices, Section 5.3 - Blinding in Device Studies

NEW QUESTION # 47
A data manager takes the INTERSECTION data in two tables wanting only the 50 records common to both tables. What operation did the data manager perform?

- A. Right outer join
- B. Full outer join
- C. Inner join
- D. Left outer join

Answer: C

Explanation:

The inner join operation retrieves only the records that exist in both tables, which is the intersection of two datasets.

In clinical data management, relational databases often store related data in multiple tables-for example, demographic data in one table and lab results in another. When a Data Manager needs to extract records that exist in both (e.g., subjects appearing in both demographics and labs), an inner join is used.

According to the GCDMP (Chapter: Database Design and Build), joins are fundamental relational operations ensuring data consistency and integrity across multiple data domains.

Inner join: Returns matching records from both tables (intersection).

Left/right outer joins: Return all records from one table and matching records from the other (preserving nonmatches).

Full outer join: Returns all records from both tables, whether matched or not.

Therefore, to select only the 50 records common to both tables, the correct operation is an inner join.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Build, Section 4.3 - Relational Database Concepts and Joins ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Processing and Validation

NEW QUESTION # 48

In a physical therapy study, range of motion is assessed by a physical therapist at each site using a study-provided goniometer. Which is the most appropriate quality control method for the range of motion measurement?

- A. Reviewing data listings for illogical changes in range of motion between visits
- B. Comparison to the measurement from the previous visit
- C. Programmed edit checks to detect out-of-range values upon data entry
- D. Independent assessment by a second physical therapist during the visit

Answer: D

Explanation:

In this scenario, the variable of interest-range of motion (ROM)-is a clinically measured, observer-dependent variable. The accuracy and reliability of such data depend primarily on the precision and consistency of the measurement technique, not merely on data entry validation. Therefore, the most appropriate quality control (QC) method is independent verification of the measurement by a second qualified assessor during the visit (Option D).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Quality Assurance and Control), quality control procedures must be tailored to the nature of the data. For clinically assessed variables, especially those involving human judgment (e.g., physical measurements, imaging assessments, or subjective scoring), real-time verification by an independent qualified assessor ensures that data are valid and reproducible at the point of collection. This approach directly addresses measurement bias, observer variability, and instrument misuse, which are primary sources of data error in clinical outcome assessments.

Other options, while valuable, address only data consistency or plausibility after collection:

Option A (comparison to previous visit) and Option C (reviewing data listings) are retrospective data reviews, suitable for identifying trends but not preventing measurement error.

Option B (programmed edit checks) detects only extreme or impossible values, not measurement inaccuracies due to technique or observer inconsistency.

The GCDMP and ICH E6 (R2) Good Clinical Practice guidelines emphasize that data quality assurance should begin at the source, through standardized procedures, instrument calibration, and dual assessments for observer-dependent measures. Having an independent second assessor ensures inter-rater reliability and provides direct confirmation that the recorded value reflects an accurate and valid measurement.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.4 - Measurement Quality and Verification ICH E6 (R2) Good Clinical Practice, Section 2.13 - Quality Systems and Data Integrity FDA Guidance for Industry: Patient-Reported Outcome Measures and Clinical Outcome Assessment Data, Section 5.3 - Quality Control of Clinician-Assessed Data SCDM GCDMP Chapter: Source Data Verification and Quality Oversight Procedures

NEW QUESTION # 49

A Data Manager is importing lab data for a study. The lab data and the associated audit trail is kept at the central lab. What is necessary to maintain traceability of the transferred data at the Data Manager's location?

- A. Making changes only after data have been imported

- B. Making changes only on the copy of the received data
- C. Maintaining a copy of the data as received
- D. Making changes only for exceptions

Answer: C

Explanation:
Maintaining traceability of external data imports (such as laboratory results) is a fundamental principle of clinical data management.
According to the GCDMP (Chapter: External Data Transfers and Integration), Data Managers must retain an unaltered copy of the raw data exactly as received from the vendor.
This archived version serves as a reference for:
Data provenance verification,
Audit trail review, and
Discrepancy resolution between vendor and study database.
Since the central lab maintains its own audit trail, the Data Manager's responsibility is to preserve the original data transmission file before applying transformations, merges, or validations.
Options A, C, and D describe procedural safeguards but do not meet the regulatory requirement of traceable data lineage. Only option B (Maintaining a copy of the data as received) ensures compliance with ICH E6(R2) and FDA 21 CFR Part 11 standards for data traceability and integrity.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: External Data Transfers and Integration, Section 5.2 - Data Traceability and Version Control ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Source Data Verification FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Source Data Traceability and Archiving

NEW QUESTION # 50
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. Biomedical Research Domain Model
- B. Submission Data Tabulation Model
- C. Medical Document for Regulatory Activities
- D. Individual Case Safety Report

Answer: D

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 # 51
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