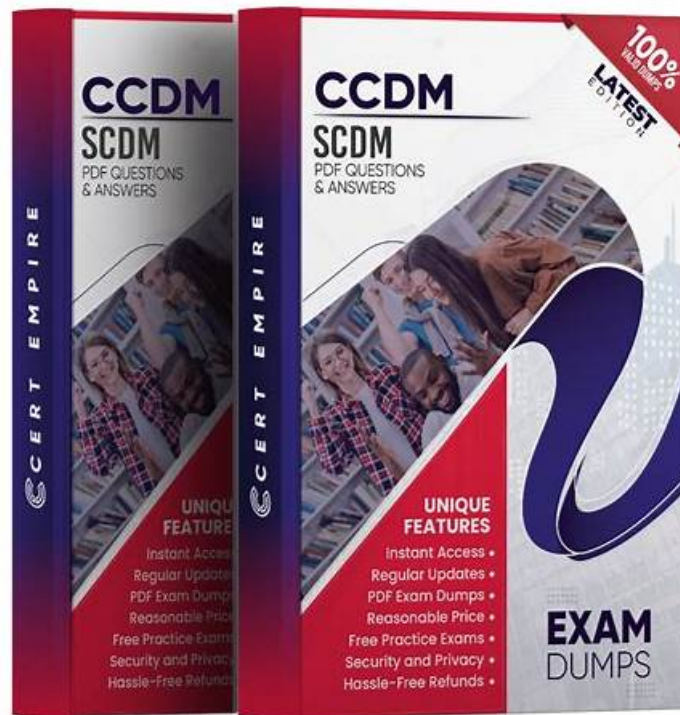


# Exam SCDM CCDM Testking | CCDM Valid Test Voucher



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The CCDM certification verifies that you are a skilled professional. PassSureExam product is designed by keeping all the rules and regulations in focus that SCDM publishes. Our main goal is that you can memorize the actual SCDM CCDM exam question to complete the Certified Clinical Data Manager (CCDM) test in time with extraordinary grades. SCDM CCDM Exam Dumps includes SCDM CCDM dumps PDF format, desktop CCDM practice exam software, and web-based CCDM practice test software.

## SCDM CCDM Exam Syllabus Topics:

| Topic   | Details  |
|---------|--|
| Topic 1 | <ul style="list-style-type: none"> <li>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.</li> </ul>                                   |
| Topic 2 | <ul style="list-style-type: none"> <li>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.</li> </ul>   |
| Topic 3 | <ul style="list-style-type: none"> <li>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.</li> </ul> |
| Topic 4 | <ul style="list-style-type: none"> <li>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.</li> </ul>   |

Topic 5

- 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.

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## Free PDF Quiz High Pass-Rate SCDM - Exam CCDM Testking

In today's technological world, more and more students are taking the Certified Clinical Data Manager (CCDM) exam online. While this can be a convenient way to take an Certified Clinical Data Manager (CCDM) exam dumps, it can also be stressful. Luckily, PassSureExam's best Certified Clinical Data Manager (CCDM) exam questions can help you prepare for your Certified Clinical Data Manager (CCDM) certification exam and reduce your stress.

### SCDM Certified Clinical Data Manager Sample Questions (Q40-Q45):

#### NEW QUESTION # 40

During testing of an ePRO system, a test fails. Which information should be found in the validation documentation?

- A. Root cause analysis of the system errors
- B. Training requirements
- C. Reconciliation datapoints
- D. Expected and actual results

**Answer: D**

Explanation:

When a system validation test fails during Electronic Patient-Reported Outcome (ePRO) system testing, the validation documentation must record the expected results (what should have occurred) and the actual results (what occurred). According to the GCDMP (Chapter: Database Validation and Testing), proper system validation documentation ensures traceability, reproducibility, and compliance with FDA 21 CFR Part 11 and ICH E6 (R2). Each test case must include:

Test objective,  
Preconditions,  
Test steps,  
Expected results,  
Actual results, and  
Pass/fail status.

If a test fails, this documentation provides the objective evidence necessary for deviation handling, issue resolution, and re-testing. While a separate root cause analysis may be performed later (option D), the validation record itself must focus on verifying outcomes against predefined expectations.

Therefore, the correct answer is B - Expected and actual results.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Validation and Testing, Section 4.4 - Documentation of Test Results FDA 21 CFR Part 11 - Validation Requirements (Section 11.10(a)) ICH E6 (R2) GCP, Section 5.5.3 - Computer System Validation and Documentation

#### NEW QUESTION # 41

Which information should an auditee expect prior to an audit?

- A. Standard operating procedures
- B. Corrective action requests
- C. Audit plan or agenda
- D. Auditor's credentials and certification number

**Answer: C**

Explanation:

Prior to an audit, the auditee should expect to receive an audit plan or agenda, which outlines the scope, objectives, schedule, and

logistics of the audit.

According to the GCDMP (Chapter: Quality Assurance and Audits), an audit plan ensures transparency, preparation, and efficient execution. It typically includes details such as:

The audit scope and objectives,

The audit team members,

Documents or processes to be reviewed, and

The audit schedule and timeframe.

This allows the auditee to prepare the necessary records, staff, and facilities. While the auditor's credentials (option A) may be shared informally, they are not a regulatory requirement. Corrective actions (option B) are outcomes of the audit, not pre-audit materials. Standard Operating Procedures (option C) may be requested during the audit but are not provided in advance.

Thus, Option D - Audit Plan or Agenda - is the correct and compliant answer.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Quality Assurance and Audits, Section 6.1 - Pre-Audit Planning and Communication ICH E6 (R2) Good Clinical Practice, Section 5.19.3 - Audit Procedures and Responsibilities FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section 8.1 - Audit Preparation and Planning

### NEW QUESTION # 42

Which of the following factors can be tested through a second test transfer?

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

**Answer: A**

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 # 43

All of the following are preparation processes the data manager needs to take prior to database closure EXCEPT:

- A. Ensuring all data expected for the study has been received.
- B. Performing SAE reconciliation between the clinical and safety databases.
- C. Ensuring study close out visits have been complete.
- D. Checking for uncoded terms in all panels that are coded.

**Answer: C**

Explanation:

Before database lock, the Data Manager must confirm that all collected data are complete, validated, and reconciled across systems. This includes:

Ensuring data completeness (B) - confirming all expected forms and data files have been received.

Verifying coded data (A) - ensuring no pending terms remain in coding dictionaries like MedDRA or WHO Drug.

Performing SAE reconciliation (C) - cross-checking the clinical database against the safety system for accuracy. However, ensuring study close-out visits (D) is not a data management function; it falls under clinical operations and monitoring responsibilities. While data management may review confirmation of site close-outs, the activity itself is not part of pre-database lock procedures.

Therefore, option D correctly identifies the exception-an activity outside the data manager's direct scope of responsibility before database closure.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.3 - Pre-Lock Validation and Reconciliation Activities ICH E6(R2) GCP, Section 5.5.3 - Data Handling and Quality Control Prior to Lock FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - Database Management and Lock Procedures

#### NEW QUESTION # 44

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

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

**Answer: B**

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 # 45

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The most important thing for preparing the CCDM exam is reviewing the essential point. In order to service the candidates better, we have issued the CCDM test prep for you. Our company has accumulated so much experience about the test. So we can predict the real test precisely. Almost all questions and answers of the real exam occur on our CCDM Guide braindumps. That means if you study our study guide, your passing rate is much higher than other candidates. Preparing the exam has shortcut.

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