

# 2026 Fantastic SCDM CCDM: Certified Clinical Data Manager Reliable Study Questions



## SCDM CCDM

Certified Clinical Data Manager Exam

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### SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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 2	<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 3	<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 4	<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 5	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

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### SCDM Certified Clinical Data Manager Sample Questions (Q75-Q80):

#### NEW QUESTION # 75

In an EDC study, an example of an edit check that would be inefficient to run at data entry is a check:

- A. Against a valid list of values.
- B. On the format of a date.
- C. Against a valid numeric range.
- **D. Across visits for consistency.**

**Answer: D**

Explanation:

In Electronic Data Capture (EDC) systems, edit checks are categorized based on when and how they are executed - typically immediate (at data entry) or batch (post-entry). Checks that require data from multiple visits or forms are generally inefficient to run at data entry because they depend on information that may not yet exist in the system.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), cross-visit consistency checks - such as comparing baseline and follow-up blood pressure or verifying date order between screening and dosing - should be executed as batch or scheduled validations, not at the point of data entry. Running these complex checks in real time can slow system performance, increase query load unnecessarily, and confuse site users if related data are not yet entered. Conversely, edit checks against valid ranges, formats, or predefined value lists (options A, C, and D) are simple, local validations ideally performed immediately at data entry to prevent basic errors.

Therefore, cross-visit consistency checks (Option B) are best executed later, making them inefficient for real-time data entry validation.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.4 - Real-Time vs. Batch Edit Checks  
 FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Edit Checks and Data Validation Logic  
 CDISC SDTM Implementation Guide - Section on Temporal Data Consistency Validation

#### NEW QUESTION # 76

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 # 77**

What does 21 CFR Part 11 dictate in regards to a minimum expectation of EDC training prior to access?

- **A. Training must be performed**
- B. Training must be face to face
- C. Training must include an exam
- D. Training must be in the user's native language

**Answer: A**

Explanation:

Under FDA 21 CFR Part 11, organizations using electronic systems must ensure that all system users are trained to perform their assigned functions before gaining access to the system. The regulation requires documented evidence of training but does not specify how it should be conducted (e.g., exam-based, in person, or language-specific).

The GCDMP (Chapter: Computerized Systems and Compliance) further clarifies that personnel training should include instruction on system functionality, audit trails, data entry procedures, and electronic signatures to maintain compliance and data integrity. Training must be performed and documented but does not require a specific format or delivery method.

Therefore, option A-Training must be performed-is correct, as it reflects the minimum regulatory expectation per FDA and SCDM standards.

Reference (CCDM-Verified Sources):

FDA 21 CFR Part 11, Section 11.10(i) - Personnel Training Requirements

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 5.4 - System Training and Documentation ICH E6(R2) GCP, Section 2.8 - Qualified Personnel and Training Requirements

#### **NEW QUESTION # 78**

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. Expected and actual results**
- D. Reconciliation datapoints

**Answer: C**

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 # 79

During a database audit, it was determined that there were more errors than expected. Who is responsible for assessing the overall impact on the analysis of the data?

- A. Data Manager
- **B. Statistician**
- C. Investigator
- D. Quality Auditor

**Answer: B**

Explanation:

The Statistician is responsible for assessing the overall impact of data errors on the analysis and study results.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control) and ICH E9 (Statistical Principles for Clinical Trials), while the Data Manager ensures data accuracy and completeness through cleaning and validation, the Statistician determines whether the observed data discrepancies are statistically significant or if they may affect the validity, power, or interpretability of the study's outcomes.

The Quality Auditor (C) identifies and reports issues but does not quantify analytical impact. The Investigator (D) is responsible for clinical oversight, not statistical assessment. Thus, after a database audit, the Statistician (B) performs a formal evaluation to determine whether the magnitude and nature of the errors could bias results or require reanalysis.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Data Audit and Impact Assessment ICH E9 - Statistical Principles for Clinical Trials, Section 3.2 - Data Quality and Analysis Impact Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Validation and Analysis Review

### NEW QUESTION # 80

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