

# 2026 CCDM: Updated Valid Test Certified Clinical Data Manager Fee

## Certified Clinical Data Manager (CCDM) Practice Exam

**Question 1: What does Clinical Data Management primarily involve?**

- A. Developing clinical protocols
- B. Ensuring accurate and timely collection, validation, and reporting of trial data
- C. Marketing clinical research findings
- D. Overseeing patient recruitment processes

Answer: B

Explanation: Clinical Data Management focuses on collecting, validating, and reporting trial data accurately and on time, which is essential for reliable study outcomes.

**Question 2: Which stakeholder is primarily responsible for overseeing regulatory compliance of clinical trial data?**

- A. Clinical Data Manager
- B. Sponsor
- C. Regulatory Bodies
- D. Site Investigator

Answer: C

Explanation: Regulatory bodies, such as the FDA, are charged with ensuring that clinical trial data meets regulatory standards.

**Question 3: Which document outlines the procedures for data collection and management in clinical trials?**

- A. Informed Consent Form
- B. Data Management Plan
- C. Clinical Study Report
- D. Investigator Brochure

Answer: B

Explanation: The Data Management Plan (DMP) details the procedures for data collection, validation, cleaning, and reporting throughout the trial.

**Question 4: What is a key responsibility of a Clinical Data Manager?**

- A. Designing marketing strategies
- B. Managing data validation and query resolution
- C. Recruiting study participants
- D. Developing new drugs

Answer: B

Explanation: Clinical Data Managers are responsible for data validation, ensuring data integrity, and managing queries to resolve discrepancies.

**Question 5: Which guideline is commonly followed to ensure data quality in clinical trials?**

- A. ICH-GCP
- B. ISO 9001
- C. Six Sigma

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## 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>• <b>Data Processing Tasks:</b> 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>
Topic 4	<ul style="list-style-type: none"> <li>• <b>Design Tasks:</b> 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 5	<ul style="list-style-type: none"> <li>• <b>Review Tasks:</b> 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>

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### SCDM Certified Clinical Data Manager Sample Questions (Q129-Q134):

#### NEW QUESTION # 129

A site study coordinator attempts to make an update in a study database in an EDC system after lock. What occurs?

- A. The change is approved by the Data Manager before it is applied
- **B. The site study coordinator is not able to make the change**
- C. The old value is replaced in all locations by the new value
- D. The change is logged as occurring after lock

**Answer: B**

Explanation:

Once a clinical database is locked, it becomes read-only - no further data modifications can be made by any users, including site personnel. This ensures that the data are finalized, consistent, and auditable for statistical analysis and regulatory submission. According to the GCDMP (Chapter: Database Lock and Archiving), the lock process involves freezing the database to prevent accidental or unauthorized changes. After lock, access permissions are restricted, and all edit and update functions are disabled. If any corrections are required post-lock, the database must be unlocked under controlled procedures (with full audit trail documentation).

Thus, option C - The site study coordinator is not able to make the change - correctly reflects standard EDC functionality and regulatory compliance.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.2 - Database Lock Procedures and Controls ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Audit Trail Requirements FDA 21 CFR Part 11 - Controls for Electronic Records and System Lock Functions

#### NEW QUESTION # 130

When reviewing local lab data from a paper study, a Data Manager notices there are lab values not entered. What should the Data Manager request data-entry personnel do?

- A. Flag the module for review
- B. Nothing
- C. Call the patient to verify the information

- **D. Issue a query**

**Answer: D**

Explanation:

When laboratory data are missing from a paper-based clinical study, the Data Manager should direct data-entry personnel to issue a query to the investigative site for clarification or correction.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), every missing, inconsistent, or out-of-range data point must be reviewed and, if necessary, resolved through the formal query management process. This ensures that all discrepancies between the source documents and database entries are properly documented, traceable, and auditable.

Data-entry staff are not authorized to infer or fill in missing information. They must escalate such discrepancies to the site via query, preserving data integrity and regulatory compliance with ICH E6 (R2) and FDA 21 CFR Part 11. Calling the patient directly (option B) would violate confidentiality and site communication protocol, while simply flagging or ignoring the issue (options A and D) would not meet GCDMP query resolution standards.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.2 - Query Management and Resolution ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication of Data Discrepancies FDA 21 CFR Part 11 - Electronic Records; Query Audit Trails Requirements

### NEW QUESTION # 131

ePRO data are collected for a study using study devices given to subjects. Which is the most appropriate quality control method for the data?

- A. Data visualizations to look for site-to-site variation
- **B. Programmed edit checks to detect out of range values upon data entry**
- C. Manual review of data by the site study coordinator at the next visit
- D. Programmed edit checks to detect out of range values after submission to the database

**Answer: B**

Explanation:

When electronic patient-reported outcomes (ePRO) devices are used, data are captured directly by subjects through validated devices and transmitted electronically to the study database. To ensure real-time data quality control, programmed edit checks should be implemented at the point of data entry - that is, as subjects input data into the device.

According to Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), front-end programmed edit checks are the optimal method to prevent entry of invalid or out-of-range values in ePRO systems. This helps maintain data accuracy at the source, minimizing downstream queries and data cleaning workload.

Options A and B involve post-submission or manual review, which is less efficient and not compliant with the principle of first-pass data validation. Option C (visualization) is a valuable secondary QC method for trends, but not for immediate data validation.

Therefore, option D is correct - programmed edit checks upon data entry ensure immediate validation and higher data integrity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Automated Edit Checks and Front-End Validation ICH E6(R2) GCP, Section 5.5.3 - Computerized System Controls and Validation FDA Guidance for Industry: Electronic Source Data in Clinical Investigations (2013), Section 6 - Real-Time Data Quality Control

### NEW QUESTION # 132

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

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

**Answer: B**

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 # 133

A Data Manager is designing a report to facilitate discussions with sites regarding late data. Which is the most important information to display on the report to encourage sites to provide data?

- A. Expected versus actual forms entered
- **B. List of outstanding forms**
- C. Number of forms entered in the last week
- D. Total number of forms entered to date

**Answer: B**

Explanation:

In managing site data timeliness, the most actionable and effective tool is a report listing all outstanding (missing or incomplete) CRFs.

According to GCDMP (Chapter: Communication and Study Reporting), Data Managers must provide site-level performance reports highlighting:

Outstanding CRFs not yet entered,

Unresolved queries, and

Pending data corrections.

Such reports help sites prioritize and address data gaps efficiently.

Option A and D are historical metrics without actionable context.

Option B gives a general overview but lacks specific site-level actionability.

Hence, option C (List of outstanding forms) provides the clearest and most motivating feedback to sites for timely data entry and query resolution.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Communication and Study Reporting, Section 5.3 - Data Timeliness and Reporting Metrics ICH

E6(R2) GCP, Section 5.1.1 - Sponsor Oversight and Data Communication Requirements FDA Guidance for Industry:

Computerized Systems Used in Clinical Investigations, Section 6.5 - Site-Level Data Timeliness Reporting

### NEW QUESTION # 134

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