

2026 SCDM CCDM: Certified Clinical Data Manager–Trustable Exam Sample Online

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">• 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.

Topic 2	<ul style="list-style-type: none"> • 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 3	<ul style="list-style-type: none"> • 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 4	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q96-Q101):

NEW QUESTION # 96

A study team member suggests that data for a small, 50-patient, 2-year study can be entered and cleaned in two weeks before lock. Which are important other considerations?

- A. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study
- **B. It would take more than two weeks to get second iteration queries generated and resolved**
- C. Processing the data in two weeks after the study is over would save money because the data manager would not be involved until the end
- D. Processing the data in two weeks after the study is over would save money because the EDC system would only be needed for a month

Answer: B

Explanation:

The most critical consideration is that data cleaning is an iterative process, and completing all necessary steps - including query generation, site resolution, and second-pass validation - cannot realistically be accomplished within two weeks after study close. According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), data cleaning must occur continuously throughout the study, not only at the end. Post-database lock activities typically include running final validation checks, resolving outstanding queries, performing reconciliation (e.g., SAEs, labs, coding), and conducting final quality review. Even in small studies, query turnaround and response cycles from sites take time - typically 2-4 weeks per iteration - making a two-week total cleaning period unrealistic.

Therefore, Option D is correct: it would take more than two weeks to handle second-round (follow-up) queries and confirm final resolutions prior to database lock.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.4 - Ongoing vs. End-of-Study Data Cleaning ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Quality and Timeliness FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Management and Cleaning

NEW QUESTION # 97

Which is the most important reason for why a data manager would review data before a monitor reviews it?

- A. The GCDMP recommends that data managers review data prior to a monitor's review.
- **B. Data can be viewed and discrepancies highlighted prior to a monitor's review.**
- C. Data managers have access to programming tools to identify discrepancies.
- D. Data managers write the Data Management Plan that specifies the data cleaning workflow.

Answer: B

Explanation:

The primary reason data managers review data before a monitor's review is to identify and flag discrepancies or inconsistencies so that site monitors can focus their efforts more efficiently during on-site or remote source data verification (SDV).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), proactive data review by data management staff ensures data completeness and accuracy by identifying missing, inconsistent, or out-of-range values. This pre-review helps streamline the monitoring process, reduces the volume of open queries, and enhances data quality.

Option A is true but not the main reason for pre-monitor review. Option C highlights a capability rather than a rationale. Option D is partially correct, but the GCDMP emphasizes process purpose, not prescriptive order. Thus, option B correctly captures the practical and process-oriented reason for early data review-to ensure data are ready and accurate for the monitor's review phase.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Data Review Timing and Purpose ICH E6(R2) GCP, Section 5.18 - Monitoring and Data Verification Requirements

NEW QUESTION # 98

Which of the following processes is the most likely to remain in a study that utilizes electronic data capture?

- A. Retrieving case report forms
- B. Updating the in-house database
- C. Tracking case report forms
- **D. Resolving queries**

Answer: D

Explanation:

In studies utilizing Electronic Data Capture (EDC) systems, many traditional paper-based processes such as tracking and retrieving CRFs are eliminated or automated. However, query management and resolution remain essential because discrepancies, missing data, and protocol deviations still require clarification and correction, regardless of the data collection medium.

According to the GCDMP (Chapter: Data Validation and Cleaning), data queries are generated automatically or manually when inconsistencies are detected by edit checks. Sites must still respond to these queries electronically to ensure the integrity and completeness of data.

A and D are obsolete with EDC (no physical CRFs).

B refers to manual data entry updates, which are replaced by direct EDC entry.

C (Resolving queries) continues as a key part of the data management workflow, even in fully electronic environments.

Thus, option C is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.4 - Query Generation and Resolution in EDC Systems ICH E6(R2) GCP, Section 5.5.3 - Data Review and Query Resolution Requirements FDA 21 CFR Part 11 - Electronic Records: Audit Trails and Query Documentation C

NEW QUESTION # 99

Which is the best way to see site variability in eligibility screening?

- **A. Plot eligibility rate by site**
- B. List eligibility waivers by site
- C. Summarize screening rate by site
- D. Graph enrollment by site

Answer: A

Explanation:

To identify site variability in eligibility screening, the most effective approach is to plot eligibility rate by site. This allows visual detection of differences in how well each site screens subjects according to protocol-defined inclusion and exclusion criteria. The GCDMP (Chapter: Data Quality Assurance and Metrics) emphasizes the importance of graphical analysis for identifying anomalies and site-level performance variability. By plotting the eligibility rate by site, data managers and clinical operations teams can quickly identify outliers-sites that screen too many or too few eligible subjects-indicating potential training issues, misunderstanding of inclusion/exclusion criteria, or even possible protocol deviations.

While summarizing screening rate (B) provides useful numeric data, it lacks visual comparability. Listing waivers (A) or enrollment counts (C) provide limited insights into eligibility consistency.

Therefore, option D-Plot eligibility rate by site-is the best analytic and visualization practice to assess site variability in screening outcomes.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.1 - Use of Metrics and Graphical Review for Site Performance ICH E6(R2) GCP, Section 5.18.4 - Identification of Systematic or Site-Specific Issues

NEW QUESTION # 100

Which is a minimum prerequisite that should be in place before choosing an EDC system?

- A. Draft validation plan
- B. Updated governance documentation
- C. Completed installation qualification
- **D. Knowledge of functional requirements**

Answer: D

Explanation:

Before selecting an Electronic Data Capture (EDC) system for a clinical trial, it is essential to have a clear understanding of the functional requirements. This serves as the minimum prerequisite to guide system selection, ensuring that the EDC solution aligns with the protocol needs, data workflow, security requirements, and regulatory compliance.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Computerized Systems and Compliance), functional requirements describe what the system must do-such as data entry capabilities, edit checks, query management, user roles, audit trails, and integration with external systems (e.g., labs, ePRO). This understanding allows sponsors and CROs to evaluate vendor systems effectively during the selection and qualification phase.

Other options:

B . Installation qualification and D. Validation plan occur after system selection.

C . Governance documentation supports operations but is not required before choosing the system.

Hence, option A is correct - the first and most essential prerequisite before EDC selection is a solid understanding of the functional requirements.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 4.2 - Requirements Gathering and System Selection FDA 21 CFR Part 11 - System Validation and Intended Use Requirements ICH E6(R2) GCP, Section 5.5.3 - Computerized System Selection and Qualification

NEW QUESTION # 101

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