

Pass Guaranteed SCDM - CCDM - Certified Clinical Data Manager–Efficient Exam Objectives

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"> 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 2	<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 3	<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 4	<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 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.

SCDM Certified Clinical Data Manager Sample Questions (Q70-Q75):

NEW QUESTION # 70

What should be done if the site continues to provide inconsistent data after several re-queries?

- A. Do nothing, the data will remain inconsistent
- B. Gently lead the site to the correct response
- C. Escalate the issue to the appropriate site contact personnel
- D. Continue to re-query until the site changes the data

Answer: C

Explanation:

If a clinical site continues to provide inconsistent or illogical data after multiple queries, the correct course of action is to escalate the issue to the appropriate site contact personnel, typically the Clinical Research Associate (CRA) or Site Monitor.

According to the Good Clinical Data Management Practices (GCDMP), persistent data discrepancies often indicate a misunderstanding of the protocol, CRF instructions, or data entry procedures at the site level. Repeatedly re-querying the same data without escalation wastes time and risks introducing bias or error. By escalating through formal communication channels, the issue can be clarified through re-training, documentation review, or site monitoring visits.

The GCDMP emphasizes that escalation ensures data accuracy, site accountability, and protocol adherence, maintaining both data quality and regulatory compliance. Data managers must document the escalation process in the Data Management Plan (DMP) and ensure proper follow-up resolution is achieved.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 4.2 - Handling Persistent Data Discrepancies ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Communication FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Issue Escalation

NEW QUESTION # 71

Which list should be provided to support communication with sites regarding late data and queries?

- A. List of outstanding data and queries by site
- B. List of subjects screened and enrolled by site
- C. List of entered and clean data by site
- D. List of user account activity by site

Answer: A

Explanation:

Effective site communication in data management relies on transparent reporting of pending issues such as open queries, missing data, and overdue updates. According to the Good Clinical Data Management Practices (GCDMP, Chapter: Communication and Metrics), the list of outstanding data and queries by site provides a direct, actionable overview of what each site needs to address, supporting accountability and timely resolution.

This list typically includes subject identifiers, query types, dates generated, and status of resolution, allowing data managers to prioritize site follow-ups. Regular distribution of this report fosters efficient collaboration between the data management team, monitors, and site staff, ultimately improving database cleanliness and timeline adherence.

Options A and B reflect general study status but do not target data issue resolution. Option C pertains to user access oversight, not data progress. Hence, option D is the correct and most operationally relevant answer.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Communication and Metrics, Section 5.2 - Site Reporting and Query Management Metrics ICH E6(R2) GCP, Section 5.18 - Site Oversight and Communication Requirements

NEW QUESTION # 72

A study is collecting ePRO assessments as well as activity-monitoring data from a wearable device. Which data should be collected from the ePRO and activity-monitoring devices to synchronize the device data with the visit data entered by the site?

- A. Geo-spatial location and study subject identifier
- B. Study subject identifier and date/time
- C. Geo-spatial location
- D. Study subject identifier

Answer: B

Explanation:

To synchronize data from electronic patient-reported outcomes (ePRO) and wearable activity-monitoring devices with site-entered visit data, both the study subject identifier and date/time are essential.

According to the GCDMP (Chapter: Data Management Planning and Study Start-up), each dataset must contain key identifiers that allow for accurate data integration and temporal alignment. In studies involving multiple digital data sources, time-stamped subject identifiers are necessary to ensure that the device-generated data correspond to the correct subject and study visit.

The subject identifier ensures data traceability and linkage to the appropriate participant, while date/time allows synchronization of device data (e.g., activity or physiological measurements) with the corresponding site-reported visit or event. Geo-spatial data (options C and D) are typically not relevant to study endpoints and pose unnecessary privacy risks under HIPAA and GDPR guidelines.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Integration and eSource Data, Section 5.2 - Data Alignment and Synchronization Principles FDA Guidance for Industry: Use of Electronic Health Record Data in Clinical Investigations, Section 4.2 - Data Linking and Synchronization ICH E6 (R2) GCP, Section 5.5.3 - Data Traceability and Integrity

NEW QUESTION # 73

What does RACI stand for?

- A. Responsibility, Accountability, Consultation, Information
- B. Responsible, Accountable, Contribute, Input
- C. Responsible, Accountable, Consulted, Informed
- D. Recommend, Approve, Calibrate, Innovate

Answer: C

Explanation:

RACI is a project management and governance framework used to define roles and responsibilities within a project. Each letter

represents a distinct role type:

Responsible (R): The person(s) who perform the work or execute the task.

Accountable (A): The individual ultimately answerable for the task's completion and success (only one per activity).

Consulted (C): Subject matter experts who provide input or guidance before decisions are made.

Informed (I): Individuals kept up to date on progress or outcomes but not directly involved in execution.

The RACI model ensures clarity in ownership and accountability, preventing duplication of effort or responsibility confusion. It is a key component of the GCDMP (Chapter: Project Management in Data Management) for ensuring clear delegation and communication within clinical data management teams.

Hence, option D is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Project Management in Data Management, Section 5.1 - Roles, Responsibilities, and RACI Matrices
Project Management Institute (PMI) Framework - Responsibility Assignment Matrices (RACI) ICH E6(R2) GCP, Section 5.1.1 - Defined Roles and Quality Oversight Responsibilities

NEW QUESTION # 74

Which is the best reason why front-end checks are usually kept minimal, when compared to back-end checks, in a paper-based clinical study?

- A. There are approvals required to raise a Data Clarification Form which could take time
- B. Data review can be performed at a later time due to the paper-based studies being smaller in size
- **C. Data entry staff should be able to enter a value into the database just as it appears in the paper CRF**
- D. There is no need to alert the site personnel immediately about a data issue, as the study has happened already

Answer: C

Explanation:

In paper-based clinical studies, front-end data checks (those performed during data entry) are intentionally kept minimal to ensure that data are entered exactly as recorded on the paper CRF. This principle ensures data integrity by maintaining fidelity between source and electronic records before any cleaning or edit validation occurs.

The GCDMP (Chapter: Data Validation and Cleaning) explains that data entry operators should input values as written, even if they appear incorrect or inconsistent, because the purpose of front-end checks is not to interpret but to capture data faithfully. The back-end edit checks-performed later by data managers-are designed to identify inconsistencies, out-of-range values, or logical errors that require clarification through queries.

This approach separates data capture from data cleaning, minimizing bias and preserving original investigator input. Hence, option A accurately states the rationale for keeping front-end checks minimal in paper-based studies.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 4.2 - Data Entry, Edit Checks, and Query Process ICH E6(R2)
GCP, Section 5.5.3 - Data Handling and System Controls FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - Data Entry and Verification Processes

NEW QUESTION # 75

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