

CCDM Cert Guide & CCDM Reliable Test Labs



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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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 2	<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.
Topic 3	<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 4	<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 5	<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.
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SCDM Certified Clinical Data Manager Sample Questions (Q35-Q40):

NEW QUESTION # 35

Which information should be communicated by the Data Manager at regular intervals throughout a study?

- A. Planned versus actual enrollment
- B. Site staffing changes
- C. Serious and unexpected safety events
- D. **Percent data entered and clean**

Answer: D

Explanation:

The Data Manager (DM) plays a critical role in maintaining transparent communication with the clinical study team regarding data quality and study progress. One of the most essential metrics regularly reported by the DM is the percentage of data entered and cleaned.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Communication and Study Reporting), these metrics provide insight into study status, data readiness for interim analysis, and timeline predictability for database lock. Regular communication includes:

Percent of CRFs entered and verified

Percent of queries resolved

Outstanding data issues or missing pages

Other options fall outside the Data Manager's direct responsibility:

A (Enrollment) is typically reported by clinical operations.

B (Staffing changes) are handled by site management.

D (Safety events) are communicated by the safety/pharmacovigilance team.

Thus, option C correctly reflects the Data Manager's responsibility for ongoing study communication.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Communication and Study Reporting, Section 5.3 - Study Metrics and Status Updates ICH E6(R2)
GCP, Section 5.1.1 - Communication and Oversight in Quality Management FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Status Reporting

NEW QUESTION # 36

Which attribute is NOT a characteristic of a standardized data collection element?

- A. **A strictly enforced requirement for the positioning of each data element on a case report form**
- B. A standard set of values used to respond to a data collection question
- C. An unambiguous definition for the data element
- D. A unique set of data storage metadata, including a variable name and data type

Answer: A

Explanation:

A standardized data collection element has well-defined metadata, consistent naming conventions, and controlled terminology to

ensure uniform data collection and interoperability across studies.

Key attributes, as per GCDMP and CDISC standards, include:

A clear definition of meaning (A)

A controlled set of response values (C)

Metadata specifications like variable names, formats, and data types (D) However, the physical positioning of a data element on a case report form (B) is a matter of form layout design, not a characteristic of data standardization. While consistent form structure aids usability, it is not part of data standardization or metadata management principles.

Hence, option B is correct - form positioning is not a standardized data element attribute.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 4.1 - Data Element Standardization CDISC CDASH Implementation Guide, Section 3.2 - Standardized Data Collection Elements and Metadata ICH E6(R2) GCP, Section 5.5.3 - Data Handling and Standardization

NEW QUESTION # 37

The Scope of Work would answer which of the following information needs?

- A. To find the name and contact information of a specific clinical data associate
- B. To look up the date of the next clinical monitoring visit for a specific site
- C. To look up which visit PK samples are taken
- D. To determine the number of data transfers budgeted for a project

Answer: D

Explanation:

The Scope of Work (SOW) is a project management document that defines what services are included in the work agreement between the sponsor and the CRO or vendor. It outlines deliverables, responsibilities, timelines, and budget allocations.

According to the GCDMP (Chapter: Project Management in Data Management), the SOW includes specifications such as:

The number and frequency of data transfers,

Database build and lock milestones,

Quality control deliverables, and

Resource allocation for data management tasks.

The SOW does not cover operational site-level details such as monitoring schedules (B), protocol sampling details (C), or personnel contact lists (D).

Therefore, option A (number of data transfers budgeted for a project) correctly identifies a use case directly addressed in the SOW.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Project Management, Section 4.1 - Scope of Work and Resource Planning ICH E6(R2) GCP, Section 5.5 - Sponsor Oversight and Data Management Responsibilities PMI Project Management Framework - Scope Definition and Deliverable Specifications

NEW QUESTION # 38

A Data Manager is importing lab data for a study. The lab data and the associated audit trail is kept at the central lab. What is necessary to maintain traceability of the transferred data at the Data Manager's location?

- A. Making changes only on the copy of the received data
- B. Maintaining a copy of the data as received
- C. Making changes only for exceptions
- D. Making changes only after data have been imported

Answer: B

Explanation:

Maintaining traceability of external data imports (such as laboratory results) is a fundamental principle of clinical data management. According to the GCDMP (Chapter: External Data Transfers and Integration), Data Managers must retain an unaltered copy of the raw data exactly as received from the vendor.

This archived version serves as a reference for:

Data provenance verification,

Audit trail review, and

Discrepancy resolution between vendor and study database.

Since the central lab maintains its own audit trail, the Data Manager's responsibility is to preserve the original data transmission file

before applying transformations, merges, or validations.

Options A, C, and D describe procedural safeguards but do not meet the regulatory requirement of traceable data lineage. Only option B (Maintaining a copy of the data as received) ensures compliance with ICH E6(R2) and FDA 21 CFR Part 11 standards for data traceability and integrity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers and Integration, Section 5.2 - Data Traceability and Version Control ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Source Data Verification FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Source Data Traceability and Archiving

NEW QUESTION # 39

Which metric will identify edit checks that may not be working properly?

- A. Average number of times each edit check has fired
- B. Count by site of the number of times any edit check fired
- **C. Count by edit check of the number of times the check fired**
- D. Average number of edit check identified discrepancies per form

Answer: C

Explanation:

The best metric to identify malfunctioning or ineffective edit checks is the count by edit check of the number of times the check fired. This allows data managers to assess whether specific edit checks are performing as intended.

According to the GCDMP, Chapter: Data Validation and Cleaning, edit checks are programmed logic conditions that identify data inconsistencies or potential errors during data entry. A properly functioning edit check should trigger only when data falls outside acceptable or logical limits. If an edit check fires too frequently or not at all, it may indicate a logic error in the check's programming or configuration.

By analyzing counts by individual edit checks, data managers can:

Identify checks that never trigger (potentially inactive or incorrectly written), Detect overactive checks (poorly designed parameters causing excessive false positives), and Optimize system performance and review efficiency.

This metric supports continuous improvement in data validation logic and contributes to cleaner, higher-quality clinical databases.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.2 - Edit Check Design and Performance Metrics FDA Guidance: Computerized Systems Used in Clinical Investigations - Section on Validation of Electronic Data Systems

NEW QUESTION # 40

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