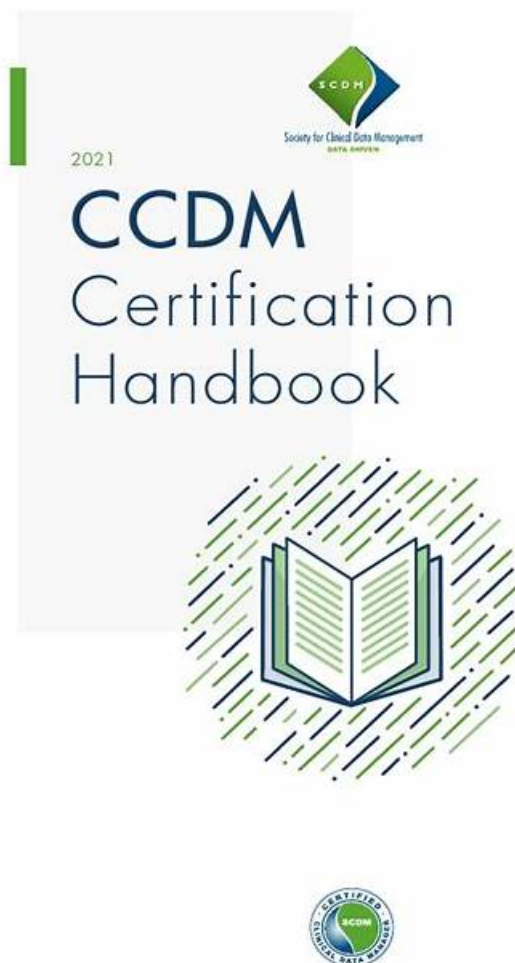


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## SCDM CCDM Exam Syllabus Topics:

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>• 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 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>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>

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### SCDM Certified Clinical Data Manager Sample Questions (Q20-Q25):

#### NEW QUESTION # 20

Which statement applies to the CRF Completion Guidelines (CCGs) for a multinational study?

- A. CCGs can instruct sites to use any abbreviations if they are documented in the subject source notes
- B. CCGs must be translated and back-translated in each local language used in the study
- C. CCGs can instruct sites to write in their local language as long as the CRA is fluent in this language
- **D. CCGs must contain the list of acceptable abbreviations to be used in the CRF**

#### Answer: D

#### Explanation:

The Case Report Form (CRF) Completion Guidelines (CCGs) are critical documents that guide site staff on how to accurately and consistently record data on CRFs across all participating sites, especially in multinational trials.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), one of the key components of the CCGs is a list of acceptable abbreviations and conventions to be used during CRF entry. This standardization ensures data consistency across languages and countries, reduces ambiguity during data review, and facilitates database design and coding accuracy.

While translation (A) may be useful for training materials, it is not required for CCGs unless specified by regulatory bodies. Options C and D are incorrect because data collection should adhere to standardized terms in English (or the study's official language) - allowing free use of local languages or arbitrary abbreviations introduces inconsistencies.

Hence, option B - "CCGs must contain the list of acceptable abbreviations to be used in the CRF" - is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 5.3 - CRF Completion Guidelines and Standardization ICH E6(R2) GCP, Section 5.5.3 - Consistency and Data Recording Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.2 - Data Entry Conventions and Documentation

#### NEW QUESTION # 21

Which of the following tasks would be reasonable during a major upgrade of a clinical data management system?

- A. All of the data formats in the archive should be updated to new standards.
- **B. The ability to access and read the clinical data archive should be tested.**
- C. All of the case report forms should be pulled and compared to the archive.
- D. The data archive should be migrated to an offsite database server.

**Answer: B**

**Explanation:**

During a major system upgrade, it is critical to verify that archived data remain accessible, readable, and intact following the implementation.

According to the GCDMP (Chapter: Database Lock and Archiving), regulatory requirements such as 21 CFR Part 11 and ICH E6(R2) mandate that archived data must remain retrievable in a human-readable format for the duration of retention (often years after study completion).

Therefore, as part of validation and verification testing, organizations must confirm that existing archives can still be accessed using the upgraded system or compatible tools.

Option A: Updating archive formats could alter original data integrity (noncompliant).

Option C: Migration offsite is an IT infrastructure task, not directly tied to the upgrade process.

Option D: Comparing CRFs to archives is unnecessary unless data corruption is suspected.

Hence, option B (testing archive accessibility) is the correct and compliant approach.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.4 - System Upgrades and Archive Validation ICH E6(R2)

GCP, Section 5.5.3 - System Validation and Data Retention FDA 21 CFR Part 11 - Data Archiving, Retention, and Retrieval Requirements

**NEW QUESTION # 22**

In a physical therapy study, range of motion is assessed by a physical therapist at each site using a study-provided goniometer. Which is the most appropriate quality control method for the range of motion measurement?

- A. Reviewing data listings for illogical changes in range of motion between visits
- B. Comparison to the measurement from the previous visit
- C. Programmed edit checks to detect out-of-range values upon data entry
- **D. Independent assessment by a second physical therapist during the visit**

**Answer: D**

**Explanation:**

In this scenario, the variable of interest-range of motion (ROM)-is a clinically measured, observer-dependent variable. The accuracy and reliability of such data depend primarily on the precision and consistency of the measurement technique, not merely on data entry validation. Therefore, the most appropriate quality control (QC) method is independent verification of the measurement by a second qualified assessor during the visit (Option D).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Quality Assurance and Control), quality control procedures must be tailored to the nature of the data. For clinically assessed variables, especially those involving human judgment (e.g., physical measurements, imaging assessments, or subjective scoring), real-time verification by an independent qualified assessor ensures that data are valid and reproducible at the point of collection. This approach directly addresses measurement bias, observer variability, and instrument misuse, which are primary sources of data error in clinical outcome assessments.

Other options, while valuable, address only data consistency or plausibility after collection:

Option A (comparison to previous visit) and Option C (reviewing data listings) are retrospective data reviews, suitable for identifying trends but not preventing measurement error.

Option B (programmed edit checks) detects only extreme or impossible values, not measurement inaccuracies due to technique or observer inconsistency.

The GCDMP and ICH E6 (R2) Good Clinical Practice guidelines emphasize that data quality assurance should begin at the source, through standardized procedures, instrument calibration, and dual assessments for observer-dependent measures. Having an independent second assessor ensures inter-rater reliability and provides direct confirmation that the recorded value reflects an accurate and valid measurement.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.4 - Measurement Quality and Verification ICH E6 (R2) Good Clinical Practice, Section 2.13 - Quality Systems and Data Integrity FDA Guidance for Industry: Patient-Reported Outcome Measures and Clinical Outcome Assessment Data, Section 5.3 - Quality Control of Clinician-Assessed Data SCDM GCDMP Chapter: Source Data Verification and Quality Oversight Procedures

**NEW QUESTION # 23**

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

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

**Answer: D**

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 # 24

Which of the following actions is particularly important in merging data from different trials?

- A. Enrollment of investigative sites with similar patient populations
- **B. Use of a common adverse event dictionary**
- C. Exclusion of studies that use a cross-over design
- D. Use of a common software platform

**Answer: B**

Explanation:

When merging data from different clinical trials, the use of a common adverse event (AE) dictionary (such as MedDRA or WHO Drug) is essential to ensure consistency and comparability across datasets.

According to the GCDMP (Chapter: Standards and Data Mapping) and CDISC SDTM Implementation Guide, data integration across studies requires standardized terminology for adverse events, medications, and clinical outcomes. Using the same AE dictionary ensures that similar terms are coded consistently, allowing accurate cross-study analysis, pooled summaries, and safety reporting.

A shared software platform (option A) is not necessary if data are mapped to standard formats (e.g., CDISC SDTM). Patient population similarity (option B) affects interpretation but not technical data merging. Study design differences (option C) may influence statistical analysis but not data integration mechanics.

Therefore, Option D - Use of a common adverse event dictionary - is the correct and most critical action for consistent multi-study data integration.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Standards and Data Mapping, Section 5.1 - Use of Standardized Coding Dictionaries CDISC SDTM Implementation Guide, Section 4.3 - Controlled Terminology and Cross-Study Integration ICH E3 and E2B - Clinical Data Standards and Safety Coding Requirements

#### NEW QUESTION # 25

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