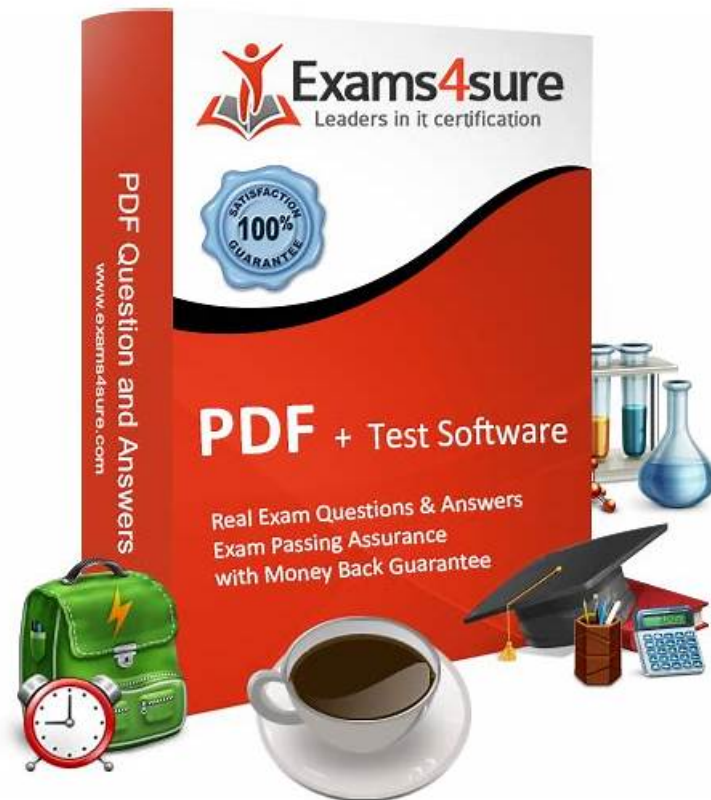


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## SCDM CCDM Exam Syllabus Topics:

Topic	Details
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Topic 1	<ul style="list-style-type: none"> <li>• <b>Testing Tasks:</b> 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 2	<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>
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>Coordination and Project Management Tasks:</b> 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 5	<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>

## SCDM Certified Clinical Data Manager Sample Questions (Q145-Q150):

### NEW QUESTION # 145

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

**Answer: B**

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 # 146

Which method would best identify inaccuracies in safety data tables for an NDA?

- A. Compare counts of appropriate patients from manual CRFs to counts in table cells
- B. Review the tables to identify any values that look odd
- **C. Compare counts of appropriate patients from line listings of CRF data to counts in table cells**
- D. Review the line listings to identify any values that look odd

**Answer: C**

Explanation:

The best method for identifying inaccuracies in safety data tables prepared for a New Drug Application (NDA) is to compare counts of appropriate patients from line listings of CRF data to the counts in table cells.

According to the GCDMP (Chapter: Data Quality Assurance and Control), line listings represent raw, patient-level data extracted directly from the clinical database, whereas summary tables are aggregated outputs used for reporting and submission. Comparing these two sources ensures data traceability and accuracy, verifying that tabulated results correctly reflect the underlying patient data. Manual CRF checks (option A) are less efficient and error-prone, as data entry is typically already validated electronically. Simply reviewing tables or listings for "odd values" (options C and D) lacks the systematic verification necessary for regulatory data integrity. Thus, comparing line listings to tables (option B) provides a quantitative cross-check between the database and output deliverables, a standard practice in NDA data validation and statistical quality control.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 5.2 - Validation of Tables, Listings, and Figures (TLFs) FDA Guidance for Industry: Submission of NDA Safety Data, Section on Data Verification and Accuracy ICH E6 (R2) GCP, Section 5.5.3 - Validation of Derived Data Outputs

#### NEW QUESTION # 147

A study collects blood pressure. Which is the best way to collect the data?

- A. Two continuous variables
- B. Check boxes for twenty-point increments
- C. High/Low radio button
- D. Coding a verbatim field with a MedDRA diagnosis

**Answer: A**

Explanation:

Blood pressure is a quantitative physiological measurement, typically consisting of two continuous numeric values: systolic and diastolic pressure. Therefore, the most appropriate and scientifically valid method of data collection is to use two continuous variables (e.g., systolic = 120 mmHg, diastolic = 80 mmHg).

According to the GCDMP (Chapter: CRF Design and Data Collection), data fields must be designed to capture the most precise, accurate, and analyzable form of clinical data. Numeric data should be collected using numeric data types to allow for range checks, calculations (e.g., mean arterial pressure), and statistical analysis.

Options such as categorical representations (radio buttons or check boxes) introduce rounding, data loss, and analytic limitations. Coding a verbatim diagnosis (option A) is inappropriate for numeric vital sign data and violates the principle of capturing data at the most granular level.

Thus, the correct and validated method per CCDM standards is two continuous variables, ensuring accuracy, traceability, and analytical flexibility.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.2 - Best Practices for Quantitative Data Capture ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Accuracy and Collection Standards FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Data Format and Structure Requirements

#### NEW QUESTION # 148

A Clinical Data Manager is drafting data element definitions for a new study. One of the definitions provided is:

"Baby's crown to heel length measured lying on back, measured physical quantity, precision of 0.1." Which of the following is missing from the definition?

- A. Enumeration
- B. Discrete values for a drop-down list
- C. Unit or dimensionality of measure
- D. Data type of the data element

**Answer: C**

Explanation:

A complete data element definition in clinical data management should include:

Name and clear description of the data element,

Data type (e.g., numeric, text, date),

Precision or scale (if numeric), and

Unit or dimensionality of measure (e.g., centimeters, inches).

In this example, while the data type ("measured physical quantity") and precision (0.1) are defined, the unit of measurement (e.g., centimeters or inches) is missing. This omission leads to ambiguity and could cause serious discrepancies when comparing or analyzing measurements.

The GCDMP (Chapter: Database Design and Build) emphasizes that units and dimensionality must be explicitly defined and consistently applied in all CRFs, metadata dictionaries, and data transformations.

Thus, option D (Unit or dimensionality of measure) is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Metadata and Data Element Definitions CDISC CDASH Implementation Guide, Section 3.3 - Data Element Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Data Accuracy and Standardized Definitions

### NEW QUESTION # 149

Which data are needed to monitor site variability in eligibility screening?

- A. Number of subjects screened and number of subjects enrolled
- B. Number of sites with high enrollment
- C. Number of sites with low enrollment
- D. Number of subjects enrolled

**Answer: A**

Explanation:

To monitor site variability in eligibility screening, you must analyze the number of subjects screened versus the number of subjects enrolled at each site. This allows identification of sites that are over- or under-screening relative to their enrollment yield.

The GCDMP (Chapter: Data Quality Assurance and Metrics) emphasizes that screening-to-enrollment ratios are critical indicators of protocol compliance and data quality. Sites with unusually low conversion rates may have unclear understanding of inclusion/exclusion criteria, requiring targeted training or monitoring.

Other options (A, C, D) provide enrollment metrics but do not reveal screening efficiency or variability, which depend on both screening and enrollment data.

Thus, option B correctly identifies the data necessary for monitoring eligibility screening performance across sites.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Metrics, Section 5.4 - Site Performance Metrics ICH E6(R2) GCP, Section 5.18 - Monitoring and Site Oversight Requirements

### NEW QUESTION # 150

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