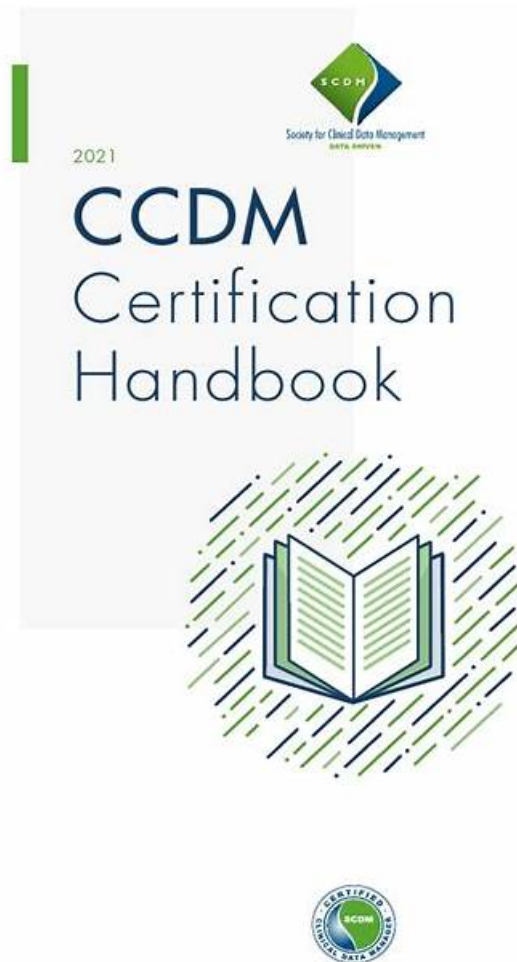# 100% Pass SCDM - CCDM–Professional Latest Study Materials

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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	• 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	• 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	• 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	• 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 (Q102-Q107):

NEW QUESTION # 102
The result set from the query below would be which of the following?
SELECT * FROM patient WHERE medical_record_number > 9000

- A. Longer than the patient table
- B. Wider than the patient table
- C. Narrower than the patient table
- D. Shorter or of equal length than the patient table

Answer: D

Explanation:
In Structured Query Language (SQL), the WHERE clause is used to filter records based on specified criteria. The query retrieves all columns from the patient table (SELECT *) but only those rows where the medical_record_number value is greater than 9000.
This means:
The number of columns (fields) remains the same as the original table.
The number of rows (records) will be equal to or less than the number of rows in the patient table, depending on how many patients meet the filter condition.
Hence, the result set can only be shorter or equal in length compared to the original table. It cannot be longer, wider, or narrower, since no new rows or columns are created.
Therefore, option B - "Shorter or of equal length than the patient table" - is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Relational Database Queries and Filtering Logic ICH E6(R2) GCP, Section 5.5.3 - Data Retrieval, Filtering, and Storage Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Query Logic and Record Subsetting

NEW QUESTION # 103
Which of the following laboratory findings is a valid adverse event reported term that facilitates auto coding?

- A. Elevated HDL
- B. Abnormal SGOT

- C. ALT
- D. Increased alkaline phosphatase, increased SGPT, increased SGOT, and elevated LDH

Answer: A

Explanation:
When coding adverse events (AEs) using MedDRA (Medical Dictionary for Regulatory Activities), valid AE terms must correspond to specific, medically meaningful concepts that match directly to a Preferred Term (PT) or Lowest Level Term (LLT) in the dictionary.
Among the options, "Elevated HDL" (High-Density Lipoprotein) represents a single, medically interpretable, and standard term that can directly match to a MedDRA LLT or PT. This makes it suitable for auto-coding, where the system automatically maps verbatim terms to MedDRA entries without manual intervention.
In contrast:
ALT (B) and Abnormal SGOT (C) are incomplete or nonspecific; they describe test names or qualitative interpretations rather than events.
Option D lists multiple findings, making it too complex for automatic mapping. Such compound entries would require manual coding review.
According to GCDMP (Chapter: Medical Coding and Dictionaries), a valid AE term should be:
Clinically interpretable (not just a lab test name)
Unambiguous
Single-concept based, not a collection of results
Thus, option A (Elevated HDL) is correct, as it aligns with MedDRA's single-concept, standard terminology structure suitable for auto-coding.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Medical Coding and Dictionaries, Section 5.3 - Auto-coding and Verbatim Term Management ICH M1 MedDRA Term Selection: Points to Consider, Section 2.1 - Coding Principles ICH E2B(R3) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

NEW QUESTION # 104
A study has an expected enrollment period of one year but has subject recruitment issues. Twelve new sites are added toward the end of the expected enrollment period to help boost enrollment. What is the most likely impact on data flow?

- A. The database set-up will need to be changed to allow for additional sites as they are added to the study.
- B. Additional sites will likely have increased query rates since site training is occurring closer to study close.
- C. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- D. A bolus of CRFs at the end of the study will result in the need to increase data entry and cleaning rates to meet existing timelines.

Answer: D

Explanation:
Adding multiple new sites late in the enrollment period creates a concentrated influx of new data near the end of the study. These sites typically start enrolling patients later, resulting in a "bolus" of Case Report Forms (CRFs) that must be entered, validated, and cleaned within a shorter timeframe to meet database lock deadlines.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Data Flow), late site activation compresses the timeline for data management tasks, necessitating increased resources for data entry, query management, and cleaning. Data management teams must anticipate this surge and plan accordingly-either by increasing staffing or revising timelines to prevent bottlenecks and maintain quality.
While option D (increased query rates) can occur, it is a secondary effect. The most direct and consistent impact is the surge in data volume requiring expedited processing near study end.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management, Section 5.3 - Managing Changes in Site Activation and Data Flow ICH E6(R2) GCP, Section 5.1 - Quality Management and Oversight

NEW QUESTION # 105
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 # 106
Electronic submission standards require that an individual subject's complete CRF should be provided as what type of file:

- A. Portable Document Format (.pdf)
- B. Statistical Analysis System (.sas)
- C. Microsoft Word (.docx)
- D. Rich Text Format (.rtf)

Answer: A

Explanation:
Electronic submission standards, as established by FDA, CDISC, and ICH, require that an individual subject's complete Case Report Form (CRF) be submitted as a Portable Document Format (.pdf) file. The PDF format is universally recognized and accepted because it ensures that the structure, format, and visual fidelity of the CRF are preserved exactly as originally designed, regardless of software or hardware environment.
According to the FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format (2006) and CDISC SDTM standards, sponsors must include a subject-level CRF in PDF form for each participant in the submission dataset. This requirement ensures that reviewers can trace data points from analysis datasets back to their source entries in the CRF, fulfilling the principles of data traceability and transparency.
The Good Clinical Data Management Practices (GCDMP) also support this requirement, emphasizing that CRF archiving should maintain readability and regulatory accessibility. Formats like RTF, DOCX, or SAS datasets are not acceptable substitutes for regulatory CRF submission because they may alter formatting, structure, or introduce modifiable content, violating FDA data integrity principles.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Archiving and Submission FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006 CDISC SDTM Implementation Guide, Section 5.3 - CRF Representation and Traceability

NEW QUESTION # 107
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