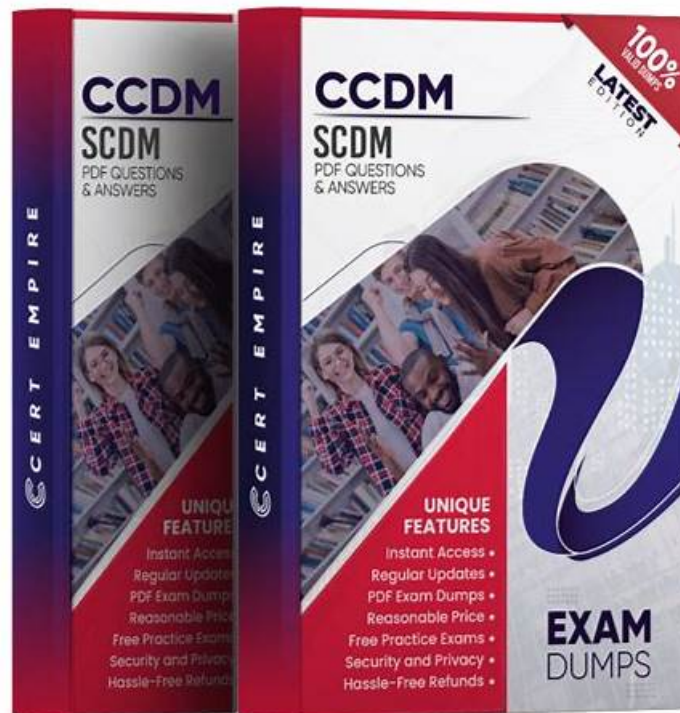


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SCDM CCDM Exam Syllabus Topics:

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">• 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"> • 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.
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In the information society, everything is changing rapidly. In order to allow users to have timely access to the latest information, our CCDM real exam has been updated. Our update includes not only the content but also the functionality of the system. The content of the CCDM training guide is the real questions and answers which are always kept to be the latest according to the efforts of the professionals. And we apply the newest technologies to the system of our CCDM exam questions.

SCDM Certified Clinical Data Manager Sample Questions (Q53-Q58):

NEW QUESTION # 53

Data from two sites are combined. One site coded gender as 1 and 2 (for Male and Female, respectively) while the other stored the data as M and F. Which term best describes the mapping?

- A. One-to-many
- B. Two-to-two
- C. Many-to-one
- D. One-to-one

Answer: D

Explanation:

When combining data from two datasets where one uses numeric codes (1 = Male, 2 = Female) and another uses text codes (M, F), each unique value in one dataset corresponds exactly to one unique value in the other.

This relationship is a one-to-one mapping, where each element in one dataset maps directly to a single corresponding element in the other.

1 → M

2 → F

Such mappings ensure consistent data harmonization during data integration and standardization phases, as outlined in the GCDMP (Chapter: Database Design and Integration).

Many-to-one (C) mapping would occur if multiple values (e.g., "Male," "M," "Man") mapped to a single standardized value, which isn't the case here.

Thus, the mapping is one-to-one, ensuring precise correspondence between both representations of gender data.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.4 - Data Mapping and Harmonization CDISC SDTM

Implementation Guide, Section 5.2 - Controlled Terminology and Mapping Rules ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Integration Principles

NEW QUESTION # 54

An organization has completed a study and wants to submit the data to the FDA using CDISC SDTM. Which of the following must be done?

- A. SDTM cannot be used in this situation
- B. Provide a letter of intent to use SDTM to the FDA
- C. Re-enter the data into an SDTM compliant system
- D. Map and transform the study data to SDTM

Answer: D

Explanation:

To submit study data to the FDA in CDISC SDTM format, the sponsor must map and transform the collected data from the study's

operational database (e.g., EDC) into SDTM-compliant domains.

According to GCDMP (Chapter: Standards and Data Integration) and CDISC SDTM Implementation Guide, this process includes: Mapping raw data elements from the clinical database to SDTM domains (e.g., DM, AE, VS).

Transforming data to comply with SDTM structural and naming conventions.

Validating the output using CDISC compliance tools (e.g., Pinnacle 21).

Re-entering data (B) is unnecessary, and a letter of intent (C) is not required. SDTM is explicitly accepted by FDA for both retrospective and prospective submissions, so (D) is incorrect.

Thus, option A is correct - map and transform existing data to SDTM format for regulatory submission.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.3 - Data Transformation and CDISC Mapping CDISC SDTM Implementation Guide, Version 3.4 - Data Conversion and Submission Requirements FDA Study Data Technical Conformance Guide, Section 2.2 - SDTM Mapping and Validation

NEW QUESTION # 55

Which Clinical Study Report section would be most useful for a Data Manager to review?

- A. Rationale for the study design
- B. Clinical narratives of adverse events
- C. Enumeration and explanation of data errors
- D. Description of statistical analysis methods

Answer: C

Explanation:

The section of the Clinical Study Report (CSR) that is most useful for a Data Manager is the one that includes the enumeration and explanation of data errors. This section provides a summary of the data quality control findings, including error rates, missing data summaries, and any issues identified during data review, validation, or database lock.

According to the GCDMP (Chapter: Data Quality Assurance and Control), post-study reviews of data errors and quality findings are essential for evaluating process performance, identifying recurring issues, and informing continuous improvement in future studies. Other sections, such as clinical narratives (A) or statistical methods (C), are outside the core scope of data management responsibilities. The data error enumeration section directly reflects the quality and integrity of the data management process and is therefore the most relevant for review.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.4 - Quality Reporting and Error Analysis ICH E3 - Structure and Content of Clinical Study Reports, Section 14.3 - Data Quality Evaluation

NEW QUESTION # 56

Which of the following ensures that the trials are conducted and the data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)?

- A. Statistical Analysis Plan (SAP)
- B. Data Management Plan (DMP)
- C. Standard Operating Procedures (SOP)
- D. CRFs

Answer: C

Explanation:

Standard Operating Procedures (SOPs) are formal, controlled documents that define standardized processes to ensure clinical trials are conducted in compliance with Good Clinical Practice (GCP), the study protocol, and regulatory requirements (such as ICH and FDA).

According to Good Clinical Data Management Practices (GCDMP) and ICH E6(R2) GCP, SOPs are fundamental to quality management systems. They describe how tasks are performed, ensuring consistency, accountability, and traceability across all studies and team members. Proper adherence to SOPs guarantees that data are accurately generated, documented, and reported in compliance with ethical and regulatory standards.

Other options serve different purposes:

SAP (B) defines statistical methodology, not compliance control.

DMP (C) focuses on study-specific data handling, not organizational compliance.

CRFs (D) are tools for data collection but do not enforce compliance by themselves.

Therefore, option A (SOP) is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Quality Management and Compliance, Section 5.1 - Role of SOPs in Regulatory Compliance ICH E6(R2) GCP, Section 2.13 and 5.1.1 - Quality Management Systems and SOP Requirements FDA 21 CFR Part 312.50 - Sponsor Responsibilities and Compliance Systems

NEW QUESTION # 57

On a dose escalation study, the Data Manager notices one site has a much higher number of queries than other sites and most are older than 30 days. The Data Safety Monitoring Board will meet in three weeks. What should the Data Manager providing CRO oversight do?

- A. Call the site directly and ask the study coordinator about the concerns
- B. Ignore it for now and check back next week
- C. Notify the CRO's Clinical Leader about the concerns
- **D. Consult the CRO's Lead Data Manager and the CRO's Project Leader**

Answer: D

Explanation:

The correct action is to consult the CRO's Lead Data Manager and CRO's Project Leader (Option C) to ensure the issue is addressed through the appropriate oversight and escalation process.

According to the GCDMP (Chapter: Project Management and Communication), when a sponsor Data Manager identifies significant data management issues under CRO oversight - such as aging queries or site performance disparities - communication must follow the established governance and escalation pathway defined in the Scope of Work (SOW) and Data Management Plan (DMP). Directly contacting the site (Option B) bypasses the CRO's chain of command and violates communication protocols. Notifying only the Clinical Leader (Option A) is insufficient, and ignoring the issue (Option D) jeopardizes the Data Safety Monitoring Board (DSMB) review timeline.

Therefore, Option C ensures a documented, collaborative approach to problem resolution within the contractual oversight structure.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 7.1 - Oversight of CRO Data Management Activities ICH E6 (R2) GCP, Section 5.2 - Contract Research Organization Responsibilities FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Roles and Communication Pathways

NEW QUESTION # 58

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