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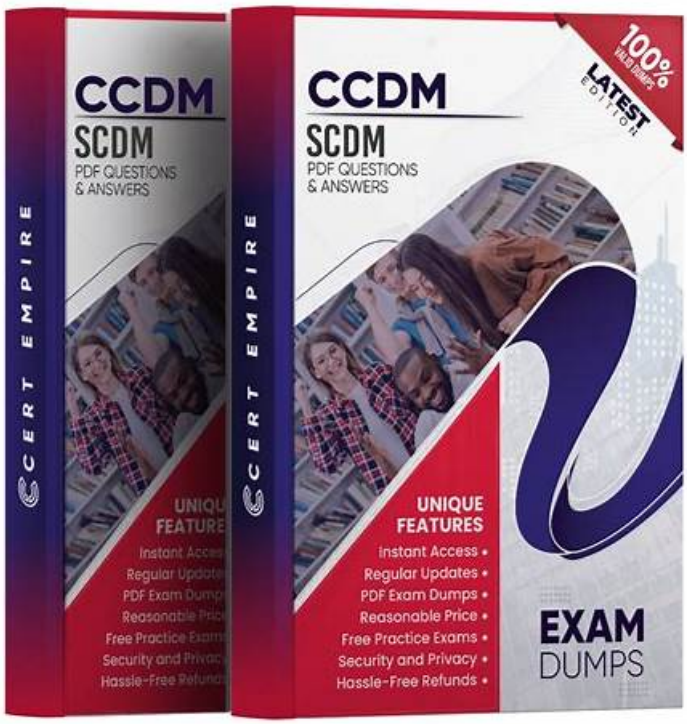

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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 3	• 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 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q140-Q145):

NEW QUESTION # 140
A Data Manager receives an audit finding of missing or undocumented training for two database developers according to the organization's training SOP and matrix. Which is the best response to the audit finding?

- A. Remove the training items from the training matrix
- B. Send the two developers to the required training
- C. Reprimand the person responsible for maintaining training documentation
- D. Identify the root cause and improve the process to prevent it

Answer: D

Explanation:
When an audit identifies missing or undocumented training, the most appropriate and compliant response is to identify the root cause of the issue and implement corrective and preventive actions (CAPA) to ensure that similar findings do not recur.
According to Good Clinical Data Management Practices (GCDMP, Chapter: Quality Management and Auditing), effective quality systems require root cause analysis (RCA) for all audit findings. The process involves:
Investigating why the documentation gap occurred (e.g., poor tracking, outdated SOP, or lack of oversight).
Correcting the immediate issue (e.g., ensuring the developers complete or document training).
Updating processes, training systems, or oversight mechanisms to prevent recurrence.
While sending the two developers to training (D) addresses the symptom, it does not resolve the systemic issue identified by the audit. Options B and C are non-compliant and do not address quality system improvement.
Therefore, option A (Identify the root cause and improve the process) is the best and CCDM-compliant response.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Quality Management and Auditing, Section 6.2 - Corrective and Preventive Actions (CAPA) ICH E6(R2) GCP, Section 5.1.1 - Quality Management and Continuous Process Improvement FDA 21 CFR Part 820.100 - Corrective and Preventive Action (CAPA) Requirements

NEW QUESTION # 141
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. Many-to-one
- B. One-to-many
- C. Two-to-two
- 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 # 142
If database auditing is used for data quality control during a study, which is the optimal timing of the audits?

- A. Periodically throughout the study
- B. Immediately following database lock
- C. After the first few cases have been entered
- D. A week or two before database lock

Answer: A

Explanation:
Database audits are conducted to ensure ongoing data accuracy, completeness, and compliance throughout the lifecycle of a clinical trial. According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control), quality audits are most effective when performed periodically during study conduct, rather than waiting until study completion.
Performing audits periodically allows early detection of data entry errors, protocol deviations, and system inconsistencies, thereby reducing the risk of large-scale data issues before database lock. This proactive approach aligns with risk-based quality management principles outlined in ICH E6(R2) and ensures corrective actions are implemented in real time.
Options A and B represent reactive quality control, which occurs too late to prevent data issues. Option C (after first few cases) provides initial validation but does not ensure continuous oversight.
Therefore, option D - "Periodically throughout the study" - represents the optimal and compliant timing for quality audits of the database.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 5.3 - Ongoing Quality Control and Auditing ICH E6(R2) GCP, Section 5.1.1 - Quality Management System and Risk-Based Monitoring FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Review and Auditing Practices

NEW QUESTION # 143
An international study collects lab values. Sites use different units in the source documents. Which of the following data collection strategies will have fewer transcription errors?

- A. Use a structured field and print standard units on the data collection form
- B. Allow values to be entered as they are in the source document and derive the units based on the magnitude of the value
- C. Allow values to be entered as they are in the source and the selection of units on the data collection form
- D. Have all sites convert the values to the same unit system on the data collection form

Answer: C

Explanation:
In international or multicenter clinical studies, laboratory data often originate from different laboratories that use varying measurement units (e.g., mg/dL vs. mmol/L). The Good Clinical Data Management Practices (GCDMP, Chapter on CRF Design and Data Collection) provides clear guidance on managing this variability to ensure data consistency, traceability, and minimized transcription errors.
The approach that results in fewer transcription errors is to allow sites to enter lab values exactly as recorded in the source document (original lab report) and to require explicit selection of the corresponding unit from a predefined list on the data collection form or within the electronic data capture (EDC) system. This method (Option B) preserves the original source data integrity while enabling centralized or automated unit conversion later during data cleaning or statistical processing.

Option B also supports compliance with ICH E6 (R2) Good Clinical Practice (GCP), which mandates that transcribed data must remain consistent with the source documents. Attempting to derive units automatically (Option A) can lead to logical errors, while forcing sites to manually convert units (Option D) introduces unnecessary complexity and increases the risk of miscalculation or inconsistent conversions. Printing only standard units on the CRF (Option C) ignores local lab practices and can lead to discrepancies between CRF entries and source records, triggering numerous data queries.
The GCDMP emphasizes that CRF design must account for local variations in measurement systems and ensure that unit selection is structured (dropdowns, controlled lists) rather than free-text to prevent typographical errors and facilitate standardization during data transformation.
Therefore, Option B-"Allow values to be entered as they are in the source and the selection of units on the data collection form"-is the most compliant, accurate, and efficient strategy for minimizing transcription errors in international lab data collection.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.4 - Laboratory Data Management and Unit Handling ICH E6 (R2) Good Clinical Practice, Section 5.18 - Data Handling and Record Retention CDISC SDTM Implementation Guide, Section 6.3 - Handling of Laboratory Data and Standardized Units FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Source Data and Accuracy of Data Entry

NEW QUESTION # 144
An organization conducts over fifty studies per year. Currently each study is specified and set-up from scratch. Which of the following organizational infrastructure options would streamline database set-up and study-to-study consistency?

- A. Improving the form or screen design process
- B. Maintaining a library of form or screen modules
- C. Implementing controlled terminology for adverse events
- D. Adopting an ODM compliant database system

Answer: B

Explanation:
To improve efficiency and ensure consistency across multiple studies, the most effective infrastructure solution is to maintain a centralized library of standardized forms or screen modules (e.g., CRF/eCRF templates).
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Database Design and Build), using a form library allows reuse of validated data collection modules for commonly collected domains such as demographics, adverse events, and vital signs. This reduces database setup time, enhances uniformity in data definitions, and ensures alignment with standards such as CDISC CDASH and SDTM.
While adopting ODM (A) provides standardized data exchange and interoperability, it does not inherently reduce setup workload. Improving design processes (C) enhances efficiency but doesn't guarantee consistency, and implementing controlled terminology (D) helps with coding standardization, not database structure.
Therefore, option B - maintaining a library of form or screen modules - provides the most direct and sustainable improvement for scalability and quality.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.3 - Use of Standard Libraries and Templates CDISC CDASH Implementation Guide, Section 3.2 - Reusable CRF Modules and Standardization ICH E6(R2) GCP, Section 5.5.3 - Standardization and Reuse in Data Collection Systems

NEW QUESTION # 145
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