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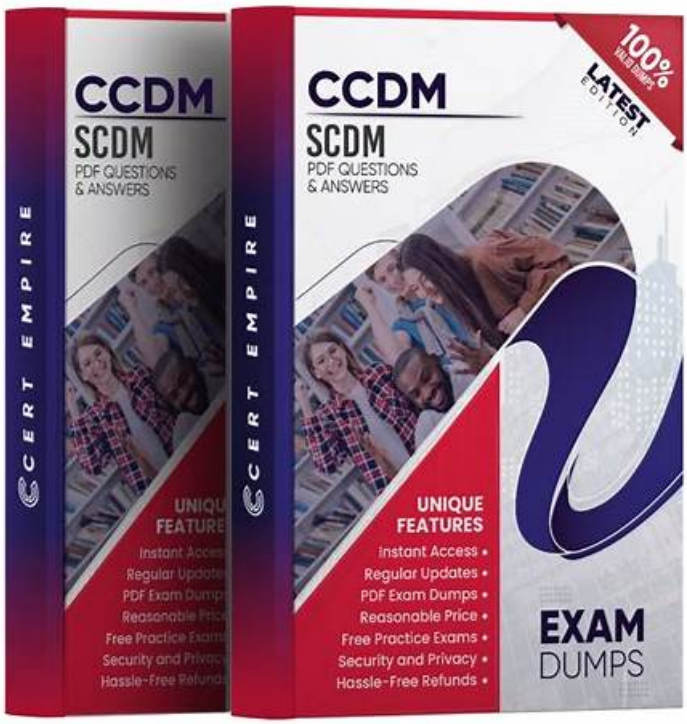

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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	• 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	• 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 5	• 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.

SCDM Certified Clinical Data Manager Sample Questions (Q99-Q104):

NEW QUESTION # 99
To ensure data quality and efficient integration of data, which of the following best describes the main topic that should be covered in initial discussions with a vendor providing the external data?

- A. Acceptable record, field, and file formats
- B. Criteria to trigger audits based on performance-monitoring reports
- C. Standard dictionary versioning and maintenance
- D. Metrics that will be used to measure data quality

Answer: A

Explanation:
In initial vendor discussions for external data integration (e.g., central lab, ECG, imaging vendors), the most critical and foundational topic is defining the acceptable record, field, and file formats.
According to the GCDMP (Chapter: External Data Transfers and Integration), establishing the Data Transfer Specifications (DTS) early in the process ensures consistent structure, proper mapping, and compatibility between the vendor's system and the sponsor's database. These specifications define:
Data structure (variable names, formats, delimiters)
File naming conventions
Frequency of transfers
Methods of secure data transmission
Discussing formats first allows later alignment on data validation, quality metrics, and dictionary standards (which occur in subsequent stages). Without format agreement, all downstream processes risk misalignment, resulting in data incompatibility and rework.
Thus, option C (Acceptable record, field, and file formats) correctly represents the foundational focus of initial vendor discussions for ensuring data quality and integration efficiency.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: External Data Transfers and Integration, Section 4.1 - Data Transfer Planning and Specification Development ICH E6(R2) GCP, Section 5.5.3 - Data Handling and System Validation FDA Guidance: Computerized Systems Used in Clinical Investigations, Section 6.3 - Data Import and Format Control

NEW QUESTION # 100
It has been identified that ten adverse events were not reported in the trial prior to the database lock. What action should be taken to determine the next step?

- A. Notify upper management immediately so the monitor can contact the site.
- B. Evaluate the potential effect of the omission on the validity of the safety and efficacy analysis.
- C. Get the AE data entered immediately so the database can be locked again.

- D. Check the data from all sites again before relocking the database.

Answer: B

Explanation:
When adverse events (AEs) are discovered after a database lock, the appropriate first step is to evaluate the impact of the missing data on the integrity, safety analysis, and regulatory validity of the study results.
According to GCDMP (Chapter: Data Quality Assurance and Control), any post-lock data discovery requires a root cause assessment and impact analysis before deciding whether to unlock the database. The key question is whether the missing AEs:
Affect primary safety endpoints,
Introduce bias in safety reporting, or
Alter efficacy conclusions.
Based on the assessment, the Data Management and Biostatistics teams determine if unlocking and correction are justified. Simply entering data immediately (A) or repeating checks (D) without analysis may violate data control procedures.
Hence, option B is correct - the first step is to assess the impact on data validity and analysis.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 5.5 - Post-Lock Findings and Impact Assessment ICH E6(R2) GCP, Section 5.1.1 - Quality Management and Risk Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Post-Lock Data Management

NEW QUESTION # 101
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. Resolving queries
- D. Tracking case report forms

Answer: C

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 # 102
For a study, body mass index is calculated from weight and height. Which information is needed to document the transformation?

- A. Algorithm and algorithm version associated with the calculated value
- B. Algorithm documented in the Data Management Plan
- C. User ID making the change and reason for change
- D. Algorithm associated with the calculated value

Answer: A

Explanation:
When derived or calculated variables (like Body Mass Index) are created, it is essential to document the algorithm used and its version to ensure full data traceability and reproducibility.

According to GCDMP (Chapter: Database Design and Derived Data), every derived field must include metadata describing:
The derivation algorithm (e.g., BMI = weight [kg] / height² [m²])
The version of the algorithm (if updates or revisions occur)
Any associated data sources or transformation rules
This ensures consistent calculation across systems, prevents discrepancies during regulatory submissions, and aligns with FDA and CDISC documentation expectations.
Option B lacks version control, which is critical for traceability. Option C describes audit trail data (not derivation metadata), and option D refers to broader documentation, not specific algorithm traceability.
Hence, option A (Algorithm and algorithm version associated with the calculated value) is the correct and compliant answer.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Derived Data and Algorithms, Section 5.3 - Documentation and Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Derived Data and Validation Traceability FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Data Definitions (Define.xml)

NEW QUESTION # 103
A study uses commercially available activity monitors and collects data for each patient weekly by selecting and downloading the data from the manufacturer's website. There are 100 patients in the study and it takes the Data Manager 20 minutes per file to download, import, and process the dat a. Assuming that the distribution of work is uniform over the six-month trial, how many Data Managers are needed for the activity data alone?

- A. Fifty percent of a Data Manager per month
- B. Two Data Managers per month
- C. One Data Manager per month
- D. Ten percent of a Data Manager per month

Answer: C

Explanation:
This question tests workload estimation and resource planning, which are fundamental competencies outlined in the Good Clinical Data Management Practices (GCDMP, Chapter on Project Management in Data Management). The task is to determine the Data Manager effort required based on the frequency and duration of data collection and processing activities.
Let's calculate step by step:
Number of patients: 100
Frequency: Weekly (once per week)
Duration: 6 months ≈ 26 weeks
Time per file: 20 minutes
Total time per week:
100 patients × 20 minutes = 2,000 minutes per week
= 2,000 ÷ 60 = 33.3 hours per week
Total hours over 6 months:
33.3 hours/week × 26 weeks = 866 hours total
A full-time Data Manager typically works ~160 hours per month, so over six months:
160 × 6 = 960 hours total full-time capacity.
Therefore, the workload of 866 hours is approximately equivalent to one full-time Data Manager working across the six-month period:
866 ÷ 960 ≈ 0.9 FTE (Full-Time Equivalent).
This aligns most closely with Option D: One Data Manager per month (i.e., a full-time resource is required throughout the duration of the trial).
According to the GCDMP Project Management chapter, accurate resource estimation is critical in ensuring data management timelines are met without overloading staff or compromising data quality. The estimation process must consider not just the raw data download time but also associated data processing, verification, and upload into the clinical database.
Other options underestimate the effort significantly:
A (10%) and B (50%) do not account for cumulative weekly workload across multiple patients.
C (Two Data Managers) overestimates, as one Data Manager working full-time can manage the load efficiently.
Therefore, Option D is correct - approximately one full-time Data Manager (1.0 FTE) is required for the activity data alone during the six-month trial.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Project Management in Data Management, Section 5.3 - Workload Estimation and Resource Allocation SCDM GCDMP, Chapter: Data Handling and Processing - Effort Estimation for Repetitive Data Tasks ICH E6 (R2) Good Clinical Practice, Section 5.1 - Quality

Management and Resource Planning FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Operational Considerations for Data Management Activities

NEW QUESTION # 104

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