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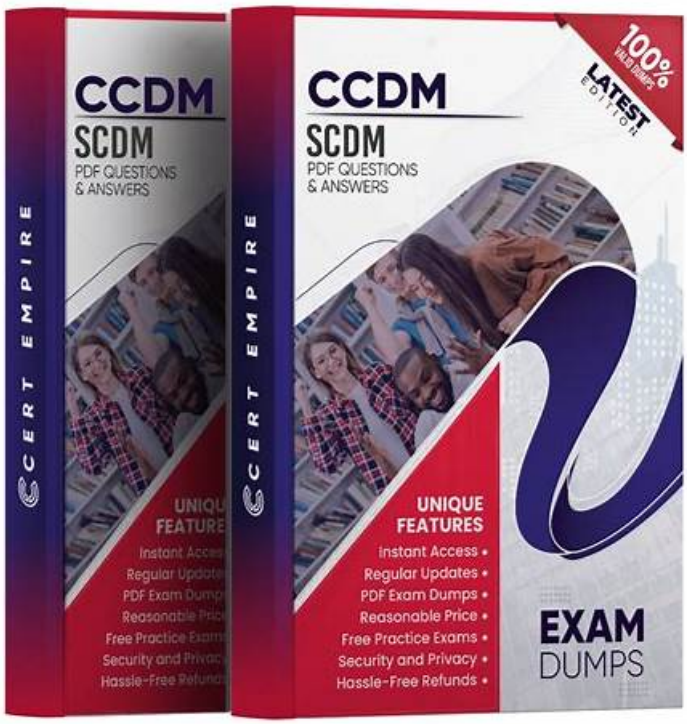

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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 3	• 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 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	• 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.

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Candidates all around the globe use their full potential only to get SCDM CCDM certification. Once the candidate is a SCDM certified, he gets multiple good career opportunities in the SCDM sector. To pass the CCDM Certification Exam a candidate needs to be updated and reliable Certified Clinical Data Manager (CCDM) prep material.

SCDM Certified Clinical Data Manager Sample Questions (Q66-Q71):

NEW QUESTION # 66
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. Consult the CRO's Lead Data Manager and the CRO's Project Leader
- B. Notify the CRO's Clinical Leader about the concerns
- C. Ignore it for now and check back next week
- D. Call the site directly and ask the study coordinator about the concerns

Answer: A

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 # 67
When a hospitalized subject in a cardiovascular trial experiences a repeated but mild episode of tachycardia, the physician decides to extend the subject's hospital stay for continued observation. How would this event be characterized?

- A. Adverse event
- B. Severe adverse event
- C. Spontaneous adverse event
- D. Serious adverse event

Answer: D

Explanation:
This event qualifies as a Serious Adverse Event (SAE) because it resulted in a prolonged hospitalization, even though the episode itself was mild.
According to ICH E2A and GCDMP (Chapter: Safety Data Handling and Reconciliation), an adverse event is considered "serious" if it results in any of the following outcomes:

Death,
Life-threatening situation,
Hospitalization or prolongation of existing hospitalization,
Persistent or significant disability/incapacity, or
Congenital anomaly/birth defect.
The severity (mild, moderate, severe) describes intensity, while seriousness describes regulatory significance and medical outcome. Thus, a mild tachycardia episode leading to extended hospital stay meets the regulatory definition of an SAE.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Safety Data Handling and Reconciliation, Section 5.2 - Definition and Classification of Serious Adverse Events ICH E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, Section II - Seriousness Criteria FDA 21 CFR 312.32 - IND Safety Reporting: Serious Adverse Event Definitions

NEW QUESTION # 68
According to the FDA Guidance for Industry, Providing Regulatory Submissions in Electronic Format (April 2006) and Good Clinical Data Management Practices (GCDMP, May 2007), which of the following is the most acceptable for a derived field?

- A. Providing CRF annotation "not entered in the database" next to the average score
- B. Providing the algorithm for calculating the average score on the CRF
- C. Providing the algorithm for calculating the average score in the dataset definition file
- D. Providing CRF annotation AVE next to the average score

Answer: C

Explanation:
In clinical data management, a derived field refers to any variable that is not directly collected from the Case Report Form (CRF) but is instead calculated or inferred from one or more collected variables (for example, calculating an average blood pressure from multiple readings). Proper documentation of derived fields is essential for ensuring data traceability, transparency, and compliance with both FDA and SCDM guidelines.
According to the Good Clinical Data Management Practices (GCDMP, May 2007), all derivations and transformations applied to clinical data must be clearly defined and documented in metadata such as the dataset definition file (also referred to as data specifications, variable definition tables, or Define.xml files). The derivation algorithm should be explicitly stated in this documentation to allow independent verification, regulatory review, and reproducibility of results.
The FDA Guidance for Industry (April 2006) on electronic submissions further emphasizes that derived fields must be supported by comprehensive metadata that defines the computational method used. This documentation enables the FDA or any regulatory body to audit and reproduce analytical results without ambiguity. Annotating or describing derivations directly on the CRF (as in options A, B, or D) is not sufficient, as CRFs represent data collection instruments-not analytical documentation.
Therefore, the correct and regulatory-compliant practice is to provide the derivation algorithm for a calculated field within the dataset definition file, aligning with both FDA and GCDMP expectations for data integrity and auditability.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Handling and Processing - Derived and Calculated Data Fields, Section 5.3.3 FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006, Section 3.2 on Dataset Documentation Requirements CDISC Define.xml Implementation Guide - Metadata and Algorithm Documentation for Derived Variables

NEW QUESTION # 69
In an EDC study, an example of an edit check that would be inefficient to run at data entry is a check:

- A. Against a valid list of values.
- B. Against a valid numeric range.
- C. On the format of a date.
- D. Across visits for consistency.

Answer: D

Explanation:
In Electronic Data Capture (EDC) systems, edit checks are categorized based on when and how they are executed - typically immediate (at data entry) or batch (post-entry). Checks that require data from multiple visits or forms are generally inefficient to run at data entry because they depend on information that may not yet exist in the system.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), cross-visit consistency checks - such as comparing baseline and follow-up blood pressure or verifying date order between screening and dosing - should be executed as batch or scheduled validations, not at the point of data entry. Running these complex checks in real time can slow system performance, increase query load unnecessarily, and confuse site users if related data are not yet entered. Conversely, edit checks against valid ranges, formats, or predefined value lists (options A, C, and D) are simple, local validations ideally performed immediately at data entry to prevent basic errors.
Therefore, cross-visit consistency checks (Option B) are best executed later, making them inefficient for real-time data entry validation.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.4 - Real-Time vs. Batch Edit Checks FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Edit Checks and Data Validation Logic CDISC SDTM Implementation Guide - Section on Temporal Data Consistency Validation

NEW QUESTION # 70
A Data Manager is importing lab data for a study. The lab data and the associated audit trail is kept at the central lab. What is necessary to maintain traceability of the transferred data at the Data Manager's location?

- A. Maintaining a copy of the data as received
- B. Making changes only after data have been imported
- C. Making changes only for exceptions
- D. Making changes only on the copy of the received data

Answer: A

Explanation:
Maintaining traceability of external data imports (such as laboratory results) is a fundamental principle of clinical data management. According to the GCDMP (Chapter: External Data Transfers and Integration), Data Managers must retain an unaltered copy of the raw data exactly as received from the vendor.
This archived version serves as a reference for:
Data provenance verification,
Audit trail review, and
Discrepancy resolution between vendor and study database.
Since the central lab maintains its own audit trail, the Data Manager's responsibility is to preserve the original data transmission file before applying transformations, merges, or validations.
Options A, C, and D describe procedural safeguards but do not meet the regulatory requirement of traceable data lineage. Only option B (Maintaining a copy of the data as received) ensures compliance with ICH E6(R2) and FDA 21 CFR Part 11 standards for data traceability and integrity.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: External Data Transfers and Integration, Section 5.2 - Data Traceability and Version Control ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Source Data Verification FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Source Data Traceability and Archiving

NEW QUESTION # 71
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