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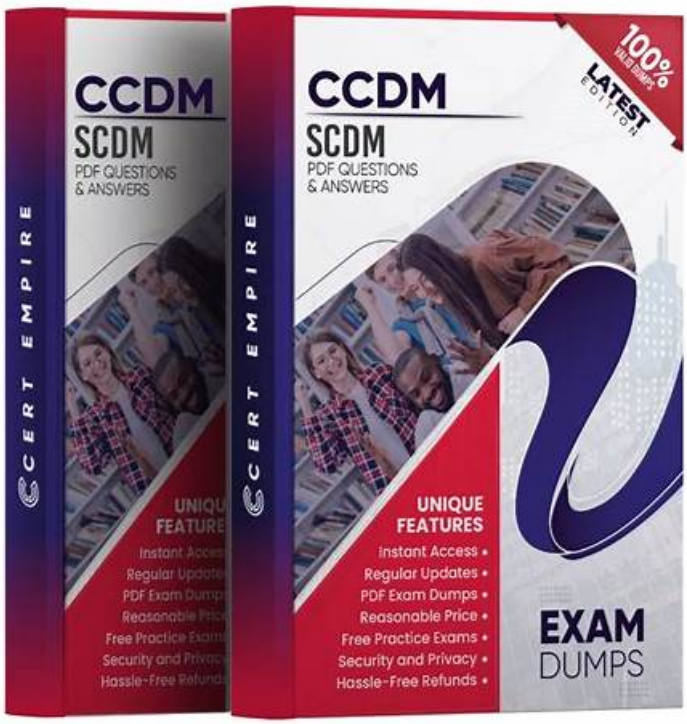

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SCDM CCDM Exam Syllabus Topics:

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	• 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	• 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	• 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.

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Learning knowledge is not only to increase the knowledge reserve, but also to understand how to apply it, and to carry out the theories and principles that have been learned into the specific answer environment. The Certified Clinical Data Manager exam dumps are designed efficiently and pointedly, so that users can check their learning effects in a timely manner after completing a section. Good practice on the success rate of CCDM Quiz guide is not fully indicate that you have mastered knowledge is skilled, therefore, the CCDM test material let the user consolidate learning content as many times as possible, although the practice seems very boring, but it can achieve the result of good consolidate knowledge.

SCDM Certified Clinical Data Manager Sample Questions (Q56-Q61):

NEW QUESTION # 56
A study is collecting pain levels three times a day. Which is the best way to collect the data?

- A. Study subjects calling into an IVRS three times a day to enter pain levels
- B. Sites calling patients daily and administering a pain questionnaire
- C. Using ePRO with reminders for data collection at each time point
- D. Using paper pain diary cards completed by study subjects

Answer: C

Explanation:
The optimal method for collecting frequent patient-reported pain data is through electronic Patient-Reported Outcomes (ePRO) with built-in reminder functionality.
According to the GCDMP (Chapter: Electronic Data Capture Systems), ePRO systems provide a validated, real-time, and user-friendly interface for subjects to record time-sensitive data accurately. The use of automated reminders ensures compliance with protocol-specified data collection times, improving data completeness and accuracy.
Paper diaries (option A) are prone to recall bias and backfilling, while daily site calls (option B) are resource-intensive and introduce human error. IVRS systems (option C) are acceptable but less efficient and user-friendly than modern ePRO applications, which can integrate timestamp validation, compliance monitoring, and real-time alerts.
ePRO systems also comply with FDA 21 CFR Part 11 and ICH E6 (R2) for audit trails, authentication, and validation, making them the preferred solution for repeated PRO data collection.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 6.1 - Use of ePRO for Repeated Measures FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 5 - ePRO Compliance and Validation ICH E6 (R2) GCP, Section 5.5.3 - Electronic Data Systems and Recordkeeping

NEW QUESTION # 57
Which is the most important reason for why a data manager would review data before a monitor reviews it?

- A. The GCDMP recommends that data managers review data prior to a monitor's review.
- B. Data can be viewed and discrepancies highlighted prior to a monitor's review.
- C. Data managers write the Data Management Plan that specifies the data cleaning workflow.
- D. Data managers have access to programming tools to identify discrepancies.

Answer: B

Explanation:
The primary reason data managers review data before a monitor's review is to identify and flag discrepancies or inconsistencies so that site monitors can focus their efforts more efficiently during on-site or remote source data verification (SDV).
According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), proactive data

review by data management staff ensures data completeness and accuracy by identifying missing, inconsistent, or out-of-range values. This pre-review helps streamline the monitoring process, reduces the volume of open queries, and enhances data quality. Option A is true but not the main reason for pre-monitor review. Option C highlights a capability rather than a rationale. Option D is partially correct, but the GCDMP emphasizes process purpose, not prescriptive order. Thus, option B correctly captures the practical and process-oriented reason for early data review-to ensure data are ready and accurate for the monitor's review phase.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Data Review Timing and Purpose ICH E6(R2) GCP, Section 5.18 - Monitoring and Data Verification Requirements

NEW QUESTION # 58
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 the algorithm for calculating the average score in the dataset definition file
- B. Providing the algorithm for calculating the average score on the CRF
- C. Providing CRF annotation "not entered in the database" next to the average score
- D. Providing CRF annotation AVE next to the average score

Answer: A

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 # 59
A sponsor may transfer responsibility for any or all of their obligations to a contract research organization. Which of the following statements is true?

- A. A description of each of the obligations being transferred to the contract research organization is not required.
- B. A general statement that all obligations have been transferred is acceptable.
- C. A description of each of the obligations being assumed by the contract research organization is required.
- D. Any written description is not transferred to the contract research organization.

Answer: C

Explanation:
Under ICH E6 (R2) Good Clinical Practice and 21 CFR Part 312.52, when a sponsor delegates or transfers obligations for a clinical trial to a Contract Research Organization (CRO), there must be a written description of each specific obligation being assumed by the CRO.
According to the Good Clinical Data Management Practices (GCDMP), while sponsors may outsource responsibilities such as data management, monitoring, or biostatistics, ultimate accountability remains with the sponsor. The documentation of the transfer of responsibilities ensures regulatory transparency and compliance.

This written agreement, often referred to as a Transfer of Obligations (TOO) document, defines exactly which duties the CRO is responsible for (e.g., CRF design, data cleaning, database lock), as well as any retained sponsor oversight. A general statement that "all obligations are transferred" (option D) is insufficient per regulatory expectations, as sponsors must retain traceability of responsibility.
Therefore, Option B is correct - a detailed written description of transferred obligations is required.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Compliance and Oversight, Section 5.2 - Sponsor and CRO Responsibilities ICH E6 (R2) Good Clinical Practice, Section 5.2.1 - Transfer of Trial-Related Duties and Functions FDA 21 CFR 312.52 - Transfer of Obligations to a Contract Research Organization

NEW QUESTION # 60
What action should be taken regarding the clinical database when MedDRA releases a new version of its dictionary?

- A. Upgrade the version immediately and recode.
- B. Identify an alternative dictionary.
- C. Evaluate the extent and impact of the changes.
- D. Continue using the existing version to code.

Answer: C

Explanation:
When a new version of MedDRA (Medical Dictionary for Regulatory Activities) is released, the correct action is to evaluate the extent and impact of the changes before implementation.
According to the GCDMP (Chapter: Medical Coding and Dictionaries), MedDRA updates are published twice yearly (March and September). Each release may introduce new terms, modify hierarchies, or retire old ones. Prior to adopting a new version, the Data Manager and Medical Coder must:
Assess the number and type of term changes,
Determine the potential effect on ongoing coding consistency, and
Decide whether migration to the new version is warranted mid-study or deferred until database lock.
Immediate recoding (option C) without evaluation may cause inconsistencies and require additional validation. Continuing with the existing version (option B) may be acceptable short-term but must be justified. Using an alternative dictionary (option D) is noncompliant, as MedDRA is the regulatory standard for safety reporting.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Medical Coding and Dictionaries, Section 6.3 - Version Control and Impact Assessment MedDRA Term Selection: Points to Consider (MSSO, Latest Version), Section 3 - Versioning and Maintenance ICH E2B(R3) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

NEW QUESTION # 61
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