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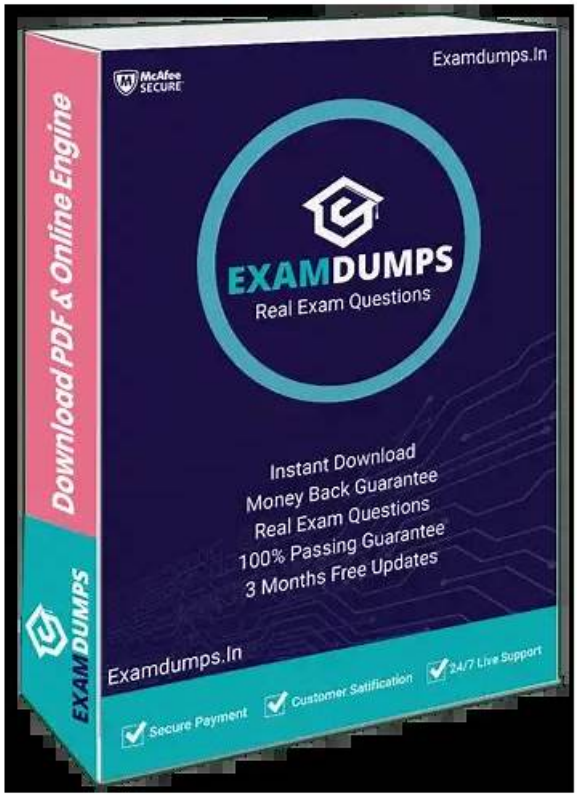

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SCDM CCDM Exam Syllabus Topics:

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	• 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	• 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	• 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	• 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.

Real CCDM Exam Dumps & Valid CCDM Test Questions

The desktop practice test design is best for self-appraisal and decreases the possibilities of disappointment in the Certified Clinical Data Manager (CCDM) Exam. It is upheld by each window PC which assists clients with clearing the SCDM CCDM certification exam with passing marks.The web-based format can be gotten online without introducing the product for the SCDM CCDM Exam. The web-based practice test is upheld by every one of the working frameworks and programs which will be useful for Certified Clinical Data Manager (CCDM) exam preparation.

SCDM Certified Clinical Data Manager Sample Questions (Q60-Q65):

NEW QUESTION # 60
A study takes body-composition measurements at baseline using a DEXA scanner. Which information is needed to correctly associate the body-composition data to the rest of the study data?

- A. Study number and visit number
- B. Subject number and visit number
- C. Study number and subject number
- D. Subject number

Answer: B

Explanation:
To properly associate body-composition data (from a DEXA scanner) with other study data, both the subject number and the visit number are required.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), every clinical data record must be uniquely identifiable and linkable to a specific subject and study event. The subject number identifies the participant, while the visit number defines the temporal context in which the measurement was taken.
Without both identifiers, data integration becomes ambiguous-especially if multiple assessments occur over time (e.g., baseline, week 12, end of study). Including both ensures data traceability, integrity, and alignment with the protocol-defined schedule of events.
Study number (option A) alone does not distinguish between visits or subjects, and visit number alone (option C) lacks linkage to the individual participant.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.4 - Data Linking and Identification Requirements ICH E6 (R2) GCP, Section 5.5.3 - Data Traceability Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Identification Requirements

NEW QUESTION # 61
ACME Intervention Co. is testing a new carotid artery stent in patients with coronary artery disease, in hopes of proving superiority over the current standard of care. After a subject signs consent, the surgeon enrolls the patient and retrieves information on which stent to use, but the surgeon does not share this information with the subject. Yesterday, the surgeon was instructed to use the control stent. Today, the surgeon has completed two surgeries: the first one the surgeon was instructed to use the control stent; the

second one the surgeon was instructed to use the test stent. In what type of trial is the surgeon participating?

- A. Cross-over
- B. Single-blind
- C. Double-blind
- D. Open label

Answer: B

Explanation:
This scenario describes a single-blind trial, in which only one party-typically the subject-is unaware of the treatment assignment, while the investigator or surgeon knows which intervention is being administered.
In this case, the surgeon receives instructions on which stent (test or control) to use, meaning they are aware of treatment allocation. However, the subject is blinded to which device is being implanted. This setup minimizes subject bias while maintaining procedural safety since the surgeon must know which product to use.
Double-blind (A): Neither subject nor investigator knows the treatment.
Open-label (B): Both subject and investigator know the treatment.
Cross-over (D): Each subject receives both treatments in different periods.
Thus, the correct answer is C. Single-blind, as only the participant remains blinded in this surgical device trial design.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Clinical Trial Phases and Protocols, Section 3.2 - Study Blinding and Randomization Concepts ICH E6(R2) GCP, Section 1.10 - Definition of Blinding/Masking FDA Guidance for Industry: Design Considerations for Pivotal Clinical Investigations for Medical Devices, Section 5.3 - Blinding in Device Studies

NEW QUESTION # 62
In development of CRF Completion Guidelines (CCGs), which is a minimum requirement?

- A. CCGs are designed from the perspective of the Study Biostatistician to ensure that the data collected can be analyzed
- B. CCGs are developed with representatives of Data Management, Biostatistics, and Marketing departments
- C. CCGs must include a version control on the updated document
- D. CCGs must be signed before database closure to include all possible protocol changes affecting CRF completion

Answer: C

Explanation:
Case Report Form Completion Guidelines (CCGs) are essential study documents that instruct site staff on how to complete each field of the CRF correctly. A minimum requirement for CCGs, according to Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), is that they must include version control.
Option A describes an important design consideration but not a minimum compliance requirement. Option B is inaccurate, as CCGs must be approved and implemented before data collection begins, not after. Option D includes an irrelevant stakeholder (Marketing).
Therefore, option C-"CCGs must include a version control on the updated document"-is correct and compliant with CCDM and GCP standards.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 4.3 - Development and Maintenance of CRF Completion Guidelines ICH E6(R2) GCP, Section 8.2.1 - Essential Documents and Version Control Requirements

NEW QUESTION # 63
A study team member suggests that data for a small, 50-patient, 2-year study can be entered and cleaned in two weeks before lock. Which are important other considerations?

- A. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study
- B. Processing the data in two weeks after the study is over would save money because the EDC system would only be needed for a month
- C. Processing the data in two weeks after the study is over would save money because the data manager would not be involved until the end
- D. It would take more than two weeks to get second iteration queries generated and resolved

Answer: D

Explanation:
The most critical consideration is that data cleaning is an iterative process, and completing all necessary steps - including query generation, site resolution, and second-pass validation - cannot realistically be accomplished within two weeks after study close.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), data cleaning must occur continuously throughout the study, not only at the end. Post-database lock activities typically include running final validation checks, resolving outstanding queries, performing reconciliation (e.g., SAEs, labs, coding), and conducting final quality review.
Even in small studies, query turnaround and response cycles from sites take time - typically 2-4 weeks per iteration - making a two-week total cleaning period unrealistic.
Therefore, Option D is correct: it would take more than two weeks to handle second-round (follow-up) queries and confirm final resolutions prior to database lock.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.4 - Ongoing vs. End-of-Study Data Cleaning ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Quality and Timeliness FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Management and Cleaning

NEW QUESTION # 64
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 in the dataset definition file
- C. Providing CRF annotation AVE next to the average score
- D. Providing the algorithm for calculating the average score on the CRF

Answer: B

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 # 65
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