SCDM CCDM Exam Questions in Convenient PDF Format

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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	• 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 3	• 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 4	• 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 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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LatestCram is one of the leading platforms that has been helping Certified Clinical Data Manager (CCDM) exam candidates for many years. Over this long time period we have helped Certified Clinical Data Manager (CCDM) exam candidates in their preparation. They got help from LatestCram SCDM CCDM Practice Questions and easily got success in the final SCDM CCDM certification exam. You can also trust LatestCram Certified Clinical Data Manager (CCDM) exam dumps and start preparation with complete peace of mind and satisfaction.

SCDM Certified Clinical Data Manager Sample Questions (Q13-Q18):

NEW QUESTION # 13
An external organization has been hired to manage SAE follow-up for a large study. Which of the following would be used as guidance for exchange of the SAE data between the EDC system and the vendor's safety management system?

- A. Medical Document for Regulatory Activities
- B. Biomedical Research Domain Model
- C. Submission Data Tabulation Model
- D. Individual Case Safety Report

Answer: D

Explanation:
The Individual Case Safety Report (ICSR) is the standard format used globally for the exchange of Serious Adverse Event (SAE) data between clinical data management systems (EDC) and safety management systems.
According to ICH E2B(R3) and Good Clinical Data Management Practices (GCDMP, Chapter: Safety Data Management and SAE Reconciliation), the ICSR provides the data structure and content standards for electronic transmission of safety data, including patient demographics, event details, outcomes, and product information. It ensures interoperability between systems by defining standardized message elements and controlled terminologies.
Other options are not applicable:
A . Medical Document for Regulatory Activities (MDRA) is not a recognized standard.
B . Biomedical Research Domain Model (BRIDG) provides conceptual modeling but not data exchange guidance.
D . SDTM is used for regulatory submission datasets, not real-time SAE exchange.
Thus, option C (Individual Case Safety Report) is correct, as it defines the internationally accepted electronic format for SAE data exchange between safety and clinical databases.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Safety Data Management and SAE Reconciliation, Section 4.3 - SAE Data Exchange and Standards
ICH E2B(R3): Electronic Transmission of Individual Case Safety Reports FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Postmarketing ICSRs (2014)

NEW QUESTION # 14
Which information is required by most systems to specify data entry screens?

- A. User role, access level, and permissions
- B. Help text, review parameters, and answers
- C. Page number and total number of pages
- D. Data type, prompt, and response format

Answer: D

Explanation:
When designing or configuring data entry screens within an Electronic Data Capture (EDC) system, three critical components are required for each field:
Data Type - Defines the nature of the data (e.g., text, numeric, date).
Prompt - The label or question displayed to the user.
Response Format - Specifies how the user enters or selects data (e.g., free text, drop-down, checkbox).
According to the GCDMP (Chapter: EDC Systems and Database Design), these three attributes form the logical data structure required to build and validate data entry interfaces. They ensure consistency in how information is captured, displayed, and validated during data entry.
While user roles (A) and help text (D) are system-level configurations, not field-level specifications, page numbers (C) relate to printed CRFs rather than digital data screens.
Therefore, option B (Data type, prompt, and response format) correctly identifies the essential information needed to define data entry screens.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: EDC Systems and Database Design, Section 4.3 - Screen Design Specifications CDISC CDASH Implementation Guide, Section 3.2 - Data Field Attributes ICH E6(R2) GCP, Section 5.5.3 - Data Capture and Input Standards

NEW QUESTION # 15
What is the purpose of providing the central laboratory vendor with a complete listing of subjects' demographic data?

- A. To assure that lab data for screening failure subjects have not been included in the lab data transmission
- B. To provide for an independent reconciliation of the patient and remote databases during study conduct
- C. To assure that all subjects have lab data for valid visits
- D. To provide for an independent reconciliation of the patient and remote databases after database lock

Answer: B

Explanation:
Providing the central laboratory vendor with a complete subject demographic listing allows ongoing reconciliation between the sponsor's EDC system and the vendor's laboratory database during study conduct.
The GCDMP (Chapter: External Data Transfers and Integration) emphasizes that subject reconciliation ensures that all laboratory data correspond to valid enrolled subjects and visits. Regular reconciliation throughout the study prevents data mismatches, missing results, or misassigned lab reports.
This proactive measure supports timely query resolution and data integrity across systems. Waiting until after database lock (as in option A) would delay corrections and risk inconsistencies. Options B and D address secondary benefits but not the primary purpose-ongoing subject-level reconciliation.
Thus, option C is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: External Data Transfers, Section 4.4 - Reconciliation and Vendor Communication ICH E6(R2) GCP, Section 5.5.3 - Data Management, Reconciliation, and Integration FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - External Data Management

NEW QUESTION # 16
A Data Manager is designing a CRF for a study for which the efficacy data are not covered by the current SDTM domains. Which search should the Data Manager do?

- A. Advise the study team not to collect the data

- B. Search for relevant data element standards
- C. Use controlled terminology covering the needed concepts
- D. Work with the study team to define new data elements

Answer: B

Explanation:
When existing SDTM (Study Data Tabulation Model) domains do not cover specific efficacy data, the best practice is to first search for relevant data element standards that may be available through CDISC CDASH (Clinical Data Acquisition Standards Harmonization) or other recognized industry standards.
Per GCDMP (Chapter: Standards and Data Integration), Data Managers must ensure that new CRF elements are consistent with standardized definitions, controlled terminology, and data models to support interoperability, future analysis, and regulatory submission.
If no existing standards exist, only then should the Data Manager collaborate with the study team to define new elements - but standard searches always come first.
Thus, option C is correct - search for relevant data element standards ensures alignment with CDISC best practices and regulatory expectations.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.1 - Use of CDISC Standards in CRF Design CDISC CDASH Implementation Guide, Section 4.1 - Standardization of Data Collection Fields FDA Study Data Technical Conformance Guide (SDTCG), Section 2.4 - Use of Standard and Custom Domains

NEW QUESTION # 17
If a data manager generated no additional manual queries on data in an EDC system and the data were deemed clean, why could the data appear to be not clean during the next review?

- A. The medical monitor can override safety information entered in the system.
- B. The data manager may have accidentally changed the data.
- C. The study coordinator can change the data due to re-review of the source.
- D. The CRA can change the data during a quality review of source to database.

Answer: C

Explanation:
In an Electronic Data Capture (EDC) system, even after a data manager completes all manual queries and marks data as "clean," the data may later appear unclean if the site (study coordinator) makes subsequent updates in the system after re-reviewing the source documents.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Electronic Data Capture Systems), site users maintain the authority to modify data entries as long as the system remains open for data entry. The EDC system audit trail captures such changes, which can automatically invalidate prior data reviews, triggering new discrepancies or changing system edit-check statuses.
This situation commonly occurs when the site identifies corrections in the source (e.g., wrong date or lab result) and updates the EDC form accordingly. These post-cleaning changes require additional review cycles to ensure the database reflects accurate and verified information before final lock.
Options B, C, and D are incorrect - CRAs and medical monitors cannot directly change EDC data; they can only raise queries or request updates.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 6.3 - Post-Cleaning Data Changes and Audit Trails ICH E6 (R2) GCP, Section 5.5.3 - Data Integrity and Change Control FDA 21 CFR Part 11 - Electronic Records: Change Documentation Requirements

NEW QUESTION # 18
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