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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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 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	• 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 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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SCDM Certified Clinical Data Manager Sample Questions (Q118-Q123):

NEW QUESTION # 118
A Data Manager is importing data from an external facility. Which is commonly checked first?

- A. Incoming files have the expected number of records
- B. Incoming files are conformant to the data transfer specifications
- C. Data in incoming files are consistent with existing data in the study database
- D. Data in the incoming files are internally consistent

Answer: B

Explanation:
When importing external data (e.g., laboratory or imaging results) into a clinical database, the first step in data import quality control is to verify that incoming files conform to the pre-specified data transfer specifications (DTS).
According to the GCDMP (Chapter: External Data Transfers and Integration), the Data Transfer Specification defines file structure, variable names, data types, delimiters, record counts, and validation rules. The initial import check confirms that the received file matches the technical and structural requirements before content or record consistency is evaluated.
Subsequent checks-such as record counts (A), data consistency with existing database (C), and internal logical consistency (D)-are performed only after the file structure is validated and confirmed to match the specifications. Failure to perform this first check may cause import errors or corrupted data loads.
Thus, the first and most critical verification step is ensuring file conformity to the agreed data transfer specifications, making option B correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: External Data Transfers, Section 4.2 - Data Transfer File Validation and Import Checks ICH E6(R2) GCP, Section 5.5.3 - Validation of Computerized Systems and Data Imports

NEW QUESTION # 119
Which Clinical Study Report section would be most useful for a Data Manager to review?

- A. Clinical narratives of adverse events
- B. Rationale for the study design
- C. Description of how data were processed
- D. Description of statistical analysis methods

Answer: C

Explanation:
The section of the Clinical Study Report (CSR) most useful for a Data Manager is the description of how data were processed.
According to the GCDMP (Chapter: Data Quality Assurance and Control), this section details the data handling methodology - including data cleaning, coding, transformation, and derivation procedures - all of which are core responsibilities of data management. Reviewing this section ensures that the data processing methods documented in the CSR align with the Data Management Plan (DMP), Data Validation Plan (DVP), and database specifications.
The statistical methods section (option A) is primarily for biostatistics, and the rationale for study design (option B) pertains to clinical and regulatory affairs. Clinical narratives (option D) are used by medical reviewers, not data managers.
By reviewing how data were processed, the Data Manager verifies that the study data lifecycle-from collection to analysis-was conducted in compliance with regulatory and GCDMP standards.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.3 - Documentation of Data Processing in Clinical Study Reports ICH E3 - Structure and Content of Clinical Study Reports, Section 11.3 - Data Handling and Processing FDA Guidance for Industry: Clinical Study Reports and Data Submission - Data Traceability and Handling Documentation

NEW QUESTION # 120
The Scope of Work would answer which of the following information needs?

- A. To look up which visit PK samples are taken
- B. To look up the date of the next clinical monitoring visit for a specific site
- C. To determine the number of database migrations budgeted for a project
- D. To find the name and contact information of a specific clinical data associate

Answer: C

Explanation:
The Scope of Work (SOW) is a contractual document that outlines the specific deliverables, responsibilities, timelines, and budgetary details for a given project between the sponsor and the contract research organization (CRO).
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), the SOW defines what work will be performed, how many resources are allocated, and the expected deliverables. This includes detailed information such as:
The number of database builds or migrations,
Timelines for deliverables (e.g., database lock),
Responsibility distribution between sponsor and CRO, and
Budget parameters for defined activities.
Therefore, if a Data Manager needs to determine how many database migrations are budgeted for a project, the SOW is the correct document to reference.
Information such as PK sample scheduling (option A), site monitoring dates (option B), or staff contact details (option D) would be found in operational plans or contact lists, not in the SOW.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Scope of Work Definition and Deliverables ICH E6 (R2) GCP, Section 5.5.3 - Documentation and Responsibilities for Data Management Tasks FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Agreements

NEW QUESTION # 121
All of the following are preparation processes the data manager needs to take prior to database closure EXCEPT:

- A. Checking for uncoded terms in all panels that are coded.
- B. Ensuring all data expected for the study has been received.
- C. Ensuring study close out visits have been complete.
- D. Performing SAE reconciliation between the clinical and safety databases.

Answer: C

Explanation:
Before database lock, the Data Manager must confirm that all collected data are complete, validated, and reconciled across systems. This includes:
Ensuring data completeness (B) - confirming all expected forms and data files have been received.
Verifying coded data (A) - ensuring no pending terms remain in coding dictionaries like MedDRA or WHO Drug.
Performing SAE reconciliation (C) - cross-checking the clinical database against the safety system for accuracy.
However, ensuring study close-out visits (D) is not a data management function; it falls under clinical operations and monitoring responsibilities. While data management may review confirmation of site close-outs, the activity itself is not part of pre-database lock procedures.
Therefore, option D correctly identifies the exception-an activity outside the data manager's direct scope of responsibility before database closure.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.3 - Pre-Lock Validation and Reconciliation Activities ICH E6(R2) GCP, Section 5.5.3 - Data Handling and Quality Control Prior to Lock FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - Database Management and Lock Procedures

NEW QUESTION # 122
Which of the following is the best reason for a statistician to review the case report form prior to using it in a study?

- A. To ensure the variable names conform to statistical programming standards
- B. To ensure the header fields will provide a unique key for each subject
- C. To ensure the data from the CRF can be analyzed for safety and efficacy
- D. To ensure the layout will make a logical, useful programming guide

Answer: C

Explanation:
The primary reason a statistician reviews the Case Report Form (CRF) is to ensure that the data being collected will support the planned statistical analyses for both safety and efficacy endpoints.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), CRF design should always align with the statistical analysis plan (SAP) to ensure that all necessary data elements are collected accurately and in analyzable formats. The statistician verifies that the CRF captures:
All endpoints specified in the protocol
Proper derivation or calculation fields
Timing of assessments
Consistency across visits and forms
Options B, C, and D address secondary or technical design considerations but not the primary analytical purpose. The review ensures that the CRF provides a complete and analyzable dataset for meeting study objectives, regulatory submissions, and statistical integrity.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 4.4 - Role of Statistics in CRF Design ICH E9 - Statistical Principles for Clinical Trials, Section 5.2 - Data Collection and Analysis Alignment FDA Guidance for Industry: E6(R2) GCP, Section 5.1 - Quality Management and Design Input from Stakeholders

NEW QUESTION # 123
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