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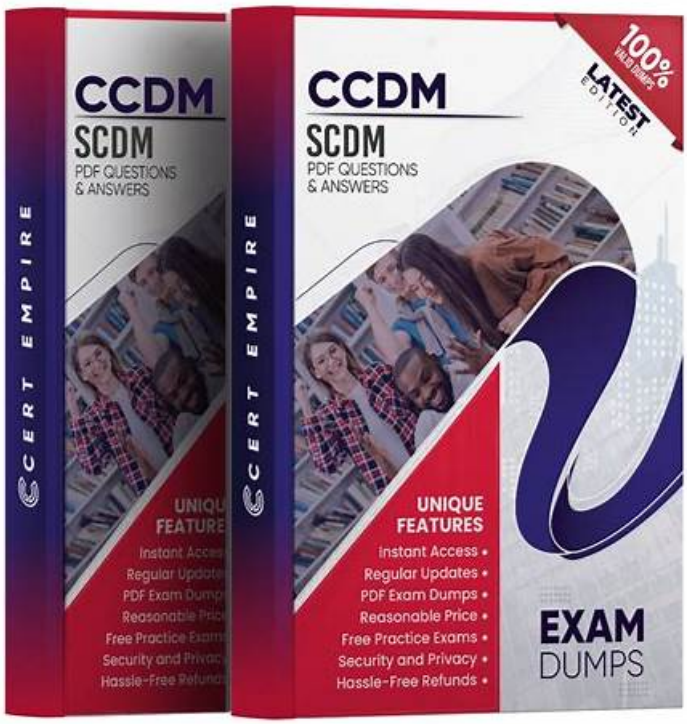

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SCDM CCDM Exam Syllabus Topics:

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	• 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	• 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	• 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 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 (Q78-Q83):

NEW QUESTION # 78
A study numbers subjects sequentially within each site and does not reuse site numbers. Which information is required when joining data across tables?

- A. Subject number
- B. Subject number and site number
- C. Study number and subject number
- D. Site number

Answer: B

Explanation:
When subjects are numbered sequentially within each site, it means that the subject identification numbers (Subject IDs) restart from 001 at each site. For example, Site 101 may have Subject 001, and Site 102 may also have a Subject 001. In such cases, the subject number alone is not globally unique across the entire study. Therefore, when integrating or joining data across multiple database tables (for example, linking demographic, adverse event, and laboratory data), both the site number and the subject number are required to create a unique key that accurately identifies each record.
According to the Good Clinical Data Management Practices (GCDMP, Chapter on CRF Design and Data Collection), every data record in a clinical trial database must be uniquely and unambiguously identified. This is typically achieved through a composite key, combining identifiers such as site number, subject number, and sometimes study number. The GCDMP specifies that a robust data structure must prevent duplication or mislinking of records across domains or tables.
Furthermore, FDA and CDISC standards (SDTM model) also emphasize the importance of unique subject identifiers (USUBJID), which are derived from concatenating the study ID, site ID, and subject ID. This ensures traceability, integrity, and accuracy of subject-level data during database joins, data exports, and regulatory submissions.
Thus, in the described scenario, since subject numbering restarts at each site, both the site number and subject number are required to uniquely identify and correctly join subject data across different datasets or tables.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.1 - Unique Subject Identification CDISC SDTM Implementation Guide, Section 5.2 - Subject and Site Identification (Variable: USUBJID) FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Data Integrity and Record Identification

NEW QUESTION # 79
Every database lock should follow documented approval of which stakeholders?

- A. Clinical/Scientific Representative, Data Manager, Biostatistician
- B. Clinical/Scientific Representative, Biostatistician
- C. Clinical/Scientific Representative, Biostatistician, Programmer

- D. Clinical/Scientific Representative, Data Manager

Answer: A

Explanation:
According to the Good Clinical Data Management Practices (GCDMP), the database lock (DBL) process signifies the formal closure of the clinical trial database, ensuring that no further changes can be made to the data before statistical analysis. This process must be documented, controlled, and approved by key study stakeholders to ensure data accuracy, completeness, and readiness for analysis.
The GCDMP specifies that database lock should occur only after all data cleaning, discrepancy resolution, and reconciliation activities are complete. The lock authorization typically requires the approval of the Clinical/Scientific Representative (to confirm clinical completeness), the Data Manager (to confirm data integrity and query closure), and the Biostatistician (to confirm readiness for statistical analysis).
This tri-party approval ensures that the database reflects final, verified data consistent with the clinical protocol, and that the statistical analysis dataset derived from the database is accurate and auditable. The approval process is documented via a Database Lock Authorization Form or Sign-off Log, which becomes part of the permanent trial master file (TMF).
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Lock and Archiving, Section 7.1 - Lock Procedures and Approvals ICH E6 (R2) GCP, Section 5.5.3 - Data Handling and Record Keeping FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Database Closure

NEW QUESTION # 80
A study is collecting ePRO assessments as well as activity-monitoring data from a wearable device. Which data should be collected from the ePRO and activity-monitoring devices to synchronize the device data with the visit data entered by the site?

- A. Study subject identifier and date/time
- B. Study subject identifier
- C. Geo-spatial location
- D. Geo-spatial location and study subject identifier

Answer: A

Explanation:
To synchronize data from electronic patient-reported outcomes (ePRO) and wearable activity-monitoring devices with site-entered visit data, both the study subject identifier and date/time are essential.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), each dataset must contain key identifiers that allow for accurate data integration and temporal alignment. In studies involving multiple digital data sources, time-stamped subject identifiers are necessary to ensure that the device-generated data correspond to the correct subject and study visit.
The subject identifier ensures data traceability and linkage to the appropriate participant, while date/time allows synchronization of device data (e.g., activity or physiological measurements) with the corresponding site-reported visit or event. Geo-spatial data (options C and D) are typically not relevant to study endpoints and pose unnecessary privacy risks under HIPAA and GDPR guidelines.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Integration and eSource Data, Section 5.2 - Data Alignment and Synchronization Principles FDA Guidance for Industry: Use of Electronic Health Record Data in Clinical Investigations, Section 4.2 - Data Linking and Synchronization ICH E6 (R2) GCP, Section 5.5.3 - Data Traceability and Integrity

NEW QUESTION # 81
Which Clinical Study Report section would be most useful for a Data Manager to review?

- A. Description of statistical analysis methods
- B. Rationale for the study design
- C. Enumeration and explanation of data errors
- D. Clinical narratives of adverse events

Answer: C

Explanation:
The section of the Clinical Study Report (CSR) that is most useful for a Data Manager is the one that includes the enumeration and

explanation of data errors. This section provides a summary of the data quality control findings, including error rates, missing data summaries, and any issues identified during data review, validation, or database lock.
According to the GCDMP (Chapter: Data Quality Assurance and Control), post-study reviews of data errors and quality findings are essential for evaluating process performance, identifying recurring issues, and informing continuous improvement in future studies. Other sections, such as clinical narratives (A) or statistical methods (C), are outside the core scope of data management responsibilities. The data error enumeration section directly reflects the quality and integrity of the data management process and is therefore the most relevant for review.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.4 - Quality Reporting and Error Analysis ICH E3 - Structure and Content of Clinical Study Reports, Section 14.3 - Data Quality Evaluation

NEW QUESTION # 82
Which information is most useful in working with sites to catch up a backlog of unresolved queries at sites?

- A. Table of outstanding queries counts by site
- B. List of late queries by site and summary table
- C. Graph of expected versus actual enrollment
- D. Graph and summary table of clean cases by site

Answer: B

Explanation:
The most effective information for addressing a backlog of unresolved queries at investigative sites is a list of late queries by site combined with a summary table.
According to the GCDMP (Chapter: Communication and Issue Escalation), timely and structured feedback to sites is critical for efficient query resolution. A detailed list of late or overdue queries, accompanied by summary statistics (e.g., counts, durations, status), enables data managers and monitors to prioritize follow-up actions, target problem areas, and provide focused support or retraining to underperforming sites.
While query count summaries (option B) are helpful for overview metrics, they lack the specific information (query ID, date, field, status) required for targeted follow-up. Graphs of enrollment or clean cases (options A and C) are unrelated to discrepancy resolution performance.
Thus, the combination of detailed lists and summarized performance metrics offers both granularity and a high-level overview - the optimal tool for query management communication.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 5.1 - Site Query Management Reports ICH E6 (R2) GCP, Section 5.18.4 - Communication Between Monitors and Sites FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Query Metrics and Site Performance Review

NEW QUESTION # 83
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