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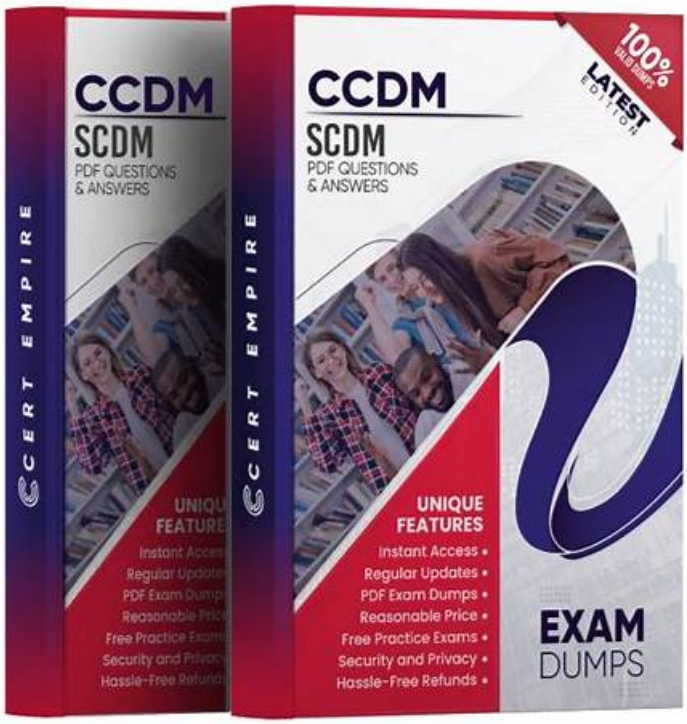

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The development of science and technology makes our life more comfortable and convenient, which also brings us more challenges. Many company requests candidates not only have work experiences, but also some professional certifications. Therefore it is necessary to get a professional CCDM Certification to pave the way for a better future. Considered many of the candidates are too busy to review, our experts designed the CCDM question dumps in accord with actual examination questions, which would help you pass the exam with high proficiency.

SCDM CCDM Exam Syllabus Topics:

Topic	Details

Topic 1	• 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 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	• 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 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	• 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.

SCDM Certified Clinical Data Manager Sample Questions (Q93-Q98):

NEW QUESTION # 93
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. 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
- B. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study
- 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 # 94
In an EDC study, user training and access must be monitored and addressed when all the following situations occur EXCEPT:

- A. A software upgrade is made that does not impact site staff or study team members.
- B. Site staff is new to the study.
- C. Study team members are reassigned to a different role within the study.

- D. Site staff moves off of the study.

Answer: A

Explanation:
In Electronic Data Capture (EDC) studies, proper user training and access management are essential for maintaining data integrity, security, and regulatory compliance. According to the Good Clinical Data Management Practices (GCDMP) and FDA 21 CFR Part 11, EDC systems must ensure that only qualified and trained personnel can access study data, and that all access rights reflect current study responsibilities.
User training and access must therefore be reviewed and updated whenever:
Site staff leave the study (access revocation is required),
New site staff are added (training and credentialing are required), and Study team members change roles (access levels must be modified accordingly).
However, if a software upgrade occurs that does not impact the functional roles, user permissions, or data handling processes, retraining or reauthorization is not required. This is because such updates do not alter compliance-critical workflows or user interactions.
Therefore, the exception is C - when a software upgrade does not affect users.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 7.1 - User Access and Training Controls FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures, Section 11.10(i) & (k) ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - System Security and User Training

NEW QUESTION # 95
Which of the following is a best practice for creating eCRFs for a study?

- A. Develop eCRFs with cross-functional team members
- B. Set up coded terms so they are available to the site user
- C. Set up features that automatically enter data into fields when bypassed
- D. Develop eCRFs that closely follow paper CRF standards

Answer: A

Explanation:
The best practice for developing electronic Case Report Forms (eCRFs) is to involve cross-functional team members throughout the design process.
According to the GCDMP (Chapter: CRF Design and Data Collection), eCRFs should be collaboratively developed by data management, clinical operations, biostatistics, medical, and regulatory teams. Each function provides a unique perspective - data managers focus on data capture and validation; statisticians ensure alignment with analysis requirements; clinicians ensure medical relevance and protocol compliance.
Collaborative development ensures that the eCRFs are fit-for-purpose, capturing all required data accurately, minimizing redundancy, and supporting downstream data analysis.
Options A and B violate good data management practice because sites should not directly access coded terms (to prevent bias), and fields should never auto-populate without explicit source verification. Option D is outdated; while paper CRFs may inform structure, EDC-optimized eCRFs should leverage system functionality rather than mimic paper.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.2 - Collaborative CRF Development ICH E6 (R2) GCP, Section 5.5.3 - Data Collection and System Validation FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 3.4 - CRF Design Considerations

NEW QUESTION # 96
A site study coordinator attempts to make an update in a study database in an EDC system after lock. What occurs?

- A. The site study coordinator is not able to make the change
- B. The change is logged as occurring after lock
- C. The old value is replaced in all locations by the new value
- D. The change is approved by the Data Manager before it is applied

Answer: A

Explanation:
Once a clinical database is locked, it becomes read-only - no further data modifications can be made by any users, including site personnel. This ensures that the data are finalized, consistent, and auditable for statistical analysis and regulatory submission.
According to the GCDMP (Chapter: Database Lock and Archiving), the lock process involves freezing the database to prevent accidental or unauthorized changes. After lock, access permissions are restricted, and all edit and update functions are disabled. If any corrections are required post-lock, the database must be unlocked under controlled procedures (with full audit trail documentation).
Thus, option C - The site study coordinator is not able to make the change - correctly reflects standard EDC functionality and regulatory compliance.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.2 - Database Lock Procedures and Controls ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Audit Trail Requirements FDA 21 CFR Part 11 - Controls for Electronic Records and System Lock Functions

NEW QUESTION # 97
A Clinical Data Manager reads a protocol for a clinical trial to test the efficacy and safety of a new blood thinner for prevention of secondary cardiac events. The stated endpoint is all-cause mortality at 1 year. Which data element would be required for the efficacy endpoint?

- A. Date of death
- B. Drug level
- C. Coagulation time
- D. Cause of death

Answer: A

Explanation:
The efficacy endpoint of all-cause mortality at one year directly depends on the date of death for each subject, making Option D - Date of death the required data element.
According to the GCDMP (Chapter: Clinical Trial Protocols and Data Planning) and ICH E3/E9 Guidelines, the primary efficacy analysis must be based on time-to-event data, particularly when the endpoint involves mortality or survival. The date of death allows accurate calculation of time from randomization to event, essential for survival analysis (e.g., Kaplan-Meier curves).
While cause of death (C) may be collected for safety or secondary analyses, all-cause mortality specifically includes any death regardless of cause. Drug levels (A) and coagulation times (B) may serve as pharmacodynamic or exploratory endpoints but do not directly measure mortality.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Protocol Review, Section 5.4 - Defining Data Required for Endpoints ICH E9 - Statistical Principles for Clinical Trials, Section 2.3 - Time-to-Event Endpoints FDA Guidance for Industry: Clinical Trial Endpoints for Drug Development and Approval

NEW QUESTION # 98
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