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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 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	• 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 (Q116-Q121):

NEW QUESTION # 116
A study has an expected enrollment period of one year but has subject recruitment issues. Twelve new sites are added toward the end of the expected enrollment period to help boost enrollment. What is the most likely impact on data flow?

- A. Additional sites will likely have increased query rates since site training is occurring closer to study close.
- B. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- C. The database set-up will need to be changed to allow for additional sites as they are added to the study.
- D. A bolus of CRFs at the end of the study will result in the need to increase data entry and cleaning rates to meet existing timelines.

Answer: D

Explanation:
Adding multiple new sites late in the enrollment period creates a concentrated influx of new data near the end of the study. These sites typically start enrolling patients later, resulting in a "bolus" of Case Report Forms (CRFs) that must be entered, validated, and cleaned within a shorter timeframe to meet database lock deadlines.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Data Flow), late site activation compresses the timeline for data management tasks, necessitating increased resources for data entry, query management, and cleaning. Data management teams must anticipate this surge and plan accordingly-either by increasing staffing or revising timelines to prevent bottlenecks and maintain quality.
While option D (increased query rates) can occur, it is a secondary effect. The most direct and consistent impact is the surge in data volume requiring expedited processing near study end.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management, Section 5.3 - Managing Changes in Site Activation and Data Flow ICH E6(R2) GCP, Section 5.1 - Quality Management and Oversight

NEW QUESTION # 117
Who has primary responsibility for ensuring accurate completion of the CRF?

- A. Site Coordinator
- B. Clinical Data Manager
- C. Investigator
- D. Clinical Research Associate

Answer: C

Explanation:
The Investigator holds the primary responsibility for ensuring the accuracy, completeness, and timeliness of Case Report Form (CRF) entries. This responsibility is mandated by regulatory requirements under ICH E6(R2) Good Clinical Practice (GCP).
The investigator may delegate CRF completion to a qualified designee (e.g., site coordinator), but the ultimate accountability remains with the investigator. The investigator's signature (electronic or manual) on the CRF serves as certification that the data accurately reflect the source documents and the patient's participation.
The GCDMP (Chapter: CRF Design and Data Collection) reinforces this by stating that while data managers ensure design quality and CRAs verify consistency with source data, the investigator is legally responsible for CRF accuracy.
Thus, option D (Investigator) is correct, as it aligns with both GCP and CCDM standards.
Reference (CCDM-Verified Sources):
ICH E6(R2) GCP, Section 4.9 - Records and Reports (Investigator Responsibilities) SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 5.1 - Investigator's Role in Data Accuracy FDA 21 CFR Part 312.62 - Investigator Recordkeeping and Record Retention

NEW QUESTION # 118
What significant difference is there in the DM role when utilizing an EDC application?

- A. Metrics generation is required
- B. Tracking of eCRFs is a monitor's responsibility

- C. Data updates are implemented by the sites
- D. Database validation is not required

Answer: C

Explanation:
The most significant difference in the Data Manager's role when using an Electronic Data Capture (EDC) system is that data updates are implemented directly by site personnel (Option A).
According to the GCDMP (Chapter: Electronic Data Capture Systems), EDC technology shifts responsibility for data entry and correction from the sponsor or CRO to the investigator site, enabling real-time data entry and validation. This eliminates the need for double entry or remote data transcription, allowing Data Managers to focus on system validation, query management, and data quality oversight rather than physical data handling.
However, the EDC system still requires full validation (contrary to Option B). Metrics generation (Option C) and CRF tracking (Option D) are important but not unique to EDC-based workflows.
Thus, the correct answer is Option A - Data updates are implemented by the sites, reflecting the most fundamental operational shift introduced by EDC systems.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 4.1 - Role of the Data Manager in EDC ICH E6 (R2) GCP, Section 5.5.3 - Electronic Data Entry and Responsibilities FDA 21 CFR Part 11 - Electronic Records and Signatures: Data Entry Responsibilities

NEW QUESTION # 119
Which action has the most impact on the performance of a relational database system?

- A. Executing a properly designed database query
- B. Loading a large lab data file into the database
- C. Making updates to data previously entered into the database
- D. Entering data into the database from CRFs

Answer: B

Explanation:
In a relational database system used in clinical data management, performance refers to how efficiently the system processes transactions, retrieves data, and handles large volumes of information without delay or data integrity issues. Among the listed options, loading a large lab data file into the database (Option B) has the most significant impact on database performance.
According to the Good Clinical Data Management Practices (GCDMP, Chapter on Database Design and Build), the bulk data load process - such as importing large external datasets (e.g., central lab data, ECG results, or imaging metadata) - can be computationally intensive. This process engages the database's input/output (I/O) subsystem, indexing mechanisms, and transaction logs simultaneously, often locking tables temporarily and consuming significant memory and processing resources.
Unlike standard CRF data entry (Option A) or record updates (Option D), which are incremental and typically processed in smaller transactional batches, bulk loading operations handle thousands or millions of rows at once. If not optimized (e.g., via staging tables, indexing strategies, or commit frequency control), such operations can degrade system performance, slow down concurrent user access, and increase the risk of transaction failure.
Executing a properly designed query (Option C) can also be resource-intensive depending on data volume and join complexity, but when queries are properly optimized (using indexed keys, efficient SQL joins, and selective retrieval), their impact is generally controlled and transient compared to large data imports.
Therefore, as outlined in the GCDMP Database Design and Build and FDA Computerized Systems Guidance, the most performance-impacting activity in a relational database is bulk loading large external datasets, making Option B the correct answer.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Build, Section 6.7 - Database Performance and Optimization FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - System Performance and Data Handling Efficiency ICH E6 (R2) Good Clinical Practice, Section 5.5 - Data Handling and Record Integrity CDISC Operational Data Model (ODM) Implementation Guide - Bulk Data Transfer and Validation Considerations

NEW QUESTION # 120
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. Drug level
- B. Cause of death
- C. Coagulation time
- D. Date of death

Answer: D

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 # 121
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