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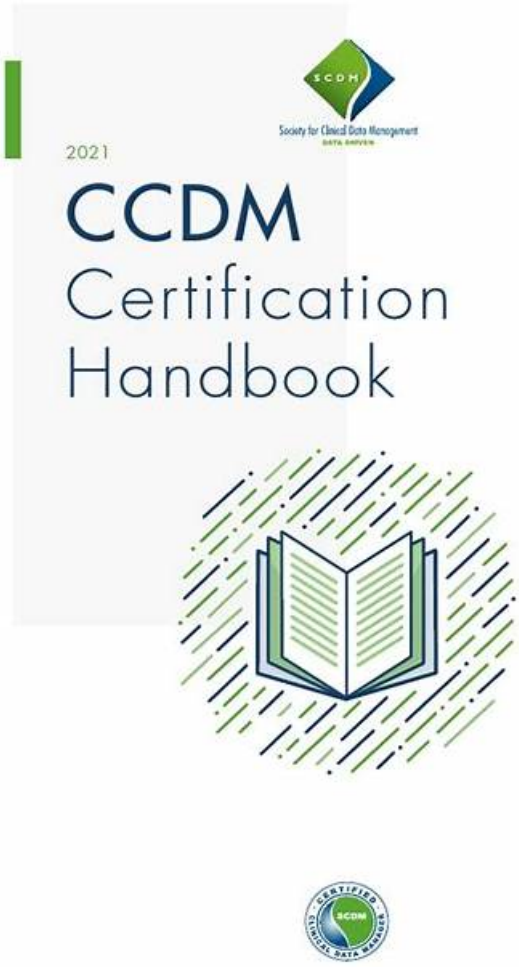

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SCDM CCDM Exam Syllabus Topics:

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	• 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 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	• 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 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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SCDM Certified Clinical Data Manager Sample Questions (Q25-Q30):

NEW QUESTION # 25
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. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- B. 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.
- C. Additional sites will likely have increased query rates since site training is occurring closer to study close.
- D. The database set-up will need to be changed to allow for additional sites as they are added to the study.

Answer: B

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 # 26
A Data Manager is drafting a report for clinical operations staff for support in responding to questions about milestone-based site payments. Which is the most important information to display?

- A. Milestones met by month, by site
- B. Milestones met by month, by type
- C. Expected versus actual milestones met to date, by site
- D. Milestones included in the last payment by site, by patient

Answer: C

Explanation:
When reporting milestone-based site payment information, the most critical information to include is expected versus actual milestones met to date, by site.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), effective reporting must support operational and financial decision-making by presenting performance indicators in a clear, actionable format. Site payments in clinical studies are typically tied to specific milestones such as subject enrollment, visit completion, or data cleaning achievements.
By comparing expected (planned) versus actual (achieved) milestones per site, the Data Manager provides clinical operations staff with an accurate view of site progress and payment eligibility. This allows for identification of delayed sites, forecasting of upcoming payments, and early intervention for underperforming centers.
While milestone summaries by month or type (options A and B) may be useful for trend analysis, they lack the operational detail required for financial tracking. Milestone data by patient (option D) is overly granular for site-level payment management.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Data Reporting for Site Performance and Payments ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication and Monitoring Reports FDA Guidance for Industry: Oversight of Clinical Investigations - Site Management and Reporting

NEW QUESTION # 27
The result set from the query below would be which of the following?
SELECT * FROM patient WHERE medical_record_number > 9000

- A. Shorter or of equal length than the patient table
- B. Wider than the patient table
- C. Longer than the patient table
- D. Narrower than the patient table

Answer: A

Explanation:
In Structured Query Language (SQL), the WHERE clause is used to filter records based on specified criteria. The query retrieves all columns from the patient table (SELECT *) but only those rows where the medical_record_number value is greater than 9000.
This means:
The number of columns (fields) remains the same as the original table.
The number of rows (records) will be equal to or less than the number of rows in the patient table, depending on how many patients meet the filter condition.
Hence, the result set can only be shorter or equal in length compared to the original table. It cannot be longer, wider, or narrower, since no new rows or columns are created.
Therefore, option B - "Shorter or of equal length than the patient table" - is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Relational Database Queries and Filtering Logic ICH E6(R2) GCP, Section 5.5.3 - Data Retrieval, Filtering, and Storage Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Query Logic and Record Subsetting

NEW QUESTION # 28
What action should be taken regarding the clinical database when MedDRA releases a new version of its dictionary?

- A. Evaluate the extent and impact of the changes.
- B. Upgrade the version immediately and recode.
- C. Identify an alternative dictionary.
- D. Continue using the existing version to code.

Answer: A

Explanation:
When a new version of MedDRA (Medical Dictionary for Regulatory Activities) is released, the correct action is to evaluate the extent and impact of the changes before implementation.
According to the GCDMP (Chapter: Medical Coding and Dictionaries), MedDRA updates are published twice yearly (March and September). Each release may introduce new terms, modify hierarchies, or retire old ones. Prior to adopting a new version, the Data Manager and Medical Coder must:

Assess the number and type of term changes,
Determine the potential effect on ongoing coding consistency, and
Decide whether migration to the new version is warranted mid-study or deferred until database lock.
Immediate recoding (option C) without evaluation may cause inconsistencies and require additional validation. Continuing with the existing version (option B) may be acceptable short-term but must be justified. Using an alternative dictionary (option D) is noncompliant, as MedDRA is the regulatory standard for safety reporting.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Medical Coding and Dictionaries, Section 6.3 - Version Control and Impact Assessment MedDRA Term Selection: Points to Consider (MSSO, Latest Version), Section 3 - Versioning and Maintenance ICH E2B(R3) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

NEW QUESTION # 29
QA is conducting an audit on a study for ophthalmology which is ready for lock. Inconsistencies are found between the database and the source. Of the identified fields containing potential data errors, which fields are considered critical for this particular study?

- A. Medical History
- B. Concomitant Medications
- C. Weight
- D. Subject Identifier

Answer: B

Explanation:
In an ophthalmology clinical study, data criticality is determined by how directly a data element affects safety evaluation, efficacy assessment, and regulatory decision-making. According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), critical data fields are those that:
Have a direct impact on the primary and secondary endpoints, or
Are essential for safety interpretation and adverse event causality assessment.
Among the listed options, Concomitant Medications (Option B) are considered critical data for ophthalmology studies. This is because many ocular treatments and investigational products can interact with systemic or topical medications, potentially affecting ocular response, intraocular pressure, corneal healing, or visual function outcomes. Any inconsistency in concomitant medication data could directly influence safety conclusions or efficacy interpretations.
Other options, while important, are less critical for this study type:
Subject Identifier (A) is essential for data traceability and audit purposes but is not directly related to safety or efficacy outcomes.
Weight (C) may be relevant in dose-dependent drug trials but is rarely a pivotal variable in ophthalmology, where local administration (eye drops, intraocular injections) is common.
Medical History (D) provides contextual background but does not have the same immediate impact on endpoint analysis as current concomitant treatments that can confound the therapeutic effect or cause ocular adverse events.
Per GCDMP and ICH E6 (R2) GCP guidelines, data validation plans must define critical data fields during study setup, reflecting therapeutic area-specific priorities. For ophthalmology, concomitant medications, ocular assessments (visual acuity, intraocular pressure, retinal thickness, etc.), and adverse events are typically designated as critical fields requiring heightened validation, source verification, and reconciliation accuracy before database lock.
Thus, when QA identifies discrepancies between the CRF and source, the Concomitant Medications field (Option B) is the most critical to address immediately to ensure clinical and regulatory data integrity.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.4 - Critical Data Fields and Data Validation Prioritization ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Source Data Verification FDA Guidance for Industry: Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring, Section 5.3 - Identification of Critical Data and Processes SCDM GCDMP Chapter: Data Quality Assurance and Control - Therapeutic Area-Specific Data Criticality Examples (Ophthalmology Studies)

NEW QUESTION # 30
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