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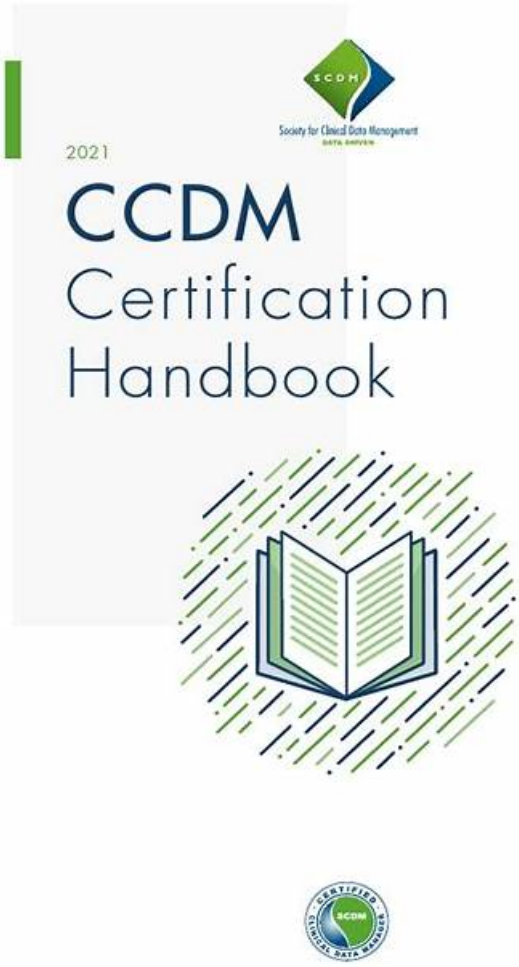

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 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	• 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	• 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 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q22-Q27):

NEW QUESTION # 22
Which metrics report listed below would best help identify trends in the clinical data?

- A. Last patient/last visit date to data lock date
- B. Number of subjects screened/enrolled
- C. Query frequency counts per data element
- D. Percent of data/visits cleaned

Answer: C

Explanation:
The Query frequency counts per data element (Option D) is the best metric for identifying data trends and potential systemic data issues in clinical trials.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control), trend analysis involves identifying recurring data issues across subjects, sites, or variables to detect training gaps, protocol misinterpretation, or CRF design flaws. A high number of queries generated for specific fields (e.g., visit date, lab values, or dosing information) may indicate systemic problems such as unclear CRF instructions or site-level misunderstandings.
While metrics such as percent of data cleaned (A) and time to database lock (B) reflect overall progress and efficiency, they do not identify specific data pattern issues. The number of subjects screened/enrolled (C) pertains to recruitment rather than data quality. Therefore, query frequency per data element provides actionable insights for quality improvement, process refinement, and early identification of potential risks.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.3 - Metrics and Trend Analysis ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Risk-Based Quality Review and Data Trends FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section 6 - Data Metrics and Trend Evaluation

NEW QUESTION # 23
Which is the MOST appropriate flow for EDC set-up and implementation?

- A. CRF "wire-frames" created, CRFs reviewed, CRFs printed, CRFs distributed to sites
- B. Database created, Subjects enrolled, Database tested, Sites trained, Database released
- C. Protocol finalized, Database created, Edit Checks created, Database tested, Sites trained

- D. Database created, Database tested, Sites trained, Protocol finalized, Database released

Answer: C

Explanation:
The correct and compliant sequence for EDC system setup and implementation begins only after the study protocol is finalized, as all case report form (CRF) designs, database structures, and validation rules derive directly from the finalized protocol.
According to GCDMP (Chapter: EDC Systems Implementation), the proper order is:
Protocol finalized - defines endpoints and data requirements.
Database created - built according to the protocol and CRFs.
Edit checks created - programmed to validate data entry accuracy.
Database tested (UAT) - ensures functionality, integrity, and compliance.
Sites trained and system released - only then can data entry begin.
Option B follows this logical and regulatory-compliant sequence. Other options (A, C, D) are either paper-based workflows or violate GCP-compliant timelines (e.g., enrolling subjects before database validation).
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.2 - System Setup and Implementation Flow ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation and User Training Before Use FDA 21 CFR Part 11 - Validation and System Release Requirements

NEW QUESTION # 24
A Data Manager receives an audit finding of missing or undocumented training for two database developers according to the organization's training SOP and matrix. Which is the best response to the audit finding?

- A. Identify the root cause and improve the process to prevent it
- B. Reprimand the person responsible for maintaining training documentation
- C. Send the two developers to the required training
- D. Remove the training items from the training matrix

Answer: A

Explanation:
When an audit identifies missing or undocumented training, the most appropriate and compliant response is to identify the root cause of the issue and implement corrective and preventive actions (CAPA) to ensure that similar findings do not recur.
According to Good Clinical Data Management Practices (GCDMP, Chapter: Quality Management and Auditing), effective quality systems require root cause analysis (RCA) for all audit findings. The process involves:
Investigating why the documentation gap occurred (e.g., poor tracking, outdated SOP, or lack of oversight).
Correcting the immediate issue (e.g., ensuring the developers complete or document training).
Updating processes, training systems, or oversight mechanisms to prevent recurrence.
While sending the two developers to training (D) addresses the symptom, it does not resolve the systemic issue identified by the audit. Options B and C are non-compliant and do not address quality system improvement.
Therefore, option A (Identify the root cause and improve the process) is the best and CCDM-compliant response.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Quality Management and Auditing, Section 6.2 - Corrective and Preventive Actions (CAPA) ICH E6(R2) GCP, Section 5.1.1 - Quality Management and Continuous Process Improvement FDA 21 CFR Part 820.100 - Corrective and Preventive Action (CAPA) Requirements

NEW QUESTION # 25
An organization conducts over fifty studies per year. Currently each study is specified and set-up from scratch. Which of the following organizational infrastructure options would streamline database set-up and study-to-study consistency?

- A. Improving the form or screen design process
- B. Maintaining a library of form or screen modules
- C. Adopting an ODM compliant database system
- D. Implementing controlled terminology for adverse events

Answer: B

Explanation:

To improve efficiency and ensure consistency across multiple studies, the most effective infrastructure solution is to maintain a centralized library of standardized forms or screen modules (e.g., CRF/eCRF templates).
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Database Design and Build), using a form library allows reuse of validated data collection modules for commonly collected domains such as demographics, adverse events, and vital signs. This reduces database setup time, enhances uniformity in data definitions, and ensures alignment with standards such as CDISC CDASH and SDTM.
While adopting ODM (A) provides standardized data exchange and interoperability, it does not inherently reduce setup workload. Improving design processes (C) enhances efficiency but doesn't guarantee consistency, and implementing controlled terminology (D) helps with coding standardization, not database structure.
Therefore, option B - maintaining a library of form or screen modules - provides the most direct and sustainable improvement for scalability and quality.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.3 - Use of Standard Libraries and Templates CDISC CDASH Implementation Guide, Section 3.2 - Reusable CRF Modules and Standardization ICH E6(R2) GCP, Section 5.5.3 - Standardization and Reuse in Data Collection Systems

NEW QUESTION # 26
In reviewing the adverse events for a subject, a data manager notices one recorded as "worsening of migraine." After reviewing the rest of the adverse events and finding no other migraine recordings, what is the data manager's next step?

- A. Query the site for the first adverse event occurrence of migraine.
- B. Look for any adverse event instance of headache and assume the events are similar.
- C. Check the medical history for recording of a history of migraines.
- D. Query the site for more information on the adverse event, "worsening of migraine."

Answer: D

Explanation:
When a data inconsistency arises - such as a record of "worsening of migraine" without prior documentation of a migraine episode - the Data Manager should query the site for clarification (Option D).
According to the GCDMP (Chapter: Data Validation and Cleaning), data managers must raise a clarification query whenever data appear incomplete, inconsistent, or ambiguous. The site must confirm whether "worsening of migraine" refers to a new event or an exacerbation of a preexisting condition. This clarification ensures accurate safety reporting and appropriate medical coding (e.g., MedDRA classification).
Checking the medical history (Option C) may help but does not resolve the inconsistency. Assuming a relationship (Option A or B) without verification would violate Good Clinical Data Management Practice and potentially misrepresent the adverse event.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.3 - Query Generation and Resolution ICH E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, Section II - Data Clarification Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Query Management

NEW QUESTION # 27
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