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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	• 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	• 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 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 (Q93-Q98):

NEW QUESTION # 93
What does RACI stand for?

- A. Responsible, Accountable, Contribute, Input
- B. Responsibility, Accountability, Consultation, Information
- C. Responsible, Accountable, Consulted, Informed
- D. Recommend, Approve, Calibrate, Innovate

Answer: C

Explanation:
RACI is a project management and governance framework used to define roles and responsibilities within a project. Each letter represents a distinct role type:
Responsible (R): The person(s) who perform the work or execute the task.
Accountable (A): The individual ultimately answerable for the task's completion and success (only one per activity).
Consulted (C): Subject matter experts who provide input or guidance before decisions are made.
Informed (I): Individuals kept up to date on progress or outcomes but not directly involved in execution.
The RACI model ensures clarity in ownership and accountability, preventing duplication of effort or responsibility confusion. It is a key component of the GCDMP (Chapter: Project Management in Data Management) for ensuring clear delegation and communication within clinical data management teams.
Hence, option D is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management in Data Management, Section 5.1 - Roles, Responsibilities, and RACI Matrices
Project Management Institute (PMI) Framework - Responsibility Assignment Matrices (RACI) ICH E6(R2) GCP, Section 5.1.1 - Defined Roles and Quality Oversight Responsibilities

NEW QUESTION # 94
What are the first logical specifications that need approval when building an efficient EDC database?

- A. eCRF Guidelines
- B. Metric Reports
- C. Edit Check Logic
- D. eCRF Fields

Answer: D

Explanation:
In the EDC database build process, the first logical specifications that require approval are the electronic Case Report Form (eCRF) fields.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Database Design and Build), eCRF field specifications define what data elements are collected, their data types, permitted values, field lengths, and any associated metadata.
Approval of these specifications forms the foundation for subsequent design components such as edit check programming, query management rules, and data validation logic.
Edit checks (B) are developed only after fields and structures are finalized.
Metric reports (C) and eCRF guidelines (D) are downstream documentation or tools, not logical specifications required at the build start.
Therefore, option A (eCRF fields) is correct, as their approval marks the first formal milestone in the EDC system development life cycle.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 4.2 - Logical Design and eCRF Field Specifications ICH E6(R2) GCP, Section 5.5.3 - System Design and Validation Documentation FDA 21 CFR Part 11 - System Validation and Documentation Controls

NEW QUESTION # 95

There is a modification to the CRF and a sudden increase in the number of queries generated in the EDC system. Which action is most likely to reduce the number of queries?

- A. Have the monitor close the queries
- B. Review the edit checks for correctness
- C. Make some of the existing edit checks manually
- D. Introduce a source data verification process

Answer: B

Explanation:

When a CRF modification leads to a sudden increase in EDC queries, the most likely cause is an error or misconfiguration in the edit checks introduced during or after the change. Therefore, the first step should be to review the edit checks for correctness.

The GCDMP (Chapter: Database Design and Validation) emphasizes that any database or CRF modification should trigger retesting of affected validation rules. Incorrect logic, thresholds, or missing conditional statements in automated edit checks can cause false or redundant queries, leading to unnecessary data management burden and site frustration.

Manually handling edit checks (option A) or adding SDV (option B) does not address the root cause. Having monitors close queries (option D) would mask the problem rather than resolve it.

Thus, the correct corrective measure is Option C - review and validate the edit checks to ensure proper functionality.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Validation, Section 5.5 - Edit Check Testing and Review ICH E6 (R2) GCP, Section 5.5.3 - Validation and Change Control for Electronic Systems FDA 21 CFR Part 11 - System Validation and Change Documentation

NEW QUESTION # 96

A study takes body-composition measurements at baseline using a DEXA scanner. Which information is needed to correctly associate the body-composition data to the rest of the study data?

- A. Subject number and visit number
- B. Study number and subject number
- C. Study number and visit number
- D. Subject number

Answer: A

Explanation:

To properly associate body-composition data (from a DEXA scanner) with other study data, both the subject number and the visit number are required.

According to the GCDMP (Chapter: Data Management Planning and Study Start-up), every clinical data record must be uniquely identifiable and linkable to a specific subject and study event. The subject number identifies the participant, while the visit number defines the temporal context in which the measurement was taken.

Without both identifiers, data integration becomes ambiguous-especially if multiple assessments occur over time (e.g., baseline, week 12, end of study). Including both ensures data traceability, integrity, and alignment with the protocol-defined schedule of events.

Study number (option A) alone does not distinguish between visits or subjects, and visit number alone (option C) lacks linkage to the individual participant.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.4 - Data Linking and Identification Requirements ICH E6 (R2) GCP, Section 5.5.3 - Data Traceability Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Identification Requirements

NEW QUESTION # 97

An external organization has been hired to manage SAE follow-up for a large study. Which of the following would be used as guidance for exchange of the SAE data between the EDC system and the vendor's safety management system?

- A. Medical Document for Regulatory Activities
- B. Submission Data Tabulation Model
- C. Individual Case Safety Report
- D. Biomedical Research Domain Model

Answer: C

Explanation:
The Individual Case Safety Report (ICSR) is the standard format used globally for the exchange of Serious Adverse Event (SAE) data between clinical data management systems (EDC) and safety management systems.
According to ICH E2B(R3) and Good Clinical Data Management Practices (GCDMP, Chapter: Safety Data Management and SAE Reconciliation), the ICSR provides the data structure and content standards for electronic transmission of safety data, including patient demographics, event details, outcomes, and product information. It ensures interoperability between systems by defining standardized message elements and controlled terminologies.
Other options are not applicable:
A . Medical Document for Regulatory Activities (MDRA) is not a recognized standard.
B . Biomedical Research Domain Model (BRIDG) provides conceptual modeling but not data exchange guidance.
D . SDTM is used for regulatory submission datasets, not real-time SAE exchange.
Thus, option C (Individual Case Safety Report) is correct, as it defines the internationally accepted electronic format for SAE data exchange between safety and clinical databases.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Safety Data Management and SAE Reconciliation, Section 4.3 - SAE Data Exchange and Standards
ICH E2B(R3): Electronic Transmission of Individual Case Safety Reports FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Postmarketing ICSRs (2014)

NEW QUESTION # 98
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