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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 (Q149-Q154):

NEW QUESTION # 149

Which is the MOST appropriate flow for EDC set-up and implementation?

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

Answer: D

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 # 150

What does RACI stand for?

- A. Responsible, Accountable, Consulted, Informed
- B. Responsibility, Accountability, Consultation, Information

- C. Recommend, Approve, Calibrate, Innovate
- D. Responsible, Accountable, Contribute, Input

Answer: A

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 # 151

Data from two sites are combined. One site coded gender as 1 and 2 (for Male and Female, respectively) while the other stored the data as M and F. Which term best describes the mapping?

- A. One-to-many
- B. Two-to-two
- C. One-to-one
- D. Many-to-one

Answer: C

Explanation:

When combining data from two datasets where one uses numeric codes (1 = Male, 2 = Female) and another uses text codes (M, F), each unique value in one dataset corresponds exactly to one unique value in the other.

This relationship is a one-to-one mapping, where each element in one dataset maps directly to a single corresponding element in the other.

1 → M

2 → F

Such mappings ensure consistent data harmonization during data integration and standardization phases, as outlined in the GCDMP (Chapter: Database Design and Integration).

Many-to-one (C) mapping would occur if multiple values (e.g., "Male," "M," "Man") mapped to a single standardized value, which isn't the case here.

Thus, the mapping is one-to-one, ensuring precise correspondence between both representations of gender data.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.4 - Data Mapping and Harmonization CDISC SDTM
Implementation Guide, Section 5.2 - Controlled Terminology and Mapping Rules ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Integration Principles

NEW QUESTION # 152

Data characterizing the safety profile of a drug are collected to provide information for which of the following?

- A. Efficacy meta-analyses
- B. Quality of life calculations
- C. Product labeling
- D. Survival curves

Answer: C

Explanation:

Safety data collected during a clinical trial are used primarily to support product labeling, ensuring accurate communication of a drug's risks, contraindications, and adverse reactions to healthcare providers and patients.

According to the GCDMP (Chapter: Safety Data Handling and Reconciliation) and ICH E2A/E2F guidelines, all adverse events (AEs), serious adverse events (SAEs), and laboratory abnormalities are analyzed and summarized to define the safety profile of an investigational product. These data form the basis for regulatory submissions such as the Clinical Study Report (CSR) and product labeling (e.g., prescribing information), as required by the FDA and other regulatory authorities.

While safety data may contribute indirectly to analyses such as survival curves (option A) or quality of life metrics (option D), their primary regulatory function is to inform product labeling and post-marketing surveillance documentation.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Safety Data Handling and Reconciliation, Section 4.3 - Use of Safety Data in Regulatory Submissions ICH E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting FDA Guidance for Industry: Adverse Event Reporting and Labeling Requirements

NEW QUESTION # 153

A Clinical Data Manager is drafting data element definitions for a new study. One of the definitions provided is:

"Baby's crown to heel length measured lying on back, measured physical quantity, precision of 0.1." Which of the following is missing from the definition?

- A. Discrete values for a drop-down list
- **B. Unit or dimensionality of measure**
- C. Data type of the data element
- D. Enumeration

Answer: B

Explanation:

A complete data element definition in clinical data management should include:

Name and clear description of the data element,

Data type (e.g., numeric, text, date),

Precision or scale (if numeric), and

Unit or dimensionality of measure (e.g., centimeters, inches).

In this example, while the data type ("measured physical quantity") and precision (0.1) are defined, the unit of measurement (e.g., centimeters or inches) is missing. This omission leads to ambiguity and could cause serious discrepancies when comparing or analyzing measurements.

The GCDMP (Chapter: Database Design and Build) emphasizes that units and dimensionality must be explicitly defined and consistently applied in all CRFs, metadata dictionaries, and data transformations.

Thus, option D (Unit or dimensionality of measure) is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Metadata and Data Element Definitions CDISC CDASH Implementation Guide, Section 3.3 - Data Element Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Data Accuracy and Standardized Definitions

NEW QUESTION # 154

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