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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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 2	<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 3	<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 4	<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.
Topic 5	<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.

SCDM Certified Clinical Data Manager Sample Questions (Q147-Q152):

NEW QUESTION # 147

A relational database has tables for PATIENT_DEMOGRAPHY and VITAL_SIGNS data collected during a visit. The primary key for the VITAL_SIGNS table is a composite key that includes the unique patient identifier, visit number, and vital signs parameter name. The two tables are joined on the patient identifier. What will be the number of records in the result set?

- A. One record per patient per visit
- B. One record per visit
- C. One record per patient per visit per vital sign parameter
- D. One record per patient

Answer: C

Explanation:

In a relational database structure, each record in a table is uniquely identified by a primary key. In this case, the VITAL_SIGNS table uses a composite primary key consisting of:

Patient Identifier,

Visit Number, and

Vital Signs Parameter Name.

This means each record represents a unique measurement of a specific parameter (e.g., blood pressure, pulse) for a patient at a specific visit.

When joining PATIENT_DEMOGRAPHY and VITAL_SIGNS tables on the patient identifier, the result set will include one record for every combination of patient, visit, and parameter - i.e., one record per patient per visit per vital sign parameter.

Therefore, option C correctly describes the expected number of records.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Primary and Foreign Key Relationships in Relational Models
CDISC SDTM Implementation Guide, Section 5.3 - Observation-Level Data Structures ICH E6(R2) GCP, Section 5.5.3 - Data Organization and Integration Principles

NEW QUESTION # 148

According to the FDA Guidance for Industry, Providing Regulatory Submissions in Electronic Format (April 2006) and Good Clinical Data Management Practices (GCDMP, May 2007), which of the following is the most acceptable for a derived field?

- A. Providing CRF annotation "not entered in the database" next to the average score
- B. Providing the algorithm for calculating the average score in the dataset definition file
- C. Providing the algorithm for calculating the average score on the CRF
- D. Providing CRF annotation AVE next to the average score

Answer: B

Explanation:

In clinical data management, a derived field refers to any variable that is not directly collected from the Case Report Form (CRF) but is instead calculated or inferred from one or more collected variables (for example, calculating an average blood pressure from multiple readings). Proper documentation of derived fields is essential for ensuring data traceability, transparency, and compliance with both FDA and SCDM guidelines.

According to the Good Clinical Data Management Practices (GCDMP, May 2007), all derivations and transformations applied to clinical data must be clearly defined and documented in metadata such as the dataset definition file (also referred to as data specifications, variable definition tables, or Define.xml files). The derivation algorithm should be explicitly stated in this documentation to allow independent verification, regulatory review, and reproducibility of results.

The FDA Guidance for Industry (April 2006) on electronic submissions further emphasizes that derived fields must be supported by comprehensive metadata that defines the computational method used. This documentation enables the FDA or any regulatory body to audit and reproduce analytical results without ambiguity. Annotating or describing derivations directly on the CRF (as in options A, B, or D) is not sufficient, as CRFs represent data collection instruments-not analytical documentation.

Therefore, the correct and regulatory-compliant practice is to provide the derivation algorithm for a calculated field within the dataset definition file, aligning with both FDA and GCDMP expectations for data integrity and auditability.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Handling and Processing - Derived and Calculated Data Fields, Section 5.3.3 FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006, Section 3.2 on Dataset Documentation Requirements CDISC Define.xml Implementation Guide - Metadata and Algorithm Documentation for Derived Variables

NEW QUESTION # 149

A study uses and collects pacemaker interrogation data for each patient weekly by selecting and downloading the data from the manufacturer's website. There are 200 patients in the study and it takes the Data Manager 30 minutes per file to download, import, and process the data. Assuming that the distribution of work is uniform over the six-month trial, how many Data Managers are needed for the activity data alone?

- A. Fifty percent of a Data Manager per month
- B. Two Data Managers per month
- C. One Data Manager per month
- D. Two and a half Data Managers per month

Answer: A

Explanation:

Let's calculate the workload:

$200 \text{ patients} \times 30 \text{ minutes} = 6,000 \text{ minutes/week}$

$6,000 \text{ minutes} \div 60 = 100 \text{ hours/week}$

Over 6 months (~26 weeks): $100 \times 26 = 2,600 \text{ hours total}$

Assuming a full-time Data Manager works approximately 160 hours/month, over 6 months (960 hours) per full-time equivalent (FTE):

$2,600 \div 960 \approx 2.7 \text{ FTEs total for the entire study period}$

To find the average per month, we divide evenly over 6 months:

$2.7 \div 6 \approx 0.45 \text{ FTE per month, or approximately 50\% of a Data Manager per month.}$

Thus, the correct answer is B. Fifty percent of a Data Manager per month.

This estimate follows GCDMP best practices in resource planning, ensuring adequate data management capacity for ongoing external data handling activities.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Project Management, Section 5.3 - Resource Estimation and Workload Planning ICH E6(R2) GCP, Section 5.1.1 - Quality Systems and Adequate Staffing

NEW QUESTION # 150

A Data Manager is designing a CRF for a study for which the efficacy data are not covered by the current SDTM domains. Which of the following should the Data Manager consult first?

- A. A CDISC therapeutic-area implementation guide
- B. Data elements used in clinical registries in the therapeutic area
- C. Forms used by other sponsors in the same therapeutic area
- D. SNOMED terms used in the therapeutic area

Answer: A

Explanation:

When efficacy data are not covered by existing CDISC SDTM domains, the first resource the Data Manager should consult is the CDISC Therapeutic Area Implementation Guide (TAIG) for that therapeutic field.

According to the GCDMP (Chapter: Standards and Data Mapping), CDISC's Therapeutic Area User Guides (TAUGs) and Implementation Guides provide standardized data structures, variable definitions, controlled terminology, and implementation examples for specific diseases or therapeutic areas. These guides ensure consistency across studies, promote interoperability, and

align data collection with regulatory submission expectations.

Consulting other sponsors' forms or external registries (options A and C) can be informative but do not provide authoritative CDISC-compliant standards. SNOMED terms (option B) address medical terminology, not structural data domain definitions. Therefore, Option D is correct-CDISC TA Implementation Guides are the recognized primary reference when extending or designing SDTM-compliant CRFs.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Standards and Data Mapping, Section 4.2 - Use of CDISC Standards CDISC Therapeutic Area User Guides (TAUGs) - Implementation Guidance for Domain Extension FDA Data Standards Catalog - CDISC Therapeutic Area Standards

NEW QUESTION # 151

In a physical therapy study, range of motion is assessed by a physical therapist at each site using a study-provided goniometer. Which is the most appropriate quality control method for the range of motion measurement?

- A. Programmed edit checks to detect out-of-range values upon data entry
- B. Reviewing data listings for illogical changes in range of motion between visits
- C. Comparison to the measurement from the previous visit
- **D. Independent assessment by a second physical therapist during the visit**

Answer: D

Explanation:

In this scenario, the variable of interest-range of motion (ROM)-is a clinically measured, observer-dependent variable. The accuracy and reliability of such data depend primarily on the precision and consistency of the measurement technique, not merely on data entry validation. Therefore, the most appropriate quality control (QC) method is independent verification of the measurement by a second qualified assessor during the visit (Option D).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Quality Assurance and Control), quality control procedures must be tailored to the nature of the data. For clinically assessed variables, especially those involving human judgment (e.g., physical measurements, imaging assessments, or subjective scoring), real-time verification by an independent qualified assessor ensures that data are valid and reproducible at the point of collection. This approach directly addresses measurement bias, observer variability, and instrument misuse, which are primary sources of data error in clinical outcome assessments.

Other options, while valuable, address only data consistency or plausibility after collection:

Option A (comparison to previous visit) and Option C (reviewing data listings) are retrospective data reviews, suitable for identifying trends but not preventing measurement error.

Option B (programmed edit checks) detects only extreme or impossible values, not measurement inaccuracies due to technique or observer inconsistency.

The GCDMP and ICH E6 (R2) Good Clinical Practice guidelines emphasize that data quality assurance should begin at the source, through standardized procedures, instrument calibration, and dual assessments for observer-dependent measures. Having an independent second assessor ensures inter-rater reliability and provides direct confirmation that the recorded value reflects an accurate and valid measurement.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.4 - Measurement Quality and Verification ICH E6 (R2) Good Clinical Practice, Section 2.13 - Quality Systems and Data Integrity FDA Guidance for Industry: Patient-Reported Outcome Measures and Clinical Outcome Assessment Data, Section 5.3 - Quality Control of Clinician-Assessed Data SCDM GCDMP Chapter: Source Data Verification and Quality Oversight Procedures

NEW QUESTION # 152

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