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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	• 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 3	• 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 4	• 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 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 (Q90-Q95):

NEW QUESTION # 90
In the EDC database, which factors are considered when defining user roles?

- A. Protocol Review and Data Entry
- B. Patient Recruitment and Protocol Review
- C. Data Review and Analysis Programming
- D. Data Entry and Data Review

Answer: D

Explanation:
In Electronic Data Capture (EDC) systems, user roles are defined based on the functions and permissions required for specific study tasks. The most fundamental and universally applicable roles are Data Entry (performed by site staff) and Data Review (performed by monitors or data managers).
According to the GCDMP (Chapter: Technology and Electronic Data Capture Systems), defining user roles involves:
Assigning functional access levels (e.g., entry, review, query resolution).
Ensuring role-based security to protect data integrity.
Complying with 21 CFR Part 11 and ICH E6(R2) access control standards.
Options B, C, and D include functions (protocol review, analysis programming) not directly controlled within an EDC system.
Thus, option A (Data Entry and Data Review) correctly represents the two core factors considered when defining user roles.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Technology and Electronic Data Capture Systems, Section 4.3 - User Access, Roles, and Permissions
ICH E6(R2) GCP, Section 5.5.3 - System Access and Security Controls FDA 21 CFR Part 11 - Access Control and Audit Trail Requirements

NEW QUESTION # 91
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 per vital sign parameter
- B. One record per patient per visit
- C. One record per patient
- D. One record per visit

Answer: A

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 # 92
Which of the following actions is particularly important in merging data from different trials?

- A. Use of a common adverse event dictionary
- B. Enrollment of investigative sites with similar patient populations
- C. Use of a common software platform
- D. Exclusion of studies that use a cross-over design

Answer: A

Explanation:
When merging data from different clinical trials, the use of a common adverse event (AE) dictionary (such as MedDRA or WHO Drug) is essential to ensure consistency and comparability across datasets.
According to the GCDMP (Chapter: Standards and Data Mapping) and CDISC SDTM Implementation Guide, data integration across studies requires standardized terminology for adverse events, medications, and clinical outcomes. Using the same AE dictionary ensures that similar terms are coded consistently, allowing accurate cross-study analysis, pooled summaries, and safety reporting.
A shared software platform (option A) is not necessary if data are mapped to standard formats (e.g., CDISC SDTM). Patient population similarity (option B) affects interpretation but not technical data merging. Study design differences (option C) may influence statistical analysis but not data integration mechanics.
Therefore, Option D - Use of a common adverse event dictionary - is the correct and most critical action for consistent multi-study data integration.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Standards and Data Mapping, Section 5.1 - Use of Standardized Coding Dictionaries CDISC SDTM Implementation Guide, Section 4.3 - Controlled Terminology and Cross-Study Integration ICH E3 and E2B - Clinical Data Standards and Safety Coding Requirements

NEW QUESTION # 93
Which statement is true regarding User Acceptance Testing (UAT) in an EDC application?

- A. Data should not be collected in a production environment until UAT is completed
- B. System tools in EDC do not remove the need for UAT
- C. The extent of UAT (i.e., the number of test cases and rules) cannot be risk-based
- D. Every rule should be tested with at least one "pass" and one "fail" scenario

Answer: A

Explanation:
In Electronic Data Capture (EDC) system validation, User Acceptance Testing (UAT) is a mandatory phase that must be completed before data collection begins in the production environment.
According to the GCDMP (Chapter: Database Design, Validation, and Testing) and FDA 21 CFR Part 11, UAT ensures that the EDC system meets all protocol-specific, functional, and regulatory requirements before it is deployed for live use. The goal is to verify that the system performs exactly as intended by simulating real-world user interactions with test data in a validated test environment.
Data collection prior to UAT completion would violate validation requirements and risk noncompliance with ICH E6 (R2) GCP Section 5.5.3, which mandates that all computerized systems be validated and tested before use.
While options A and C describe correct components of testing strategy, the key regulatory requirement is that UAT must be completed and approved before live data entry begins. Option D is incorrect - risk-based UAT is an accepted modern validation approach under both FDA and GAMP5 principles.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Validation, Section 5.3 - User Acceptance Testing FDA 21 CFR Part 11 - Validation of Electronic Systems (Section 11.10(a)) ICH E6 (R2) GCP, Section 5.5.3 - Validation Before Use in Production Environment

NEW QUESTION # 94
The result set from the query below would be which of the following?
SELECT Pt_ID, MRN, SSN FROM patient

- A. Wider than the patient table

- B. Shorter than the patient table
- C. Longer than the patient table
- D. Narrower than the patient table

Answer: D

Explanation:
In a SQL (Structured Query Language) database, the SELECT statement specifies which columns to display from a table. In this query, only three columns - Pt_ID, MRN, and SSN - are being selected from the patient table.
This means the resulting dataset will contain:
The same number of rows (records) as the original table (assuming no WHERE filter), and Fewer columns than the full table.
In database terminology:
"Wider" refers to more columns (fields).
"Narrower" refers to fewer columns (fields).
Since this query retrieves only 3 columns (out of potentially many in the original table), the result set is narrower than the patient table, making option D correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.1 - Relational Databases and Query Logic ICH E6(R2) GCP, Section 5.5.3 - Data Retrieval and Integrity Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Database Query Controls

NEW QUESTION # 95
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