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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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	• 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 3	• 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	• 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	• 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.

SCDM Certified Clinical Data Manager Sample Questions (Q80-Q85):

NEW QUESTION # 80
With the implementation of EDC, which company Standard Operating Procedure (SOP) would require updates for new procedures of handling data?

- A. Data Review and Validation
- B. Handling External Data
- C. Coding Medical and Clinical Terms
- D. Data Backup, Recovery, and Contingency Plans

Answer: A

Explanation:
When a company transitions from paper-based data capture to Electronic Data Capture (EDC) systems, one of the most critical areas requiring procedural updates is the Data Review and Validation SOP. The introduction of EDC systems fundamentally changes how data is collected, reviewed, validated, and queried.
According to the Good Clinical Data Management Practices (GCDMP), the implementation of EDC introduces real-time data entry and review, automated edit checks, and electronic query management. These functionalities necessitate revised procedures to define how data validation, discrepancy management, and monitoring are conducted electronically. The SOP must specify roles, responsibilities, system access controls, and processes for electronic source verification (eSource), ensuring compliance with 21 CFR Part 11 and ICH E6 (R2) requirements.
Other SOPs such as Handling External Data or Data Backup may require minor updates, but the Data Review and Validation SOP undergoes the most extensive change because EDC technology shifts validation responsibilities from post-data entry review to real-time oversight within the system.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 6.3 - SOP Adaptation for EDC Implementation FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Handling and Validation

NEW QUESTION # 81
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 visit
- B. One record per patient
- C. One record per patient per visit per vital sign parameter
- D. One record per patient per visit

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 # 82
During testing of an ePRO system, a test fails. Which information should be found in the validation documentation?

- A. Expected and actual results
- B. Training requirements
- C. Reconciliation datapoints
- D. Root cause analysis of the system errors

Answer: A

Explanation:
When a system validation test fails during Electronic Patient-Reported Outcome (ePRO) system testing, the validation documentation must record the expected results (what should have occurred) and the actual results (what occurred).
According to the GCDMP (Chapter: Database Validation and Testing), proper system validation documentation ensures traceability, reproducibility, and compliance with FDA 21 CFR Part 11 and ICH E6 (R2). Each test case must include:
Test objective,
Preconditions,
Test steps,
Expected results,
Actual results, and
Pass/fail status.
If a test fails, this documentation provides the objective evidence necessary for deviation handling, issue resolution, and re-testing.
While a separate root cause analysis may be performed later (option D), the validation record itself must focus on verifying outcomes against predefined expectations.
Therefore, the correct answer is B - Expected and actual results.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Validation and Testing, Section 4.4 - Documentation of Test Results FDA 21 CFR Part 11 - Validation Requirements (Section 11.10(a)) ICH E6 (R2) GCP, Section 5.5.3 - Computer System Validation and Documentation

NEW QUESTION # 83
A protocol is updated mid-study to add an additional procedure about which data needs to be collected. Which of these statements applies?

- A. The DMP should be updated to reflect the changes to the protocol, but this update does not need to be communicated
- B. The DMP should be updated to reflect the changes to the protocol and stakeholders notified
- C. The DMP does not need to be updated until the end of the trial and all updates are included in the DMP to indicate what happened in the trial
- D. The DMP does not need to be updated as it represents the data at the beginning of the trial only

Answer: B

Explanation:
When a protocol is amended mid-study, resulting in additional data collection requirements, the Data Management Plan (DMP) must be updated accordingly and all relevant stakeholders must be notified.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the DMP is a living document that defines all data management processes for a clinical study. It must accurately reflect the current data flow, CRF design, validation procedures, and reporting structure. Any protocol amendments affecting data capture, structure, or analysis require immediate DMP revision and distribution to ensure alignment across data management, clinical, and biostatistics teams.
Failure to update and communicate DMP changes can lead to misalignment in data handling and introduce compliance risks during

audits or inspections. Therefore, Option B is correct: the DMP must be updated and the change communicated to all stakeholders (e.g., sponsor, CRO, clinical operations, biostatistics).
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Plan (DMP), Section 5.3 - Maintaining and Updating the DMP ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Documentation of Protocol Changes and Data Handling Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Data Management Documentation

NEW QUESTION # 84
What is the main reason 21 CFR Part 11 requires that EDC systems maintain an audit trail?

- A. To preserve source document verifications
- B. To preserve data integrity
- C. To preserve data availability
- D. To preserve the ability for modifications

Answer: B

Explanation:
The primary purpose of maintaining an audit trail as required under 21 CFR Part 11 is to preserve data integrity. According to the U.S. FDA's regulation on electronic records and signatures, every change to electronic data must be traceable, including information about who made the change, when it was made, and what the change entailed.
The Good Clinical Data Management Practices (GCDMP) outlines that an audit trail provides a permanent, chronological record of all modifications to clinical data. This ensures transparency and allows the reconstruction of the course of data entry and modification. The regulation aims to prevent unauthorized or undocumented data manipulation, thereby maintaining the accuracy, reliability, and validity of electronic records.
The FDA 21 CFR Part 11, Section 11.10(e) explicitly mandates that systems must use secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. This ensures the data remains trustworthy and defensible in regulatory reviews or inspections.
Therefore, the main reason for requiring an audit trail is to preserve data integrity - ensuring that all data captured, modified, or transmitted is authentic, accurate, and complete throughout the study lifecycle.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Compliance and Data Integrity FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures, Section 11.10(e) ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Integrity and System Validation

NEW QUESTION # 85
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