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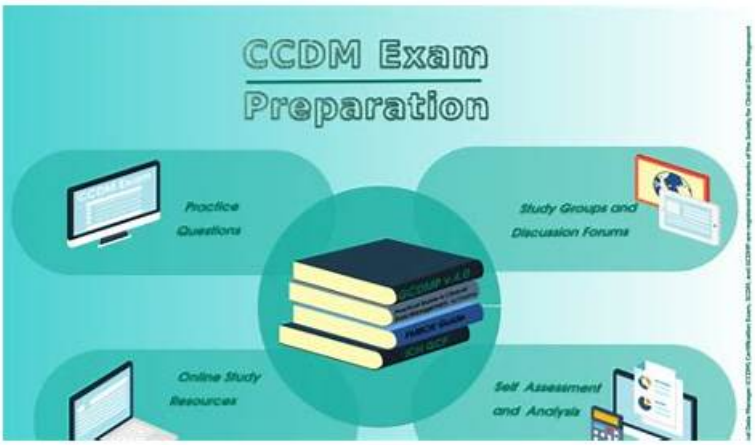

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 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	• 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.

SCDM Certified Clinical Data Manager Sample Questions (Q114-Q119):

NEW QUESTION # 114
Who has primary responsibility for ensuring accurate completion of the CRF?

- A. Investigator
- B. Clinical Research Associate
- C. Site Coordinator
- D. Clinical Data Manager

Answer: A

Explanation:
The Investigator holds the primary responsibility for ensuring the accuracy, completeness, and timeliness of Case Report Form (CRF) entries. This responsibility is mandated by regulatory requirements under ICH E6(R2) Good Clinical Practice (GCP).
The investigator may delegate CRF completion to a qualified designee (e.g., site coordinator), but the ultimate accountability remains with the investigator. The investigator's signature (electronic or manual) on the CRF serves as certification that the data accurately reflect the source documents and the patient's participation.
The GCDMP (Chapter: CRF Design and Data Collection) reinforces this by stating that while data managers ensure design quality and CRAs verify consistency with source data, the investigator is legally responsible for CRF accuracy.
Thus, option D (Investigator) is correct, as it aligns with both GCP and CCDM standards.
Reference (CCDM-Verified Sources):
ICH E6(R2) GCP, Section 4.9 - Records and Reports (Investigator Responsibilities) SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 5.1 - Investigator's Role in Data Accuracy FDA 21 CFR Part 312.62 - Investigator Recordkeeping and Record Retention

NEW QUESTION # 115
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. Coding Medical and Clinical Terms
- C. Handling External Data
- 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 # 116
Which of the following processes is the most likely to remain in a study that utilizes electronic data capture?

- A. Updating the in-house database
- B. Retrieving case report forms
- C. Tracking case report forms
- D. Resolving queries

Answer: D

Explanation:
In studies utilizing Electronic Data Capture (EDC) systems, many traditional paper-based processes such as tracking and retrieving CRFs are eliminated or automated. However, query management and resolution remain essential because discrepancies, missing data, and protocol deviations still require clarification and correction, regardless of the data collection medium.
According to the GCDMP (Chapter: Data Validation and Cleaning), data queries are generated automatically or manually when inconsistencies are detected by edit checks. Sites must still respond to these queries electronically to ensure the integrity and completeness of data.
A and D are obsolete with EDC (no physical CRFs).
B refers to manual data entry updates, which are replaced by direct EDC entry.
C (Resolving queries) continues as a key part of the data management workflow, even in fully electronic environments.
Thus, option C is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.4 - Query Generation and Resolution in EDC Systems ICH E6(R2) GCP, Section 5.5.3 - Data Review and Query Resolution Requirements FDA 21 CFR Part 11 - Electronic Records: Audit Trails and Query Documentation C

NEW QUESTION # 117
Which document describes what study subjects expect with respect to data disclosure during and after a study?

- A. Study data sharing plan
- B. Study protocol
- C. ICH essential documents
- D. Informed consent form

Answer: D

Explanation:
The Informed Consent Form (ICF) is the document that explicitly describes what study subjects can expect regarding data disclosure, privacy, and confidentiality during and after participation in a clinical trial. According to ICH E6 (R2) Good Clinical Practice and FDA Human Subject Protection Regulations (21 CFR Parts 50 and 56), participants must be fully informed about how their personal and clinical data will be collected, used, stored, and shared - both during the study and in any subsequent data-sharing or publication activities.
The GCDMP reiterates that clinical data managers must ensure that all data handling practices align with the privacy commitments made in the ICF. This includes compliance with data protection regulations such as HIPAA (in the U.S.) and GDPR (in the EU).
The ICF defines the permissible scope of data use, ensuring ethical management and subject protection.
Documents like the protocol or data sharing plan may outline procedures and responsibilities but do not directly inform participants of their rights and data use expectations. Only the ICF is designed for that ethical communication purpose.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Ethics, Privacy, and Data Security ICH E6 (R2) Good Clinical Practice, Sections 4.8.10 & 4.8.12 FDA 21 CFR Part 50 - Protection of Human Subjects, Informed Consent Requirements

NEW QUESTION # 118
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 per visit per vital sign parameter
- C. One record per patient
- D. One record per patient per visit

Answer: B

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 # 119
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