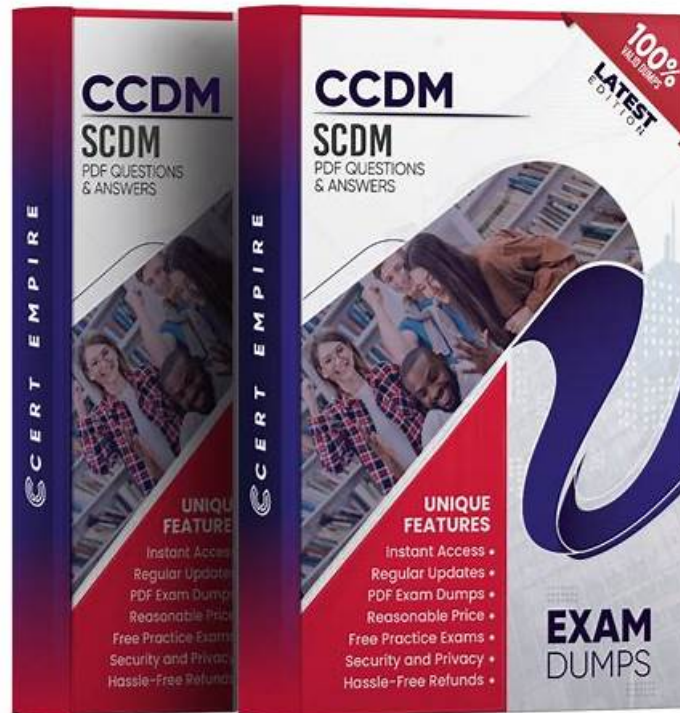


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SCDM CCDM Exam Syllabus Topics:

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"> • 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

- 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 (Q42-Q47):

NEW QUESTION # 42

If a data manager generated no additional manual queries on data in an EDC system and the data were deemed clean, why could the data appear to be not clean during the next review?

- A. The study coordinator can change the data due to re-review of the source.
- B. The data manager may have accidentally changed the data.
- C. The CRA can change the data during a quality review of source to database.
- D. The medical monitor can override safety information entered in the system.

Answer: A

Explanation:

In an Electronic Data Capture (EDC) system, even after a data manager completes all manual queries and marks data as "clean," the data may later appear unclean if the site (study coordinator) makes subsequent updates in the system after re-reviewing the source documents.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Electronic Data Capture Systems), site users maintain the authority to modify data entries as long as the system remains open for data entry. The EDC system audit trail captures such changes, which can automatically invalidate prior data reviews, triggering new discrepancies or changing system edit-check statuses.

This situation commonly occurs when the site identifies corrections in the source (e.g., wrong date or lab result) and updates the EDC form accordingly. These post-cleaning changes require additional review cycles to ensure the database reflects accurate and verified information before final lock.

Options B, C, and D are incorrect - CRAs and medical monitors cannot directly change EDC data; they can only raise queries or request updates.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 6.3 - Post-Cleaning Data Changes and Audit Trails ICH E6 (R2) GCP, Section 5.5.3 - Data Integrity and Change Control FDA 21 CFR Part 11 - Electronic Records: Change Documentation Requirements

NEW QUESTION # 43

The primary reason for system validation is to:

- A. Allow a system to be used by its intended users.
- B. Meet regulatory requirements.
- C. Fulfill the validation plan.
- D. Prove the system being tested works as intended.

Answer: D

Explanation:

The primary purpose of system validation in clinical data management is to demonstrate and document that the computerized system performs as intended-accurately, reliably, and consistently-throughout its lifecycle.

According to the Good Clinical Data Management Practices (GCDMP, Chapter on System Validation) and FDA 21 CFR Part 11, validation ensures that all system functions (e.g., data entry, edit checks, audit trails, security) work as designed, providing data integrity, traceability, and regulatory compliance. The focus is on fitness for intended use, meaning the system reliably produces correct and reproducible results in the context of its operational environment.

While meeting regulatory requirements (option C) and fulfilling a validation plan (option B) are components of the process, they are not the ultimate purpose. The essential goal is ensuring that the system performs as intended, maintaining accuracy and data integrity for clinical trial operations.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and System Validation, Section 5.2 - Purpose and Scope of System Validation
FDA 21 CFR Part 11 - Validation of Computerized Systems for Intended Use ICH E6(R2) GCP, Section 5.5.3 - Computerized System Validation and Data Integrity

NEW QUESTION # 44

In the EDC database, which factors are considered when defining user roles?

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

Answer: A

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 # 45

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. Informed consent form
- D. ICH essential documents

Answer: C

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 # 46

When implementing a study utilizing an EDC application, it would be appropriate to use free text fields for which of the following?

- A. Date of birth
- B. Urine sedimentation rate
- C. Adverse event verbatim term
- D. Body Mass Index

Answer: C

Explanation:

In Electronic Data Capture (EDC) systems, free text fields should be used only when a predefined list of acceptable responses cannot accommodate the full variability of input data - most notably for Adverse Event (AE) verbatim terms.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), AE verbatim terms are initially entered as free text by site staff to accurately capture the investigator's exact medical description of the event. These verbatim terms are later coded using standardized dictionaries such as MedDRA during medical coding, ensuring both flexibility and standardization in reporting.

Conversely, fields such as urine sedimentation rate (A), date of birth (C), and Body Mass Index (D) require structured numeric or date formats to enable validation, range checks, and consistency across datasets. Free text would compromise data integrity, accuracy, and validation efficiency for these structured data elements.

Reference (CCDM-Verified Sources):



SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.3 - Use of Free Text and Coded Fields ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Structure and Validation MedDRA Introductory Guide, Section 2.3 - Verbatim Entry and Coding Requirements

NEW QUESTION # 47

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