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Certified Clinical Data Manager (CCDM) Practice Exam

Question 1: What does Clinical Data Management primarily involve?
A. Developing clinical protocols
B. Ensuring accurate and timely collection, validation, and reporting of trial data
C. Marketing clinical research findings
D. Overseeing patient recruitment processes
Answer: B
Explanation: Clinical Data Management focuses on collecting, validating, and reporting trial data accurately and on time, which is essential for reliable study outcomes.

Question 2: Which stakeholder is primarily responsible for overseeing regulatory compliance of clinical trial data?
A. Clinical Data Manager
B. Sponsor
C. Regulatory Bodies
D. Site Investigator
Answer: C
Explanation: Regulatory bodies, such as the FDA, are charged with ensuring that clinical trial data meets regulatory standards.

Question 3: Which document outlines the procedures for data collection and management in clinical trials?
A. Informed Consent Form
B. Data Management Plan
C. Clinical Study Report
D. Investigator Brochure
Answer: B
Explanation: The Data Management Plan (DMP) details the procedures for data collection, validation, cleaning, and reporting throughout the trial.

Question 4: What is a key responsibility of a Clinical Data Manager?
A. Designing marketing strategies
B. Managing data validation and query resolution
C. Recruiting study participants
D. Developing new drugs
Answer: B
Explanation: Clinical Data Managers are responsible for data validation, ensuring data integrity, and managing queries to resolve discrepancies.

Question 5: Which guideline is commonly followed to ensure data quality in clinical trials?
A. ICH-GCP
B. ISO 9001
C. Six Sigma

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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	• 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 3	• 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 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	• 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q122-Q127):

NEW QUESTION # 122
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. Data Backup, Recovery, and Contingency Plans
- C. Handling External Data
- D. Coding Medical and Clinical Terms

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 # 123
The result set from the query below would be which of the following?
SELECT * FROM patient WHERE medical_record_number > 9000

- A. Wider than the patient table
- B. Shorter or of equal length than the patient table
- C. Narrower than the patient table
- D. Longer than the patient table

Answer: B

Explanation:
In Structured Query Language (SQL), the WHERE clause is used to filter records based on specified criteria. The query retrieves all columns from the patient table (SELECT *) but only those rows where the medical_record_number value is greater than 9000.
This means:
The number of columns (fields) remains the same as the original table.
The number of rows (records) will be equal to or less than the number of rows in the patient table, depending on how many patients meet the filter condition.
Hence, the result set can only be shorter or equal in length compared to the original table. It cannot be longer, wider, or narrower, since no new rows or columns are created.
Therefore, option B - "Shorter or of equal length than the patient table" - is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Relational Database Queries and Filtering Logic ICH E6(R2) GCP, Section 5.5.3 - Data Retrieval, Filtering, and Storage Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Query Logic and Record Subsetting

NEW QUESTION # 124
A Clinical Data Manager is drafting data element definitions for a new study. One of the definitions provided is:
"Baby's crown to heel length measured lying on back, measured physical quantity, precision of 0.1." Which of the following is missing from the definition?

- A. Unit or dimensionality of measure
- B. Enumeration
- C. Data type of the data element
- D. Discrete values for a drop-down list

Answer: A

Explanation:
A complete data element definition in clinical data management should include:
Name and clear description of the data element,
Data type (e.g., numeric, text, date),
Precision or scale (if numeric), and
Unit or dimensionality of measure (e.g., centimeters, inches).
In this example, while the data type ("measured physical quantity") and precision (0.1) are defined, the unit of measurement (e.g., centimeters or inches) is missing. This omission leads to ambiguity and could cause serious discrepancies when comparing or analyzing measurements.
The GCDMP (Chapter: Database Design and Build) emphasizes that units and dimensionality must be explicitly defined and consistently applied in all CRFs, metadata dictionaries, and data transformations.
Thus, option D (Unit or dimensionality of measure) is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Metadata and Data Element Definitions CDISC CDASH Implementation Guide, Section 3.3 - Data Element Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Data Accuracy and Standardized Definitions

NEW QUESTION # 125
Which metric will identify edit checks that may not be working properly?

- A. Count by edit check of the number of times the check fired
- B. Count by site of the number of times any edit check fired
- C. Average number of times each edit check has fired
- D. Average number of edit check identified discrepancies per form

Answer: A

Explanation:
The best metric to identify malfunctioning or ineffective edit checks is the count by edit check of the number of times the check fired. This allows data managers to assess whether specific edit checks are performing as intended.
According to the GCDMP, Chapter: Data Validation and Cleaning, edit checks are programmed logic conditions that identify data inconsistencies or potential errors during data entry. A properly functioning edit check should trigger only when data falls outside acceptable or logical limits. If an edit check fires too frequently or not at all, it may indicate a logic error in the check's programming or configuration.
By analyzing counts by individual edit checks, data managers can:
Identify checks that never trigger (potentially inactive or incorrectly written), Detect overactive checks (poorly designed parameters causing excessive false positives), and Optimize system performance and review efficiency.
This metric supports continuous improvement in data validation logic and contributes to cleaner, higher-quality clinical databases.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.2 - Edit Check Design and Performance Metrics FDA Guidance: Computerized Systems Used in Clinical Investigations - Section on Validation of Electronic Data Systems

NEW QUESTION # 126
The result set from the query below would be which of the following?
SELECT Pt_ID, MRN, SSN FROM patient

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

Answer: A

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 # 127
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