2026 CCDM: Reliable Answers Certified Clinical Data Manager Real Questions

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 Certified Clinical Data Manager Sample Questions (Q64-Q69):

NEW QUESTION # 64
An astute monitor discovers that a site is using nebulized albuterol rather than the inhaler provided in the study screening kit for the albuterol challenge. Which is the best response from the Data Manager?

- A. Contact the Ethics Committee
- B. Update the CRF Completion Guidelines and notify all sites of the update
- C. Query the site to enter a Protocol Violation
- D. No response is needed, the problem does not impact data

Answer: C

Explanation:
In this scenario, the site has deviated from the approved study protocol by using a different formulation (nebulized albuterol instead of inhaler). This is considered a protocol deviation or violation, depending on study definitions.
Per GCDMP (Chapter: Data Validation and Cleaning) and ICH E6(R2), Data Managers are responsible for ensuring that all protocol deviations affecting data integrity or subject safety are accurately captured and documented within the clinical database.
The appropriate action is to issue a data query prompting the site to record the deviation in the designated section (e.g., "Protocol Deviations" CRF).
Option A: Incorrect - it affects data comparability.
Option B: Escalation to the Ethics Committee is handled by the sponsor, not the Data Manager.
Option C: Updating the CRF guidelines is premature; first, the deviation must be logged and assessed.
Therefore, option D (Query the site to enter a Protocol Violation) is the correct and compliant action.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 6.2 - Query Management and Protocol Deviations ICH E6(R2) GCP, Section 4.5 - Compliance with Protocol FDA Guidance for Industry: Oversight of Clinical Investigations - Compliance and Protocol Deviation Reporting

NEW QUESTION # 65
Which method would best identify inaccuracies in safety data tables for an NDA?

- A. Compare counts of appropriate patients from line listings of CRF data to counts in table cells
- B. Review the line listings to identify any values that look odd
- C. Compare counts of appropriate patients from manual CRFs to counts in table cells
- D. Review the tables to identify any values that look odd

Answer: A

Explanation:
The best method for identifying inaccuracies in safety data tables prepared for a New Drug Application (NDA) is to compare counts of appropriate patients from line listings of CRF data to the counts in table cells.
According to the GCDMP (Chapter: Data Quality Assurance and Control), line listings represent raw, patient-level data extracted directly from the clinical database, whereas summary tables are aggregated outputs used for reporting and submission. Comparing these two sources ensures data traceability and accuracy, verifying that tabulated results correctly reflect the underlying patient data.
Manual CRF checks (option A) are less efficient and error-prone, as data entry is typically already validated electronically. Simply reviewing tables or listings for "odd values" (options C and D) lacks the systematic verification necessary for regulatory data integrity.
Thus, comparing line listings to tables (option B) provides a quantitative cross-check between the database and output deliverables, a standard practice in NDA data validation and statistical quality control.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 5.2 - Validation of Tables, Listings, and Figures (TLFs) FDA Guidance for Industry: Submission of NDA Safety Data, Section on Data Verification and Accuracy ICH E6 (R2) GCP, Section 5.5.3 - Validation of Derived Data Outputs

NEW QUESTION # 66

A Data Manager is importing data from an external facility. Which is commonly checked first?

- A. Data in the incoming files are internally consistent
- B. Incoming files are conformant to the data transfer specifications
- C. Data in incoming files are consistent with existing data in the study database
- D. Incoming files have the expected number of records

Answer: B

Explanation:

When importing external data (e.g., laboratory or imaging results) into a clinical database, the first step in data import quality control is to verify that incoming files conform to the pre-specified data transfer specifications (DTS).

According to the GCDMP (Chapter: External Data Transfers and Integration), the Data Transfer Specification defines file structure, variable names, data types, delimiters, record counts, and validation rules. The initial import check confirms that the received file matches the technical and structural requirements before content or record consistency is evaluated.

Subsequent checks-such as record counts (A), data consistency with existing database (C), and internal logical consistency (D)-are performed only after the file structure is validated and confirmed to match the specifications. Failure to perform this first check may cause import errors or corrupted data loads.

Thus, the first and most critical verification step is ensuring file conformity to the agreed data transfer specifications, making option B correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers, Section 4.2 - Data Transfer File Validation and Import Checks ICH E6(R2) GCP, Section 5.5.3 - Validation of Computerized Systems and Data Imports

NEW QUESTION # 67

Which database table structure is most appropriate for vital signs data collected at every-other visit for each patient in a study?

- A. One record per patient
- B. One record per visit
- C. One record per patient per study
- D. One record per patient per visit

Answer: D

Explanation:

In a relational clinical database, the most efficient and normalized structure for data collected repeatedly over time-such as vital signs-is one record per patient per visit.

Each patient will have multiple records, one for each visit when vital signs are assessed. This structure supports:

Time-based analysis (e.g., trends across visits),

Accurate data linkage with visit-level metadata, and

Efficient querying for longitudinal data.

According to the GCDMP (Chapter: Database Design and Build), the relational design principle dictates that data should be stored at the lowest unique level of observation. Since vital signs vary by both patient and visit, the combination of patient ID + visit ID forms a unique key for each record.

Option A (per visit) lacks patient identification, while options B and D aggregate data too broadly, losing temporal detail.

Thus, option C (One record per patient per visit) correctly represents the normalized design structure.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 4.2 - Normalization and Table Structure CDISC SDTM Implementation Guide, Section 5.3 - Visit-Level and Observation-Level Data Structures ICH E6(R2) GCP, Section 5.5.3 - Data Handling Principles

NEW QUESTION # 68

A Clinical Data Manager reads a protocol for a clinical trial to test the efficacy of an antiviral to counteract a new epidemic. The stated primary efficacy endpoint is 3-month survival. Which data element is needed for the primary efficacy endpoint?

- A. Date of autopsy
- B. Death date
- C. Birth date

- D. Cause of death

Answer: B

Explanation:
When the primary efficacy endpoint in a clinical trial is 3-month survival, the key data element required is the death date. This is because the survival endpoint is determined by calculating whether the subject lived or died within a defined time frame from study enrollment or randomization.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the Clinical Data Manager (CDM) must identify and ensure the capture of all critical data elements necessary to evaluate the study endpoints. For time-to-event analyses (e.g., survival studies), accurate event dates (death date) are essential for endpoint derivation and statistical analysis.
Other data elements such as cause of death or date of autopsy (options B and C) may support secondary analyses or safety reviews but are not necessary to determine the survival endpoint itself. Similarly, birth date (option D) contributes to demographic data but is unrelated to the primary efficacy outcome.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.4 - Critical Data Identification for Endpoints ICH E9 - Statistical Principles for Clinical Trials, Section 2.2.3 - Time-to-Event Data Considerations FDA Guidance for Industry: Clinical Trial Endpoints for Drug Development

NEW QUESTION # 69

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