

CCDM New Braindumps Questions & Valid Exam

CCDM Braindumps

CCDM questions with correct answers

A CDM receives a diet order that does not match diets offered by the facility. What should the CDM do? Correct Answer-who is responsible to request change should be determined by facilities policies and procedures, if no policy exists confer with RDN

A client complains to family members that they hate the food. The client is on a 2 gm lower sodium diet. What should the CDM do first? Correct Answer--Meet with client

- Discuss what their diet is/why
- Relay info to RDN and RN
- Discuss liberalizing diet with physician
- Follow up with client
- Document

A client on an 1800 diabetic diet consistently has high blood glucose levels. During meal times the client is observed eating other's desserts. What is most appropriate for CDM to do? Correct Answer--explain diet order to client order and why

- If they still insist on eating others desserts let them
- Document conversation

Be research has not shown benefits for restricting sodium, cholesterol, fat, and carbs in older adults the RDN and CDM should Correct Answer-individualize diets for older adults in healthcare communities to the least restricted diet

What are the CMS guidelines Correct Answer--client centered

- liberalized diets should be the norm

Our SCDM CCDM exam questions are created and curated by industry specialists. Experts at TestKingIT strive to provide applicants with valid and updated SCDM CCDM exam questions to prepare from, as well as increased learning experiences. We are confident in the quality of the SCDM CCDM preparational material we provide and back it up with a money-back guarantee.

SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	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 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	• 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	• 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 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 (Q130-Q135):

NEW QUESTION # 130

For a study, body mass index is calculated from weight and height. Which information is needed to document the transformation?

- A. Algorithm and algorithm version associated with the calculated value
- B. User ID making the change and reason for change
- C. Algorithm documented in the Data Management Plan
- D. Algorithm associated with the calculated value

Answer: A

Explanation:

When derived or calculated variables (like Body Mass Index) are created, it is essential to document the algorithm used and its version to ensure full data traceability and reproducibility.

According to GCDMP (Chapter: Database Design and Derived Data), every derived field must include metadata describing:

The derivation algorithm (e.g., BMI = weight [kg] / height² [m²])

The version of the algorithm (if updates or revisions occur)

Any associated data sources or transformation rules

This ensures consistent calculation across systems, prevents discrepancies during regulatory submissions, and aligns with FDA and CDISC documentation expectations.

Option B lacks version control, which is critical for traceability. Option C describes audit trail data (not derivation metadata), and option D refers to broader documentation, not specific algorithm traceability.

Hence, option A (Algorithm and algorithm version associated with the calculated value) is the correct and compliant answer.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Derived Data and Algorithms, Section 5.3 - Documentation and Metadata Requirements ICH E6(R2)

GCP, Section 5.5.3 - Derived Data and Validation Traceability FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Data Definitions (Define.xml)

NEW QUESTION # 131

Which of the following factors can be tested through a second test transfer?

- A. Transfer method
- B. Change management

- C. File format
- D. Transfer frequency

Answer: C

Explanation:

In the context of database design and external data management, a test data transfer (or trial data load) is performed to ensure the proper configuration, structure, and integrity of data imported from an external vendor or system. The second test transfer is specifically useful to confirm that data structures and formats are consistently aligned between the sending and receiving systems after initial adjustments have been made from the first test.

According to the Good Clinical Data Management Practices (GCDMP), the file format - including variables, data types, field lengths, delimiters, and encoding - must be validated during test transfers to confirm compatibility and ensure accurate loading into the target database. Once the initial test identifies and corrects errors (e.g., mismatched variable names or data types), the second transfer verifies that the corrections have been implemented correctly and that the file structure functions as intended.

Testing change management (A) involves procedural controls, not data transfers. The transfer method (C) and transfer frequency (D) are validated during initial process setup, not during subsequent test transfers.

Therefore, option B (File format) is correct, as the second test transfer verifies the technical integrity of the file structure before live production transfers begin.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers and Data Integration, Section 5.2

- Test Transfers and File Validation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3

- Data Import and Validation Controls

NEW QUESTION # 132

During a database audit, it was determined that there were more errors than expected. Who is responsible for assessing the overall impact on the analysis of the data?

- A. Data Manager
- B. Investigator
- C. Statistician
- D. Quality Auditor

Answer: C

Explanation:

The Statistician is responsible for assessing the overall impact of data errors on the analysis and study results.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control) and ICH E9 (Statistical Principles for Clinical Trials), while the Data Manager ensures data accuracy and completeness through cleaning and validation, the Statistician determines whether the observed data discrepancies are statistically significant or if they may affect the validity, power, or interpretability of the study's outcomes.

The Quality Auditor (C) identifies and reports issues but does not quantify analytical impact. The Investigator (D) is responsible for clinical oversight, not statistical assessment. Thus, after a database audit, the Statistician (B) performs a formal evaluation to determine whether the magnitude and nature of the errors could bias results or require reanalysis.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Data

Audit and Impact Assessment ICH E9 - Statistical Principles for Clinical Trials, Section 3.2 - Data Quality and Analysis Impact

Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Validation and Analysis

Review

NEW QUESTION # 133

To ensure data quality and efficient integration of data, which of the following best describes the main topic that should be covered in initial discussions with a vendor providing the external data?

- A. Metrics that will be used to measure data quality
- B. Standard dictionary versioning and maintenance
- C. Criteria to trigger audits based on performance-monitoring reports
- D. Acceptable record, field, and file formats

Answer: D

Explanation:

In initial vendor discussions for external data integration (e.g., central lab, ECG, imaging vendors), the most critical and foundational topic is defining the acceptable record, field, and file formats.

According to the GCDMP (Chapter: External Data Transfers and Integration), establishing the Data Transfer Specifications (DTS) early in the process ensures consistent structure, proper mapping, and compatibility between the vendor's system and the sponsor's database. These specifications define:

Data structure (variable names, formats, delimiters)

File naming conventions

Frequency of transfers

Methods of secure data transmission

Discussing formats first allows later alignment on data validation, quality metrics, and dictionary standards (which occur in subsequent stages). Without format agreement, all downstream processes risk misalignment, resulting in data incompatibility and rework.

Thus, option C (Acceptable record, field, and file formats) correctly represents the foundational focus of initial vendor discussions for ensuring data quality and integration efficiency.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers and Integration, Section 4.1 - Data Transfer Planning and Specification

Development ICH E6(R2) GCP, Section 5.5.3 - Data Handling and System Validation FDA Guidance: Computerized Systems

Used in Clinical Investigations, Section 6.3 - Data Import and Format Control

NEW QUESTION # 134

Which mode of data entry is most commonly used in EDC systems?

- A. Third party compare
- B. Blind verification
- C. Single entry
- D. Double entry

Answer: C

Explanation:

The most common mode of data entry in Electronic Data Capture (EDC) systems is single data entry.

According to the GCDMP (Chapter: Electronic Data Capture Systems), EDC systems have built-in edit checks, validation rules, and audit trails that ensure data accuracy and integrity at the point of entry. These real-time validation capabilities make double data entry (a legacy practice from paper studies) unnecessary.

EDC systems automatically verify data as they are entered by site staff, generating queries for inconsistencies or out-of-range values immediately. Blind verification (option B) and third-party comparisons (option D) are not standard data entry modes but may be used for specialized reconciliation or external data imports.

Thus, single data entry (Option C) is the industry standard approach, ensuring both efficiency and compliance with FDA 21 CFR Part 11 and ICH E6 (R2) data integrity requirements.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 5.4 -

Data Entry and Verification Processes ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Computerized Systems and Data

Validation FDA 21 CFR Part 11 - Electronic Records and Electronic Signatures: Validation and Data Entry Requirements

NEW QUESTION # 135

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