

100% Pass Quiz 2025 SCDM Unparalleled Exam CCDM Vce

CDM Test 2023-2024 Questions and Answers 100% Correct

A Certified Dietary Manager is dissatisfied with prices from current vendors. The Manager should first:

- a. ask vendors to lower their prices.
- b. ask the consultant to recommend other vendors.
- c. complete a comparison study of vendors.
- d. discontinue purchasing from the current vendors. - ANSWER-c. complete a comparison study of vendors.

The best way to prepare frozen peas is to:

- a: slowly cook the peas at 200°F (93.3°C) so they do not dry out.
- b. cook them rapidly until they reach an internal temperature of 140°F (60.0°C).
- c. cook them to 120°F (48.9°C) and hold them in the steam table to come up to temperature.
- d. cook them in batches throughout the service time. - ANSWER-d. cook them in batches throughout the service time.

Beans and legumes are essential protein substitutes for clients who are:

Choose one answer.

- a. lactose intolerant.
- b. vegan.
- c. ovo-lacto-vegetarian.
- d. lacto vegetarian. - ANSWER-b. vegan.

When preparing goals for the foodservice department, a Certified Dietary Manager must show that the goals are:

Choose one answer.

- a. narrow.
- b. broad.
- c. listed on the bulletin board.
- d. transferrable to other departments. - ANSWER-b. broad.

When purchasing food, a Certified Dietary Manager must develop specifications to ensure that:

Choose one answer.

- a. government commodities are used when available.
- b. eggs are delivered in a timely manner.
- c. milk arrives at a temperature below 41°F (5°C).
- d. canned fruits are packed in water or juice. - ANSWER-c. milk arrives at a temperature below 41°F (5°C).

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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 2	<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 3	<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 4	<ul style="list-style-type: none"> 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 5	<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.

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SCDM Certified Clinical Data Manager Sample Questions (Q93-Q98):

NEW QUESTION # 93

A study uses commercially available activity monitors and collects data for each patient weekly by selecting and downloading the data from the manufacturer's website. There are 100 patients in the study and it takes the Data Manager 20 minutes per file to download, import, and process the data. Assuming that the distribution of work is uniform over the six-month trial, how many Data Managers are needed for the activity data alone?

- A. Two Data Managers per month
- B. One Data Manager per month**
- C. Fifty percent of a Data Manager per month
- D. Ten percent of a Data Manager per month

Answer: B

Explanation:

This question tests workload estimation and resource planning, which are fundamental competencies outlined in the Good Clinical Data Management Practices (GCDMP, Chapter on Project Management in Data Management). The task is to determine the Data Manager effort required based on the frequency and duration of data collection and processing activities.

Let's calculate step by step:

Number of patients: 100

Frequency: Weekly (once per week)

Duration: 6 months \approx 26 weeks

Time per file: 20 minutes

Total time per week:

$$100 \text{ patients} \times 20 \text{ minutes} = 2,000 \text{ minutes per week}$$

$$= 2,000 \div 60 = 33.3 \text{ hours per week}$$

Total hours over 6 months:

$$33.3 \text{ hours/week} \times 26 \text{ weeks} = 866 \text{ hours total}$$

A full-time Data Manager typically works \sim 160 hours per month, so over six months:

$$160 \times 6 = 960 \text{ hours total full-time capacity.}$$

Therefore, the workload of 866 hours is approximately equivalent to one full-time Data Manager working across the six-month period:

$$866 \div 960 \approx 0.9 \text{ FTE (Full-Time Equivalent).}$$

This aligns most closely with Option D: One Data Manager per month (i.e., a full-time resource is required throughout the duration of

the trial).

According to the GCDMP Project Management chapter, accurate resource estimation is critical in ensuring data management timelines are met without overloading staff or compromising data quality. The estimation process must consider not just the raw data download time but also associated data processing, verification, and upload into the clinical database.

Other options underestimate the effort significantly:

A (10%) and B (50%) do not account for cumulative weekly workload across multiple patients.

C (Two Data Managers) overestimates, as one Data Manager working full-time can manage the load efficiently.

Therefore, Option D is correct - approximately one full-time Data Manager (1.0 FTE) is required for the activity data alone during the six-month trial.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Project Management in Data Management, Section 5.3 - Workload Estimation and Resource Allocation SCDM GCDMP, Chapter: Data Handling and Processing - Effort Estimation for Repetitive Data Tasks ICH E6 (R2) Good Clinical Practice, Section 5.1 - Quality Management and Resource Planning FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Operational Considerations for Data Management Activities

NEW QUESTION # 94

When reviewing local lab data from a paper study, a Data Manager notices there are lab values not entered. What should the Data Manager request data-entry personnel do?

- A. Nothing
- B. Flag the module for review
- **C. Issue a query**
- D. Call the patient to verify the information

Answer: C

Explanation:

When laboratory data are missing from a paper-based clinical study, the Data Manager should direct data-entry personnel to issue a query to the investigative site for clarification or correction.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), every missing, inconsistent, or out-of-range data point must be reviewed and, if necessary, resolved through the formal query management process. This ensures that all discrepancies between the source documents and database entries are properly documented, traceable, and auditable.

Data-entry staff are not authorized to infer or fill in missing information. They must escalate such discrepancies to the site via query, preserving data integrity and regulatory compliance with ICH E6 (R2) and FDA 21 CFR Part 11. Calling the patient directly (option B) would violate confidentiality and site communication protocol, while simply flagging or ignoring the issue (options A and D) would not meet GCDMP query resolution standards.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.2 - Query Management and Resolution ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication of Data Discrepancies FDA 21 CFR Part 11 - Electronic Records; Query Audit Trails Requirements

NEW QUESTION # 95

An organization has completed a study and wants to submit the data to the FDA using CDISC SDTM. Which of the following must be done?

- A. Re-enter the data into an SDTM compliant system
- **B. Map and transform the study data to SDTM**
- C. Provide a letter of intent to use SDTM to the FDA
- D. SDTM cannot be used in this situation

Answer: B

Explanation:

To submit study data to the FDA in CDISC SDTM format, the sponsor must map and transform the collected data from the study's operational database (e.g., EDC) into SDTM-compliant domains.

According to GCDMP (Chapter: Standards and Data Integration) and CDISC SDTM Implementation Guide, this process includes: Mapping raw data elements from the clinical database to SDTM domains (e.g., DM, AE, VS).

Transforming data to comply with SDTM structural and naming conventions.

Validating the output using CDISC compliance tools (e.g., Pinnacle 21).

Re-entering data (B) is unnecessary, and a letter of intent (C) is not required. SDTM is explicitly accepted by FDA for both retrospective and prospective submissions, so (D) is incorrect.

Thus, option A is correct - map and transform existing data to SDTM format for regulatory submission.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.3 - Data Transformation and CDISC Mapping CDISC SDTM Implementation Guide, Version 3.4 - Data Conversion and Submission Requirements FDA Study Data Technical Conformance Guide, Section 2.2 - SDTM Mapping and Validation

NEW QUESTION # 96

An international study collects lab values. Sites use different units in the source documents. Which of the following data collection strategies will have fewer transcription errors?

- A. Allow values to be entered as they are in the source and the selection of units on the data collection form
- B. Allow values to be entered as they are in the source document and derive the units based on the magnitude of the value
- C. Use a structured field and print standard units on the data collection form
- D. Have all sites convert the values to the same unit system on the data collection form

Answer: A

Explanation:

In international or multicenter clinical studies, laboratory data often originate from different laboratories that use varying measurement units (e.g., mg/dL vs. mmol/L). The Good Clinical Data Management Practices (GCDMP, Chapter on CRF Design and Data Collection) provides clear guidance on managing this variability to ensure data consistency, traceability, and minimized transcription errors.

The approach that results in fewer transcription errors is to allow sites to enter lab values exactly as recorded in the source document (original lab report) and to require explicit selection of the corresponding unit from a predefined list on the data collection form or within the electronic data capture (EDC) system. This method (Option B) preserves the original source data integrity while enabling centralized or automated unit conversion later during data cleaning or statistical processing.

Option B also supports compliance with ICH E6 (R2) Good Clinical Practice (GCP), which mandates that transcribed data must remain consistent with the source documents. Attempting to derive units automatically (Option A) can lead to logical errors, while forcing sites to manually convert units (Option D) introduces unnecessary complexity and increases the risk of miscalculation or inconsistent conversions. Printing only standard units on the CRF (Option C) ignores local lab practices and can lead to discrepancies between CRF entries and source records, triggering numerous data queries.

The GCDMP emphasizes that CRF design must account for local variations in measurement systems and ensure that unit selection is structured (dropdowns, controlled lists) rather than free-text to prevent typographical errors and facilitate standardization during data transformation.

Therefore, Option B—"Allow values to be entered as they are in the source and the selection of units on the data collection form"—is the most compliant, accurate, and efficient strategy for minimizing transcription errors in international lab data collection.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.4 - Laboratory Data Management and Unit Handling ICH E6 (R2) Good Clinical Practice, Section 5.18 - Data Handling and Record Retention CDISC SDTM Implementation Guide, Section 6.3 - Handling of Laboratory Data and Standardized Units FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Source Data and Accuracy of Data Entry

NEW QUESTION # 97

A study is using blood pressure as an efficacy measure. Which is the best way to collect the data?

- A. Collecting the data from the medical record
- B. Measurement using existing equipment at sites
- C. Asking the study subjects what their blood pressure usually runs
- D. Measurement using study-provisioned equipment

Answer: D

Explanation:

When a clinical study uses blood pressure (BP) as an efficacy endpoint, the most reliable and standardized method of data collection

is through study-provisioned equipment.

According to the GCDMP (Chapter: CRF Design and Data Collection), data collected for primary efficacy endpoints must be consistent, accurate, and standardized across all investigative sites. Using study-provided calibrated equipment ensures that measurements are taken under uniform conditions, eliminating inter-site variability due to differences in devices, calibration, or measurement methods.

Collecting BP data from medical records (option A) risks inconsistent timing and techniques. Using each site's own equipment (option B) introduces variability, while patient self-reports (option D) lack reliability and objectivity.

Thus, the best practice is to provision and standardize all equipment used to collect endpoint-related physiological data, ensuring regulatory-quality results suitable for analysis.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.1 - Standardization of Clinical Measurements ICH E6 (R2) GCP, Section 5.5.3 - Data Accuracy and Equipment Standardization FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Data Capture and Standardization Requirements

NEW QUESTION # 98

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