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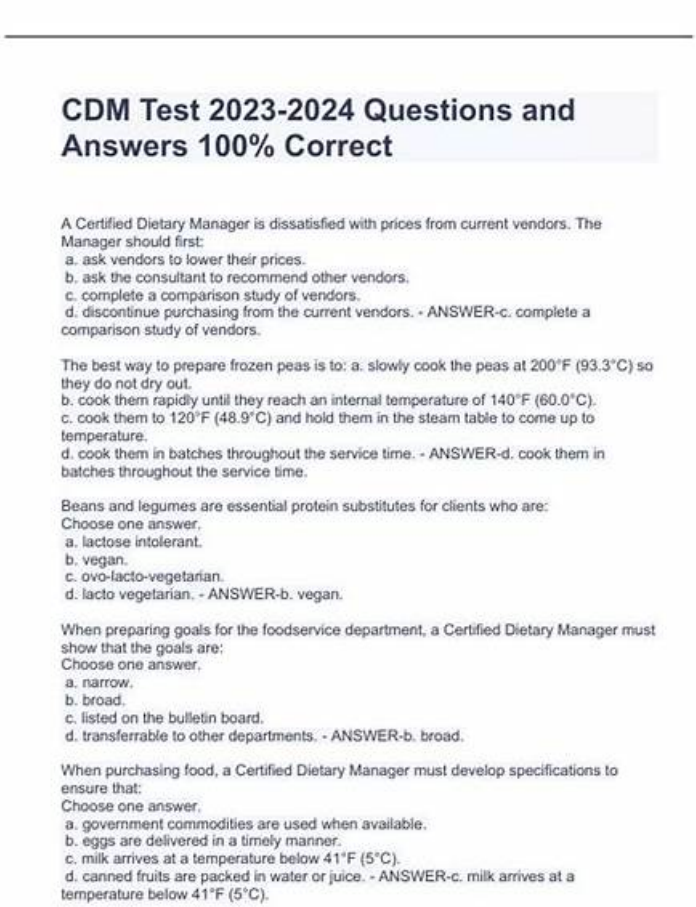

CDM Test 2023-2024 Questions and Answers 100% Correct

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	• 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 2	• 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	• 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	• 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 5	• 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 (Q109-Q114):

NEW QUESTION # 109
When a hospitalized subject in a cardiovascular trial experiences a repeated but mild episode of tachycardia, the physician decides to extend the subject's hospital stay for continued observation. How would this event be characterized?

- A. Severe adverse event
- B. Spontaneous adverse event
- C. Serious adverse event
- D. Adverse event

Answer: C

Explanation:
This event qualifies as a Serious Adverse Event (SAE) because it resulted in a prolonged hospitalization, even though the episode itself was mild.
According to ICH E2A and GCDMP (Chapter: Safety Data Handling and Reconciliation), an adverse event is considered "serious" if it results in any of the following outcomes:
Death,
Life-threatening situation,
Hospitalization or prolongation of existing hospitalization,
Persistent or significant disability/incapacity, or
Congenital anomaly/birth defect.
The severity (mild, moderate, severe) describes intensity, while seriousness describes regulatory significance and medical outcome.
Thus, a mild tachycardia episode leading to extended hospital stay meets the regulatory definition of an SAE.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Safety Data Handling and Reconciliation, Section 5.2 - Definition and Classification of Serious Adverse Events ICH E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, Section II - Seriousness Criteria FDA 21 CFR 312.32 - IND Safety Reporting: Serious Adverse Event Definitions

NEW QUESTION # 110
The primary reason for system validation is to:

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

Answer: B

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 # 111
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. Shorter than the patient table
- C. Longer than the patient table
- D. Wider 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 # 112
A Data Manager is designing a report to facilitate discussions with sites regarding late dat a. Which is the most important information to display on the report to encourage sites to provide data?

- A. Total number of forms entered to date

- B. Number of forms entered in the last week
- C. List of outstanding forms
- D. Expected versus actual forms entered

Answer: C

Explanation:
In managing site data timeliness, the most actionable and effective tool is a report listing all outstanding (missing or incomplete) CRFs.
According to GCDMP (Chapter: Communication and Study Reporting), Data Managers must provide site-level performance reports highlighting:
Outstanding CRFs not yet entered,
Unresolved queries, and
Pending data corrections.
Such reports help sites prioritize and address data gaps efficiently.
Option A and D are historical metrics without actionable context.
Option B gives a general overview but lacks specific site-level actionability.
Hence, option C (List of outstanding forms) provides the clearest and most motivating feedback to sites for timely data entry and query resolution.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Communication and Study Reporting, Section 5.3 - Data Timeliness and Reporting Metrics ICH E6(R2) GCP, Section 5.1.1 - Sponsor Oversight and Data Communication Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Site-Level Data Timeliness Reporting

NEW QUESTION # 113
Which of the following is the best reason for a statistician to review the case report form prior to using it in a study?

- A. To ensure the header fields will provide a unique key for each subject
- B. To ensure the layout will make a logical, useful programming guide
- C. To ensure the data from the CRF can be analyzed for safety and efficacy
- D. To ensure the variable names conform to statistical programming standards

Answer: C

Explanation:
The primary reason a statistician reviews the Case Report Form (CRF) is to ensure that the data being collected will support the planned statistical analyses for both safety and efficacy endpoints.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), CRF design should always align with the statistical analysis plan (SAP) to ensure that all necessary data elements are collected accurately and in analyzable formats. The statistician verifies that the CRF captures:
All endpoints specified in the protocol
Proper derivation or calculation fields
Timing of assessments
Consistency across visits and forms
Options B, C, and D address secondary or technical design considerations but not the primary analytical purpose. The review ensures that the CRF provides a complete and analyzable dataset for meeting study objectives, regulatory submissions, and statistical integrity.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 4.4 - Role of Statistics in CRF Design ICH E9 - Statistical Principles for Clinical Trials, Section 5.2 - Data Collection and Analysis Alignment FDA Guidance for Industry: E6(R2) GCP, Section 5.1 - Quality Management and Design Input from Stakeholders

NEW QUESTION # 114
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