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CCDM 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">• 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 | <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. |
| Topic 3 | <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 4 | <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 5 | <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. |

SCDM Certified Clinical Data Manager Sample Questions (Q52-Q57):

NEW QUESTION # 52

During testing of an ePRO system, a test fails. Which information should be found in the validation documentation?

- A. Training requirements
- B. Root cause analysis of the system errors
- C. Reconciliation datapoints
- D. Expected and actual results

Answer: D

Explanation:

When a system validation test fails during Electronic Patient-Reported Outcome (ePRO) system testing, the validation documentation must record the expected results (what should have occurred) and the actual results (what occurred).

According to the GCDMP (Chapter: Database Validation and Testing), proper system validation documentation ensures traceability, reproducibility, and compliance with FDA 21 CFR Part 11 and ICH E6 (R2). Each test case must include:

Test objective,

Preconditions,

Test steps,

Expected results,

Actual results, and

Pass/fail status.

If a test fails, this documentation provides the objective evidence necessary for deviation handling, issue resolution, and re-testing.

While a separate root cause analysis may be performed later (option D), the validation record itself must focus on verifying outcomes against predefined expectations.

Therefore, the correct answer is B - Expected and actual results.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Validation and Testing, Section 4.4 -

Documentation of Test Results FDA 21 CFR Part 11 - Validation Requirements (Section 11.10(a)) ICH E6 (R2) GCP, Section

5.5.3 - Computer System Validation and Documentation

NEW QUESTION # 53

For ease of data processing, the study team would like the database codes for a copyrighted rating scale preprinted on the CRF. What is the most critical task that the CRF designer must do to ensure the data collected on the CRF for the scale are reliable and will support the results of the final analysis?

- A. Consult the independent source and determine database codes will not influence subject responses.
- B. Complete the requested changes to the instrument and ensure the correct database codes are associated with the appropriate responses.
- C. Consult the independent source of the rating scale for approval and document that continued validity of the tool is not compromised.
- D. Consult the study statistician regarding the change and determine that database codes will not influence the analysis.

Answer: C

Explanation:

When using a copyrighted or validated rating scale (e.g., Hamilton Depression Scale, Visual Analog Pain Scale), any modification to the original instrument, including preprinting database codes on the CRF, must be approved by the instrument's owner or licensing authority to ensure the validity and reliability of the instrument are not compromised.

According to the GCDMP (Chapter: CRF Design and Data Collection), validated rating scales are psychometrically tested tools. Any visual or structural modification (such as adding codes, changing layout, or rewording questions) can invalidate prior validation results. Therefore, the CRF designer must consult the independent source (copyright holder) for approval and document that the validity of the tool remains intact.

Merely consulting statisticians (option B) or verifying database alignment (option D) does not ensure compliance. Thus, Option C ensures scientific and regulatory integrity.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 6.1 - Use of Validated Instruments and Rating Scales ICH E6 (R2) GCP, Section 5.5.3 - Validation of Instruments and Data Capture Tools FDA Guidance for Industry: Patient-Reported Outcome Measures - Use in Medical Product Development to Support Labeling Claims, Section 4 - Instrument Modification and Validation

NEW QUESTION # 54

Data from two sites are combined. One site coded gender as 1 and 2 (for Male and Female, respectively) while the other stored the data as M and F. Which term best describes the mapping?

- A. One-to-one
- B. Many-to-one
- C. Two-to-two
- D. One-to-many

Answer: A

Explanation:

When combining data from two datasets where one uses numeric codes (1 = Male, 2 = Female) and another uses text codes (M, F), each unique value in one dataset corresponds exactly to one unique value in the other.

This relationship is a one-to-one mapping, where each element in one dataset maps directly to a single corresponding element in the other.

1 → M

2 → F

Such mappings ensure consistent data harmonization during data integration and standardization phases, as outlined in the GCDMP (Chapter: Database Design and Integration).

Many-to-one (C) mapping would occur if multiple values (e.g., "Male," "M," "Man") mapped to a single standardized value, which isn't the case here.

Thus, the mapping is one-to-one, ensuring precise correspondence between both representations of gender data.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.4 - Data Mapping and Harmonization CDISC SDTM Implementation Guide, Section 5.2 - Controlled Terminology and Mapping Rules ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Integration Principles

NEW QUESTION # 55

Which document contains the details of when, to whom, and in what manner the vendor data will be sent?

- A. Data Management Plan
- **B. Data Transfer Agreement**
- C. Project Plan
- D. Communication Plan

Answer: B

Explanation:

A Data Transfer Agreement (DTA) defines the operational and technical details for transferring data between a sponsor and an external vendor (e.g., central lab, ECG vendor). It is a formalized, controlled document specifying what data will be sent, when transfers will occur, the transfer method, file structure, encryption or security protocols, and the recipients of the data.

The DTA is developed jointly by the sponsor and vendor before production data transfers begin. According to the GCDMP, Chapter on External Data Transfers, this agreement ensures both parties share a clear understanding of timing, responsibility, and data content to minimize errors and ensure regulatory compliance.

The Data Management Plan (DMP) outlines general data handling processes but does not capture the technical specifics of vendor data transfer logistics. The Project Plan (A) and Communication Plan (B) are broader operational tools and not specific to data transfer protocols.

Hence, option C (Data Transfer Agreement) is the correct answer, as it precisely governs the procedural and technical framework of vendor data exchange.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers, Section 4.1 - Data Transfer Agreements and Specifications ICH E6(R2) Good Clinical Practice, Section 5.5 - Trial Management, Data Handling, and Record Keeping

NEW QUESTION # 56

Which Clinical Study Report section would be most useful for a Data Manager to review?

- A. Description of statistical analysis methods
- B. Clinical narratives of adverse events
- **C. Description of how data were processed**
- D. Rationale for the study design

Answer: C

Explanation:

The section of the Clinical Study Report (CSR) most useful for a Data Manager is the description of how data were processed. According to the GCDMP (Chapter: Data Quality Assurance and Control), this section details the data handling methodology - including data cleaning, coding, transformation, and derivation procedures - all of which are core responsibilities of data management. Reviewing this section ensures that the data processing methods documented in the CSR align with the Data Management Plan (DMP), Data Validation Plan (DVP), and database specifications.

The statistical methods section (option A) is primarily for biostatistics, and the rationale for study design (option B) pertains to clinical and regulatory affairs. Clinical narratives (option D) are used by medical reviewers, not data managers.

By reviewing how data were processed, the Data Manager verifies that the study data lifecycle-from collection to analysis-was conducted in compliance with regulatory and GCDMP standards.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.3 - Documentation of Data Processing in Clinical Study Reports ICH E3 - Structure and Content of Clinical Study Reports, Section 11.3 - Data Handling and Processing FDA Guidance for Industry: Clinical Study Reports and Data Submission - Data Traceability and Handling Documentation

NEW QUESTION # 57

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