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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	• 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 2	• 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 3	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	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	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 (Q86-Q91):

NEW QUESTION # 86

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. Call the patient to verify the information
- D. Issue a query

Answer: D

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 # 87

Which metric reveals the timeliness of the site-work dimension of site performance?

- A. Time from final protocol to first patient enrolled
- B. Time from Last Patient Last Visit to database lock
- C. Median and range of time from query generation to resolution
- D. Time from site contract execution to first patient enrolled

Answer: C

Explanation:

The site-work dimension of site performance evaluates how efficiently sites manage and resolve data-related tasks - particularly query resolution, data entry, and correction timelines. Among the given metrics, the median and range of time from query generation to resolution (D) directly measures the site's responsiveness and data management efficiency.

According to the GCDMP (Chapter on Metrics and Performance Measurement), this indicator helps identify sites that delay query resolution, which can impact overall study timelines and data quality. Tracking this metric allows the data management team to proactively provide additional training or communication to underperforming sites.

Other options measure different aspects of project progress:

A reflects overall database closure speed.

B and C relate to study startup and enrollment readiness, not ongoing data work.

Thus, option D accurately represents a site performance timeliness metric, aligning with CCDM principles for operational performance measurement.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Metrics and Performance Management, Section 5.4 - Site Query Resolution Metrics ICH E6(R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Performance Oversight

NEW QUESTION # 88

ACME Intervention Co. is testing a new carotid artery stent in patients with coronary artery disease, in hopes of proving superiority over the current standard of care. After a subject signs consent, the surgeon enrolls the patient and retrieves information on which stent to use, but the surgeon does not share this information with the subject. Yesterday, the surgeon was instructed to use the control stent. Today, the surgeon has completed two surgeries: the first one the surgeon was instructed to use the control stent; the second one the surgeon was instructed to use the test stent. In what type of trial is the surgeon participating?

- A. Single-blind
- B. Double-blind
- C. Open label
- D. Cross-over

Answer: A

Explanation:

This scenario describes a single-blind trial, in which only one party-typically the subject-is unaware of the treatment assignment, while the investigator or surgeon knows which intervention is being administered.

In this case, the surgeon receives instructions on which stent (test or control) to use, meaning they are aware of treatment allocation. However, the subject is blinded to which device is being implanted. This setup minimizes subject bias while maintaining procedural safety since the surgeon must know which product to use.

Double-blind (A): Neither subject nor investigator knows the treatment.

Open-label (B): Both subject and investigator know the treatment.

Cross-over (D): Each subject receives both treatments in different periods.

Thus, the correct answer is C. Single-blind, as only the participant remains blinded in this surgical device trial design.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Clinical Trial Phases and Protocols, Section 3.2 - Study Blinding and Randomization Concepts ICH E6(R2) GCP, Section 1.10 - Definition of Blinding/Masking FDA Guidance for Industry: Design Considerations for Pivotal Clinical Investigations for Medical Devices, Section 5.3 - Blinding in Device Studies

NEW QUESTION # 89

What are the key deliverables for User Acceptance Testing?

- A. Test Plan/Script/Results
- B. Project Plan
- C. eCRF Completion Guidelines
- D. Training

Answer: A

Explanation:

The key deliverables for User Acceptance Testing (UAT) are the Test Plan, Test Scripts, and Test Results.

According to the GCDMP (Chapter: Database Design and Validation), UAT is the final validation step before a clinical database is released for production. It confirms that the system performs according to user requirements and protocol specifications.

The deliverables include:

UAT Test Plan: Defines testing objectives, scope, acceptance criteria, and responsibilities.

UAT Test Scripts: Provide step-by-step instructions for testing database functionality, edit checks, and workflows.

UAT Test Results: Document actual test outcomes versus expected outcomes, including any deviations and their resolutions.

These deliverables form part of the system validation documentation required under FDA 21 CFR Part 11 and ICH E6 (R2) to demonstrate that the database has been properly validated.

Project Plans (option A) and Training (option B) occur in earlier phases, while eCRF Completion Guidelines (option D) support site data entry, not system validation.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Validation, Section 5.3 - User Acceptance Testing Deliverables FDA 21 CFR Part 11 - Validation Documentation Requirements ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - System Validation Records

NEW QUESTION # 90

In a study conducted using paper CRFs, a discrepancy is discovered in a CRF to database QC audit. What is the reason why this discrepancy would be considered an audit finding?

- A. Discrepancy not explained by the data quality control audit plan
- B. Discrepancy not explained by the CRF completion guidelines
- C. Discrepancy not explained by the protocol
- **D. Discrepancy not explained by the data handling conventions**

Answer: D

Explanation:

In a CRF-to-database quality control (QC) audit, auditors compare data recorded on the paper Case Report Form (CRF) with data entered in the electronic database. If discrepancies exist that cannot be explained by documented data handling conventions, they are classified as audit findings.

Per GCDMP (Chapter: Data Quality Assurance and Control), data handling conventions define acceptable data entry practices, transcription rules, and allowable transformations. These conventions ensure that CRF data are consistently interpreted and entered. If a discrepancy deviates from these established rules, it indicates a process gap or error in data entry, validation, or training. Discrepancies justified by protocol design or CRF guidelines would not constitute findings.

Therefore, option C (Discrepancy not explained by the data handling conventions) correctly identifies the criterion for a true QC audit finding.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.1 - Data Handling Conventions and QC Auditing ICH E6(R2) GCP, Section 5.1 - Quality Management and Documentation of Deviations FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Verification and Audit Findings

NEW QUESTION # 91

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