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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:

- ask vendors to lower their prices.
- ask the consultant to recommend other vendors.
- complete a comparison study of vendors.
- 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	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	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 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 (Q31-Q36):

NEW QUESTION # 31

An asthma study is taking into account local air quality and receives that data from the national weather bureau. Which information is needed to link research subject data to the air-quality readings?

- A. Location, time and subject identifiers
- B. Location identifier
- **C. Location and time identifiers**
- D. Location, time, subject and site identifiers

Answer: C

Explanation:

When integrating external environmental data such as air quality readings with clinical study data, it is essential to use location and time identifiers to properly align the environmental data with subject-level data.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Management Planning and Study Start-up), external data sources (like national weather or pollution databases) must be merged using common linkage variables that allow synchronization without breaching subject confidentiality. In this case:

Location identifiers (e.g., city, postal code, or region) align the subject's study site or residential area with the environmental dataset. Time identifiers (e.g., date and time of data collection) ensure that the environmental readings correspond to the same period as the subject's clinical observations.

Including subject identifiers (option C or D) is unnecessary and would pose privacy and data protection risks. Instead, linkage is typically done at the aggregate (site or regional) level, maintaining compliance with HIPAA and GDPR.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Integration and External Data Handling, Section 4.3 - Linking External Data Sources ICH E6 (R2) GCP, Section 5.5.3 - Data Traceability and External Data Management FDA Guidance for Industry: Use of Electronic Health Record Data in Clinical Investigations, Section 5.2 - Linking and Integration Principles

NEW QUESTION # 32

Which attribute is NOT a characteristic of a standardized data collection element?

- A. A unique set of data storage metadata, including a variable name and data type
- B. A standard set of values used to respond to a data collection question
- C. An unambiguous definition for the data element
- **D. A strictly enforced requirement for the positioning of each data element on a case report form**

Answer: D

Explanation:

A standardized data collection element has well-defined metadata, consistent naming conventions, and controlled terminology to ensure uniform data collection and interoperability across studies.

Key attributes, as per GCDMP and CDISC standards, include:

A clear definition of meaning (A)

A controlled set of response values (C)

Metadata specifications like variable names, formats, and data types (D) However, the physical positioning of a data element on a case report form (B) is a matter of form layout design, not a characteristic of data standardization. While consistent form structure aids usability, it is not part of data standardization or metadata management principles.

Hence, option B is correct - form positioning is not a standardized data element attribute.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 4.1 - Data Element Standardization CDISC CDASH

Implementation Guide, Section 3.2 - Standardized Data Collection Elements and Metadata ICH E6(R2) GCP, Section 5.5.3 - Data Handling and Standardization

NEW QUESTION # 33

According to the FDA Guidance for Industry, Providing Regulatory Submissions in Electronic Format (April 2006) and Good Clinical Data Management Practices (GCDMP, May 2007), which of the following is the most acceptable for a derived field?

- A. Providing CRF annotation "not entered in the database" next to the average score
- B. Providing CRF annotation AVE next to the average score
- **C. Providing the algorithm for calculating the average score in the dataset definition file**
- D. Providing the algorithm for calculating the average score on the CRF

Answer: C

Explanation:

In clinical data management, a derived field refers to any variable that is not directly collected from the Case Report Form (CRF) but is instead calculated or inferred from one or more collected variables (for example, calculating an average blood pressure from multiple readings). Proper documentation of derived fields is essential for ensuring data traceability, transparency, and compliance with both FDA and SCDM guidelines.

According to the Good Clinical Data Management Practices (GCDMP, May 2007), all derivations and transformations applied to clinical data must be clearly defined and documented in metadata such as the dataset definition file (also referred to as data specifications, variable definition tables, or Define.xml files). The derivation algorithm should be explicitly stated in this documentation to allow independent verification, regulatory review, and reproducibility of results.

The FDA Guidance for Industry (April 2006) on electronic submissions further emphasizes that derived fields must be supported by comprehensive metadata that defines the computational method used. This documentation enables the FDA or any regulatory body to audit and reproduce analytical results without ambiguity. Annotating or describing derivations directly on the CRF (as in options A, B, or D) is not sufficient, as CRFs represent data collection instruments-not analytical documentation.

Therefore, the correct and regulatory-compliant practice is to provide the derivation algorithm for a calculated field within the dataset definition file, aligning with both FDA and GCDMP expectations for data integrity and auditability.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Handling and Processing - Derived and Calculated Data Fields, Section 5.3.3 FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006, Section 3.2 on Dataset Documentation Requirements CDISC Define.xml Implementation Guide - Metadata and Algorithm Documentation for Derived Variables

NEW QUESTION # 34

The Scope of Work would answer which of the following information needs?

- A. To find the name and contact information of a specific clinical data associate
- B. To look up the date of the next clinical monitoring visit for a specific site
- C. To look up which visit PK samples are taken
- **D. To determine the number of database migrations budgeted for a project**

Answer: D

Explanation:

The Scope of Work (SOW) is a contractual document that outlines the specific deliverables, responsibilities, timelines, and budgetary details for a given project between the sponsor and the contract research organization (CRO).

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), the SOW defines what work will be performed, how many resources are allocated, and the expected deliverables. This includes detailed information such as:

The number of database builds or migrations,

Timelines for deliverables (e.g., database lock),

Responsibility distribution between sponsor and CRO, and

Budget parameters for defined activities.

Therefore, if a Data Manager needs to determine how many database migrations are budgeted for a project, the SOW is the correct document to reference.

Information such as PK sample scheduling (option A), site monitoring dates (option B), or staff contact details (option D) would be found in operational plans or contact lists, not in the SOW.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Scope of Work Definition and Deliverables ICH E6 (R2) GCP, Section 5.5.3 - Documentation and Responsibilities for Data Management Tasks FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Agreements

NEW QUESTION # 35

Which of the following is a best practice for creating eCRFs for a study?

- **A. Develop eCRFs with cross-functional team members**
- B. Develop eCRFs that closely follow paper CRF standards
- C. Set up features that automatically enter data into fields when bypassed
- D. Set up coded terms so they are available to the site user

Answer: A

Explanation:

The best practice for developing electronic Case Report Forms (eCRFs) is to involve cross-functional team members throughout the design process.

According to the GCDMP (Chapter: CRF Design and Data Collection), eCRFs should be collaboratively developed by data management, clinical operations, biostatistics, medical, and regulatory teams. Each function provides a unique perspective - data managers focus on data capture and validation; statisticians ensure alignment with analysis requirements; clinicians ensure medical relevance and protocol compliance.

Collaborative development ensures that the eCRFs are fit-for-purpose, capturing all required data accurately, minimizing redundancy, and supporting downstream data analysis.

Options A and B violate good data management practice because sites should not directly access coded terms (to prevent bias), and fields should never auto-populate without explicit source verification. Option D is outdated; while paper CRFs may inform structure, EDC-optimized eCRFs should leverage system functionality rather than mimic paper.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.2 - Collaborative CRF Development ICH E6 (R2) GCP, Section 5.5.3 - Data Collection and System Validation FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 3.4 - CRF Design Considerations

NEW QUESTION # 36

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