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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 Certified Clinical Data Manager Sample Questions (Q148-Q153):

NEW QUESTION # 148

What is the purpose of providing the central laboratory vendor with a complete listing of subjects' demographic data?

- A. To provide for an independent reconciliation of the patient and remote databases after database lock
- B. To assure that lab data for screening failure subjects have not been included in the lab data transmission
- C. To assure that all subjects have lab data for valid visits
- D. To provide for an independent reconciliation of the patient and remote databases during study conduct

Answer: D

Explanation:

Providing the central laboratory vendor with a complete subject demographic listing allows ongoing reconciliation between the sponsor's EDC system and the vendor's laboratory database during study conduct.

The GCDMP (Chapter: External Data Transfers and Integration) emphasizes that subject reconciliation ensures that all laboratory data correspond to valid enrolled subjects and visits. Regular reconciliation throughout the study prevents data mismatches, missing results, or misassigned lab reports.

This proactive measure supports timely query resolution and data integrity across systems. Waiting until after database lock (as in option A) would delay corrections and risk inconsistencies. Options B and D address secondary benefits but not the primary purpose-ongoing subject-level reconciliation.

Thus, option C is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers, Section 4.4 - Reconciliation and Vendor Communication ICH E6(R2) GCP, Section 5.5.3 - Data Management, Reconciliation, and Integration FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - External Data Management

NEW QUESTION # 149

Which of the following laboratory findings is a valid adverse event reported term that facilitates auto coding?

- A. Abnormal SGOT
- B. Elevated HDL
- C. ALT
- D. Increased alkaline phosphatase, increased SGPT, increased SGOT, and elevated LDH

Answer: B

Explanation:

When coding adverse events (AEs) using MedDRA (Medical Dictionary for Regulatory Activities), valid AE terms must correspond to specific, medically meaningful concepts that match directly to a Preferred Term (PT) or Lowest Level Term (LLT) in the dictionary.

Among the options, "Elevated HDL" (High-Density Lipoprotein) represents a single, medically interpretable, and standard term that can directly match to a MedDRA LLT or PT. This makes it suitable for auto-coding, where the system automatically maps verbatim terms to MedDRA entries without manual intervention.

In contrast:

ALT (B) and Abnormal SGOT (C) are incomplete or nonspecific; they describe test names or qualitative interpretations rather than events.

Option D lists multiple findings, making it too complex for automatic mapping. Such compound entries would require manual coding review.

According to GCDMP (Chapter: Medical Coding and Dictionaries), a valid AE term should be:

Clinically interpretable (not just a lab test name)

Unambiguous

Single-concept based, not a collection of results

Thus, option A (Elevated HDL) is correct, as it aligns with MedDRA's single-concept, standard terminology structure suitable for auto-coding.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Medical Coding and Dictionaries, Section 5.3 - Auto-coding and Verbatim Term Management ICH M1 MedDRA Term Selection: Points to Consider, Section 2.1 - Coding Principles ICH E2B(R3) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

NEW QUESTION # 150

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

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

Answer: A

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 # 151

A study budgeted forty hours allocated over the three months following first protocol draft for Data Management Plan (DMP) creation. If there is a problem with this approach, what is it?

- A. No time was allocated for maintenance of the DMP
- B. There is no problem with the approach
- C. Forty hours is too little time to budget for DMP creation
- D. Forty hours is too much time to budget for DMP creation

Answer: A

Explanation:

The main issue with this approach is that no time has been allocated for ongoing maintenance and updates of the Data Management Plan (DMP) throughout the study lifecycle.

According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the DMP is a living document - it must be continuously maintained and updated as study procedures evolve, particularly after protocol amendments, database modifications, or changes in data validation or reconciliation procedures.

Budgeting only for initial creation (forty hours) over three months ignores the substantial effort required for DMP version control, stakeholder communication, and mid-study updates. These updates are mandatory to maintain compliance with ICH E6 (R2) GCP Section 5.5.3, which requires that all procedural documentation accurately reflect current practices.

Thus, the problem is not the time allocated for creation but the lack of planning for ongoing maintenance.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Plan (DMP), Section 5.3 - DMP Maintenance and Version Control ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Documentation of Data Handling Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Documentation Updates

NEW QUESTION # 152

In a physical therapy study, range of motion is assessed by a physical therapist at each site using a study-provided goniometer. Which is the most appropriate quality control method for the range of motion measurement?

- A. Reviewing data listings for illogical changes in range of motion between visits
- B. Comparison to the measurement from the previous visit
- **C. Independent assessment by a second physical therapist during the visit**
- D. Programmed edit checks to detect out-of-range values upon data entry

Answer: C

Explanation:

In this scenario, the variable of interest-range of motion (ROM)-is a clinically measured, observer-dependent variable. The accuracy and reliability of such data depend primarily on the precision and consistency of the measurement technique, not merely on data entry validation. Therefore, the most appropriate quality control (QC) method is independent verification of the measurement by a second qualified assessor during the visit (Option D).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Quality Assurance and Control), quality control procedures must be tailored to the nature of the data. For clinically assessed variables, especially those involving human judgment (e.g., physical measurements, imaging assessments, or subjective scoring), real-time verification by an independent qualified assessor ensures that data are valid and reproducible at the point of collection. This approach directly addresses measurement bias, observer variability, and instrument misuse, which are primary sources of data error in clinical outcome assessments.

Other options, while valuable, address only data consistency or plausibility after collection:

Option A (comparison to previous visit) and Option C (reviewing data listings) are retrospective data reviews, suitable for identifying trends but not preventing measurement error.

Option B (programmed edit checks) detects only extreme or impossible values, not measurement inaccuracies due to technique or observer inconsistency.

The GCDMP and ICH E6 (R2) Good Clinical Practice guidelines emphasize that data quality assurance should begin at the source, through standardized procedures, instrument calibration, and dual assessments for observer-dependent measures. Having an independent second assessor ensures inter-rater reliability and provides direct confirmation that the recorded value reflects an accurate and valid measurement.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.4 - Measurement Quality and Verification ICH E6 (R2) Good Clinical Practice, Section 2.13 - Quality Systems and Data Integrity FDA Guidance for Industry: Patient-Reported Outcome Measures and Clinical Outcome Assessment Data, Section 5.3 - Quality Control of Clinician-Assessed Data SCDM GCDMP Chapter: Source Data Verification and Quality Oversight Procedures

NEW QUESTION # 153

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