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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 (Q13-Q18):

NEW QUESTION # 13

In an EDC study, user training and access must be monitored and addressed when all the following situations occur EXCEPT:

- A. Site staff is new to the study.
- B. Site staff moves off of the study.
- C. Study team members are reassigned to a different role within the study.
- **D. A software upgrade is made that does not impact site staff or study team members.**

Answer: D

Explanation:

In Electronic Data Capture (EDC) studies, proper user training and access management are essential for maintaining data integrity, security, and regulatory compliance. According to the Good Clinical Data Management Practices (GCDMP) and FDA 21 CFR Part 11, EDC systems must ensure that only qualified and trained personnel can access study data, and that all access rights reflect current study responsibilities.

User training and access must therefore be reviewed and updated whenever:

Site staff leave the study (access revocation is required),

New site staff are added (training and credentialing are required), and Study team members change roles (access levels must be modified accordingly).

However, if a software upgrade occurs that does not impact the functional roles, user permissions, or data handling processes, retraining or reauthorization is not required. This is because such updates do not alter compliance-critical workflows or user interactions.

Therefore, the exception is C - when a software upgrade does not affect users.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 7.1 - User Access and Training Controls FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures, Section 11.10(i) & (k) ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - System Security and User Training

NEW QUESTION # 14

If a data manager generated no additional manual queries on data in an EDC system and the data were deemed clean, why could the data appear to be not clean during the next review?

- A. The CRA can change the data during a quality review of source to database.
- B. The data manager may have accidentally changed the data.
- **C. The study coordinator can change the data due to re-review of the source.**
- D. The medical monitor can override safety information entered in the system.

Answer: C

Explanation:

In an Electronic Data Capture (EDC) system, even after a data manager completes all manual queries and marks data as "clean," the data may later appear unclear if the site (study coordinator) makes subsequent updates in the system after re-reviewing the source documents.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Electronic Data Capture Systems), site users maintain the authority to modify data entries as long as the system remains open for data entry. The EDC system audit trail captures such changes, which can automatically invalidate prior data reviews, triggering new discrepancies or changing system edit-check statuses.

This situation commonly occurs when the site identifies corrections in the source (e.g., wrong date or lab result) and updates the EDC form accordingly. These post-cleaning changes require additional review cycles to ensure the database reflects accurate and verified information before final lock.

Options B, C, and D are incorrect - CRAs and medical monitors cannot directly change EDC data; they can only raise queries or request updates.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 6.3 - Post-Cleaning Data Changes and Audit Trails ICH E6 (R2) GCP, Section 5.5.3 - Data Integrity and Change Control FDA 21 CFR Part

NEW QUESTION # 15

A Data Manager is designing a CRF for a study for which the efficacy data are not covered by the current SDTM domains. Which search should the Data Manager do?

- **A. Search for relevant data element standards**
- B. Advise the study team not to collect the data
- C. Use controlled terminology covering the needed concepts
- D. Work with the study team to define new data elements

Answer: A

Explanation:

When existing SDTM (Study Data Tabulation Model) domains do not cover specific efficacy data, the best practice is to first search for relevant data element standards that may be available through CDISC CDASH (Clinical Data Acquisition Standards Harmonization) or other recognized industry standards.

Per GCDMP (Chapter: Standards and Data Integration), Data Managers must ensure that new CRF elements are consistent with standardized definitions, controlled terminology, and data models to support interoperability, future analysis, and regulatory submission.

If no existing standards exist, only then should the Data Manager collaborate with the study team to define new elements - but standard searches always come first.

Thus, option C is correct - search for relevant data element standards ensures alignment with CDISC best practices and regulatory expectations.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.1 - Use of CDISC Standards in CRF Design CDISC CDASH Implementation Guide, Section 4.1 - Standardization of Data Collection Fields FDA Study Data Technical Conformance Guide (SDTCG), Section 2.4 - Use of Standard and Custom Domains

NEW QUESTION # 16

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

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

Answer: B

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 # 17

In an EDC study, an example of an edit check that would be inefficient to run at data entry is a check:

- A. Against a valid list of values.
- B. Against a valid numeric range.
- C. On the format of a date.
- **D. Across visits for consistency.**

Answer: D

Explanation:

In Electronic Data Capture (EDC) systems, edit checks are categorized based on when and how they are executed - typically immediate (at data entry) or batch (post-entry). Checks that require data from multiple visits or forms are generally inefficient to run at data entry because they depend on information that may not yet exist in the system.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), cross-visit consistency checks - such as comparing baseline and follow-up blood pressure or verifying date order between screening and dosing - should be executed as batch or scheduled validations, not at the point of data entry. Running these complex checks in real time can slow system performance, increase query load unnecessarily, and confuse site users if related data are not yet entered. Conversely, edit checks against valid ranges, formats, or predefined value lists (options A, C, and D) are simple, local validations ideally performed immediately at data entry to prevent basic errors.

Therefore, cross-visit consistency checks (Option B) are best executed later, making them inefficient for real-time data entry validation.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.4 - Real-Time vs. Batch Edit Checks
FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Edit Checks and Data Validation
CDISC SDTM Implementation Guide - Section on Temporal Data Consistency Validation

NEW QUESTION # 18

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