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CCDM Practice Test 100 Questions with Answers 2023

A client weighs 162 pounds today. One month ago, the client weighed 174 pounds. The percent of weight change is: - Correct answer 7%

The section of the minimum data set (MDS) that contains the most nutrition information is designated as: - Correct answer section K

Which of the following questions would be most appropriate to ask when taking a diet history? - Correct answer When do you usually eat

Which of the following instruments would not be used for a diet history? - Correct answer caliper

The nutrition screening indicators are often categorized as A B C D. What does the D represent? - Correct answer Diet history

A decreased intake of 250 to 300 calories per day may result in a loss of approximately one pound of body fat within how many days? - Correct answer 12 days

If a diet provides 36 grams of fat and a total of 1800 calories, the percentage of calories from fat is: - Correct answer 18%

How many milliliters of juice are equivalent to 1/2 cup? - Correct answer 120

The purpose of the certified dietary manager's role in care planning is not to? - Correct answer Monitor the clients daily weight

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SCDM Certified Clinical Data Manager Sample Questions (Q79-Q84):

NEW QUESTION # 79

Every database lock should follow documented approval of which stakeholders?

- A. Clinical/Scientific Representative, Biostatistician, Programmer
- B. Clinical/Scientific Representative, Data Manager
- **C. Clinical/Scientific Representative, Data Manager, Biostatistician**
- D. Clinical/Scientific Representative, Biostatistician

Answer: C

Explanation:

According to the Good Clinical Data Management Practices (GCDMP), the database lock (DBL) process signifies the formal closure of the clinical trial database, ensuring that no further changes can be made to the data before statistical analysis. This process must be documented, controlled, and approved by key study stakeholders to ensure data accuracy, completeness, and readiness for analysis.

The GCDMP specifies that database lock should occur only after all data cleaning, discrepancy resolution, and reconciliation activities are complete. The lock authorization typically requires the approval of the Clinical/Scientific Representative (to confirm clinical completeness), the Data Manager (to confirm data integrity and query closure), and the Biostatistician (to confirm readiness for statistical analysis).

This tri-party approval ensures that the database reflects final, verified data consistent with the clinical protocol, and that the statistical analysis dataset derived from the database is accurate and auditable. The approval process is documented via a Database Lock Authorization Form or Sign-off Log, which becomes part of the permanent trial master file (TMF).

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Lock and Archiving, Section 7.1 - Lock Procedures and Approvals ICH E6 (R2) GCP, Section 5.5.3 - Data Handling and Record Keeping FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Database Closure

NEW QUESTION # 80

Which action has the most impact on the performance of a relational database system?

- **A. Loading a large lab data file into the database**
- B. Making updates to data previously entered into the database
- C. Entering data into the database from CRFs
- D. Executing a properly designed database query

Answer: A

Explanation:

In a relational database system used in clinical data management, performance refers to how efficiently the system processes transactions, retrieves data, and handles large volumes of information without delay or data integrity issues. Among the listed options, loading a large lab data file into the database (Option B) has the most significant impact on database performance.

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Database Design and Build), the bulk data load process - such as importing large external datasets (e.g., central lab data, ECG results, or imaging metadata) - can be computationally intensive. This process engages the database's input/output (I/O) subsystem, indexing mechanisms, and transaction logs simultaneously, often locking tables temporarily and consuming significant memory and processing resources.

Unlike standard CRF data entry (Option A) or record updates (Option D), which are incremental and typically processed in smaller transactional batches, bulk loading operations handle thousands or millions of rows at once. If not optimized (e.g., via staging tables, indexing strategies, or commit frequency control), such operations can degrade system performance, slow down concurrent user access, and increase the risk of transaction failure.

Executing a properly designed query (Option C) can also be resource-intensive depending on data volume and join complexity, but when queries are properly optimized (using indexed keys, efficient SQL joins, and selective retrieval), their impact is generally controlled and transient compared to large data imports.

Therefore, as outlined in the GCDMP Database Design and Build and FDA Computerized Systems Guidance, the most performance-impacting activity in a relational database is bulk loading large external datasets, making Option B the correct answer.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Build, Section 6.7 - Database Performance and Optimization FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - System Performance and Data Handling Efficiency ICH E6 (R2) Good Clinical Practice, Section

NEW QUESTION # 81

Which of the following scenarios requires a query to be sent to the central lab first when there is a discrepancy between the final lab data transfer and the CRF?

- A. Both the central lab and the CRF data have missing data for a visit
- B. Both the central lab and the CRF have data present for a visit
- **C. The central lab has data for a visit but the CRF has missing data for the visit**
- D. The CRF has data for a visit but the central lab has missing data for the visit

Answer: C

Explanation:

During data reconciliation between a central laboratory and CRF data, the source of truth is typically the central lab database, as it provides directly measured, vendor-generated results.

When the central lab has data but the CRF does not (option C), the Data Manager must first query the central lab to confirm that the result was transmitted correctly, since discrepancies may stem from data processing or timing issues. Once confirmed, a secondary query may be issued to the site to ensure CRF completion and alignment.

Conversely, if the CRF contains data but the central lab is missing results (option B), the issue is site-level, not vendor-level.

According to the GCDMP (Chapter: External Data Transfers and Reconciliation), priority for querying depends on the authoritative source - for lab data, the central lab is considered the source of record.

Therefore, option C is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers and Reconciliation, Section 6.1 - Reconciliation of Central Lab and CRF Data
ICH E6(R2) GCP, Section 5.5.3 - Source Data Verification and Vendor Reconciliation
FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Data Reconciliation and Traceability

NEW QUESTION # 82

A study has an expected enrollment period of one year but has subject recruitment issues. Twelve new sites are added toward the end of the expected enrollment period to help boost enrollment. What is the most likely impact on data flow?

- A. Additional sites will likely have increased query rates since site training is occurring closer to study close.
- B. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- **C. A bolus of CRFs at the end of the study will result in the need to increase data entry and cleaning rates to meet existing timelines.**
- D. The database set-up will need to be changed to allow for additional sites as they are added to the study.

Answer: C

Explanation:

Adding multiple new sites late in the enrollment period creates a concentrated influx of new data near the end of the study. These sites typically start enrolling patients later, resulting in a "bolus" of Case Report Forms (CRFs) that must be entered, validated, and cleaned within a shorter timeframe to meet database lock deadlines.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Data Flow), late site activation compresses the timeline for data management tasks, necessitating increased resources for data entry, query management, and cleaning. Data management teams must anticipate this surge and plan accordingly-either by increasing staffing or revising timelines to prevent bottlenecks and maintain quality.

While option D (increased query rates) can occur, it is a secondary effect. The most direct and consistent impact is the surge in data volume requiring expedited processing near study end.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Project Management, Section 5.3 - Managing Changes in Site Activation and Data Flow
ICH E6(R2) GCP, Section 5.1 - Quality Management and Oversight

NEW QUESTION # 83

According to ICH E6, developing a Monitoring Plan is the responsibility of whom?

- A. Monitor
- B. Data Manager
- **C. Sponsor**
- D. CRO

Answer: C

Explanation:

According to ICH E6(R2) Good Clinical Practice (GCP), Section 5.18.1, the Sponsor is ultimately responsible for developing and implementing the Monitoring Plan.

The Monitoring Plan defines:

The extent and nature of monitoring (e.g., on-site, remote, risk-based).

The responsibilities of monitors.

The communication and escalation procedures for data quality and protocol compliance.

While the CRO (B) or Monitor (D) may perform monitoring activities under delegation, the Sponsor retains legal accountability for ensuring a compliant and effective plan is developed and maintained. The Data Manager (C) may contribute by outlining data review workflows, but is not responsible for authoring or owning the plan.

Therefore, option A (Sponsor) is the correct answer.

Reference (CCDM-Verified Sources):

ICH E6(R2) GCP, Section 5.18.1 - Purpose and Responsibilities for Monitoring SCDM GCDMP, Chapter: Regulatory Compliance and Oversight, Section 5.3 - Sponsor Responsibilities in Monitoring and Quality Assurance FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor Responsibilities (2013)

NEW QUESTION # 84

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