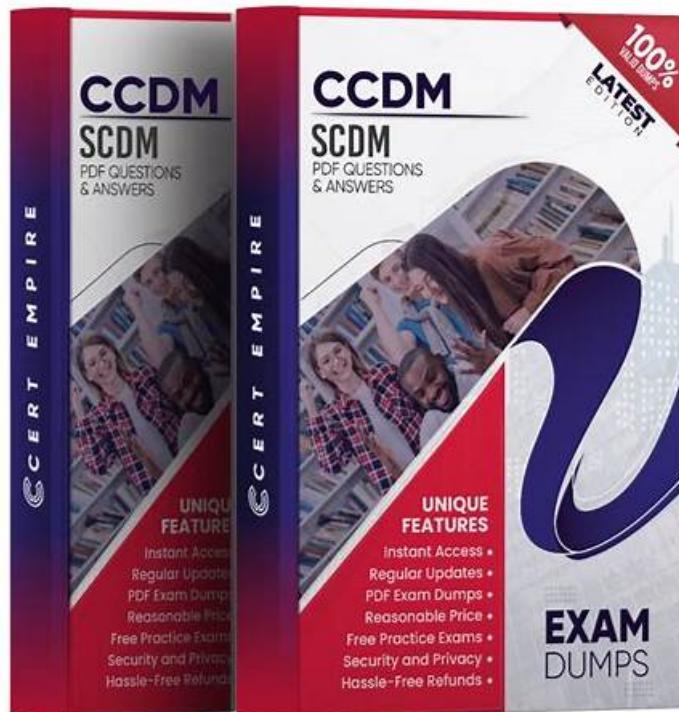


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SCDM Certified Clinical Data Manager Sample Questions (Q89-Q94):

NEW QUESTION # 89

Based on the project Gantt chart as of 01 Nov 2019, an interim analysis is scheduled to occur early Q2 of 2020. All of the following

are valid for initially assessing the status of data cleanliness EXCEPT:

- A. Identifying missing pages where visits have been completed to date
- **B. Identifying the number of discrepancies resolved to date**
- C. Determining CRF data entry status of received pages
- D. Identifying all outstanding discrepancies to date and aging

Answer: B

Explanation:

When initially assessing data cleanliness in preparation for an interim analysis, the focus should be on outstanding issues that could affect data completeness and reliability.

According to the GCDMP (Chapter: Data Quality Assurance and Control), key indicators of readiness include:

The CRF data entry status of received pages (option A) to confirm completeness.

Identification of missing pages or visits (option B) to verify subject-level completeness.

A listing of outstanding discrepancies and their aging (option D) to assess unresolved data issues.

Counting the number of discrepancies resolved to date (option C), however, does not reflect data quality or current data readiness—it indicates past actions rather than current unresolved risks. Therefore, it is not a valid measure for assessing interim data cleanliness.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.1 - Data Readiness Assessments for Analysis ICH E6 (R2) GCP, Section 5.18.4 - Ongoing Data Quality Review FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section 7 - Data Quality Indicators

NEW QUESTION # 90

To ensure data quality and efficient integration of data, which of the following best describes the main topic that should be covered in initial discussions with a vendor providing the external data?

- **A. Acceptable record, field, and file formats**
- B. Standard dictionary versioning and maintenance
- C. Metrics that will be used to measure data quality
- D. Criteria to trigger audits based on performance-monitoring reports

Answer: A

Explanation:

In initial vendor discussions for external data integration (e.g., central lab, ECG, imaging vendors), the most critical and foundational topic is defining the acceptable record, field, and file formats.

According to the GCDMP (Chapter: External Data Transfers and Integration), establishing the Data Transfer Specifications (DTS) early in the process ensures consistent structure, proper mapping, and compatibility between the vendor's system and the sponsor's database. These specifications define:

Data structure (variable names, formats, delimiters)

File naming conventions

Frequency of transfers

Methods of secure data transmission

Discussing formats first allows later alignment on data validation, quality metrics, and dictionary standards (which occur in subsequent stages). Without format agreement, all downstream processes risk misalignment, resulting in data incompatibility and rework.

Thus, option C (Acceptable record, field, and file formats) correctly represents the foundational focus of initial vendor discussions for ensuring data quality and integration efficiency.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers and Integration, Section 4.1 - Data Transfer Planning and Specification Development ICH E6(R2) GCP, Section 5.5.3 - Data Handling and System Validation FDA Guidance: Computerized Systems Used in Clinical Investigations, Section 6.3 - Data Import and Format Control

NEW QUESTION # 91

Which metric will identify edit checks that may not be working properly?

- A. Average number of times each edit check has fired
- **B. Count by site of the number of times any edit check fired**

- C. Average number of edit check identified discrepancies per form
- D. Count by edit check of the number of times the check fired

Answer: D

Explanation:

The best metric to identify malfunctioning or ineffective edit checks is the count by edit check of the number of times the check fired. This allows data managers to assess whether specific edit checks are performing as intended.

According to the GCDMP, Chapter: Data Validation and Cleaning, edit checks are programmed logic conditions that identify data inconsistencies or potential errors during data entry. A properly functioning edit check should trigger only when data falls outside acceptable or logical limits. If an edit check fires too frequently or not at all, it may indicate a logic error in the check's programming or configuration.

By analyzing counts by individual edit checks, data managers can:

Identify checks that never trigger (potentially inactive or incorrectly written), Detect overactive checks (poorly designed parameters causing excessive false positives), and Optimize system performance and review efficiency.

This metric supports continuous improvement in data validation logic and contributes to cleaner, higher-quality clinical databases.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.2 - Edit Check Design and Performance Metrics FDA Guidance: Computerized Systems Used in Clinical Investigations - Section on Validation of Electronic Data Systems

NEW QUESTION # 92

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, Biostatistician
- D. Clinical/Scientific Representative, Data Manager, Biostatistician

Answer: D

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 # 93

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

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

Answer: C

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 5.5 - Data Handling and Record Integrity CDISC Operational Data Model (ODM) Implementation Guide - Bulk Data Transfer and Validation Considerations

NEW QUESTION # 94

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