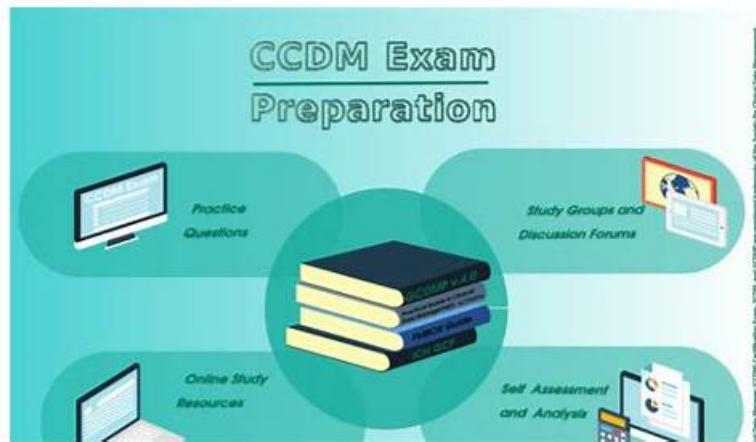


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SCDM Certified Clinical Data Manager Sample Questions (Q102-Q107):

NEW QUESTION # 102

Which type of edit check would be implemented to check the correctness of data present in a text box?

- A. Front-end check
- B. Manual Check
- C. Back-end check
- D. Programmed check

Answer: A

Explanation:

A front-end check is a type of real-time validation performed at the point of data entry-typically within an Electronic Data Capture (EDC) system or data entry interface-designed to ensure that the data entered in a text box (or any input field) is valid, logically correct, and within expected parameters before the user can proceed or save the record.

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Clearing), edit checks are essential components of data validation that ensure data accuracy, consistency, and completeness. Front-end checks are implemented within the data collection interface and are triggered immediately when data are entered. They prevent invalid entries (such as letters in numeric fields, out-of-range values, or improper date formats) from being accepted by the system.

Examples of front-end checks include:

Ensuring a numeric field accepts only numbers (e.g., weight cannot include text characters).

Validating that a date is within an allowable range (e.g., not before the subject's date of birth).

Requiring mandatory fields to be completed before moving forward.

This differs from back-end checks or programmed checks, which are typically run later in batch processes to identify data inconsistencies after entry. Manual checks are human-performed reviews, often for context or data that cannot be validated automatically (e.g., narrative assessments).

Front-end edit checks are preferred wherever possible because they prevent errors at the source, reducing the number of downstream data queries and cleaning cycles. They contribute significantly to data quality assurance, regulatory compliance, and efficiency in data management operations.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.2 - Edit Checks and Real-Time Data Validation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Data Entry and Verification Controls ICH E6 (R2) Good Clinical Practice, Section 5.5 - Data Handling and Record Integrity CDISC Operational Data Model (ODM) Specification - Edit Check Implementation Standards

NEW QUESTION # 103

During a database audit, it was determined that there were more errors than expected. Who is responsible for assessing the overall impact on the analysis of the data?

- A. Data Manager
- B. Investigator
- C. Quality Auditor
- D. Statistician

Answer: D

Explanation:

The Statistician is responsible for assessing the overall impact of data errors on the analysis and study results.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control) and ICH E9 (Statistical Principles for Clinical Trials), while the Data Manager ensures data accuracy and completeness through cleaning and validation, the Statistician determines whether the observed data discrepancies are statistically significant or if they may affect the validity, power, or interpretability of the study's outcomes.

The Quality Auditor (C) identifies and reports issues but does not quantify analytical impact. The Investigator (D) is responsible for clinical oversight, not statistical assessment. Thus, after a database audit, the Statistician (B) performs a formal evaluation to determine whether the magnitude and nature of the errors could bias results or require reanalysis.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Data Audit and Impact Assessment ICH E9 - Statistical Principles for Clinical Trials, Section 3.2 - Data Quality and Analysis Impact Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Validation and Analysis Review

NEW QUESTION # 104

Which Clinical Study Report section would be most useful for a Data Manager to review?

- A. Description of statistical analysis methods
- B. Clinical narratives of adverse events
- C. Enumeration and explanation of data errors
- D. Rationale for the study design

Answer: C

Explanation:

The section of the Clinical Study Report (CSR) that is most useful for a Data Manager is the one that includes the enumeration and explanation of data errors. This section provides a summary of the data quality control findings, including error rates, missing data summaries, and any issues identified during data review, validation, or database lock.

According to the GCDMP (Chapter: Data Quality Assurance and Control), post-study reviews of data errors and quality findings are essential for evaluating process performance, identifying recurring issues, and informing continuous improvement in future studies. Other sections, such as clinical narratives (A) or statistical methods (C), are outside the core scope of data management responsibilities. The data error enumeration section directly reflects the quality and integrity of the data management process and is therefore the most relevant for review.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.4 - Quality Reporting and Error Analysis ICH E3 - Structure and Content of Clinical Study Reports, Section 14.3 - Data Quality Evaluation

NEW QUESTION # 105

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

Answer: A

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 # 106

For a study, body mass index is calculated from weight and height. Which information is needed to document the transformation?

- A. User ID making the change and reason for change
- B. Algorithm associated with the calculated value
- C. Algorithm and algorithm version associated with the calculated value
- D. Algorithm documented in the Data Management Plan

Answer: C

Explanation:

When derived or calculated variables (like Body Mass Index) are created, it is essential to document the algorithm used and its version to ensure full data traceability and reproducibility.

According to GCDMP (Chapter: Database Design and Derived Data), every derived field must include metadata describing:

The derivation algorithm (e.g., $BMI = \text{weight} [\text{kg}] / \text{height}^2 [\text{m}^2]$)

The version of the algorithm (if updates or revisions occur)

Any associated data sources or transformation rules

This ensures consistent calculation across systems, prevents discrepancies during regulatory submissions, and aligns with FDA and CDISC documentation expectations.

Option B lacks version control, which is critical for traceability. Option C describes audit trail data (not derivation metadata), and option D refers to broader documentation, not specific algorithm traceability.

Hence, option A (Algorithm and algorithm version associated with the calculated value) is the correct and compliant answer.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Derived Data and Algorithms, Section 5.3 - Documentation and Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Derived Data and Validation Traceability FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Data Definitions (Define.xml)

NEW QUESTION # 107

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