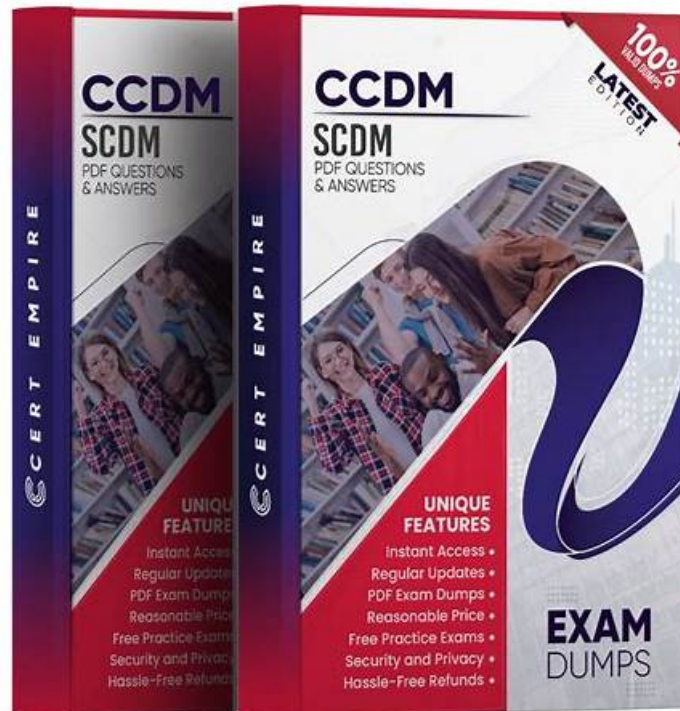


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SCDM Certified Clinical Data Manager Sample Questions (Q96-Q101):

NEW QUESTION # 96

Which is the best way to identify sites with high subject attrition?

- A. Proportion of patients for which two visit periods have passed without data by site
- B. Number of patients for which two visit periods have passed without data
- C. Number of late visits per site
- D. Proportion of late visits by site

Answer: A

Explanation:

The best method to identify sites with high subject attrition is to calculate the proportion of patients for which two visit periods have passed without data, by site.

According to the GCDMP (Chapter: Data Quality Assurance and Control), subject attrition is an important performance indicator for data completeness and site compliance. Evaluating missing or delayed data across multiple consecutive visit periods allows for early detection of potential dropouts or site-level operational issues.

By assessing this proportion at the site level, the Data Manager can distinguish between random missing data and systematic site underperformance. Counting or proportioning late visits (options B and C) identifies scheduling delays, not attrition. Looking at missing data without site context (option D) fails to identify site-specific patterns, limiting corrective action.

This metric aligns with risk-based monitoring (RBM) practices recommended by ICH E6 (R2) and FDA RBM Guidance, which promote proactive identification of sites at risk of data loss.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 5.4 - Site Performance Metrics ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Performance Evaluation FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section 6 - Site Performance Metrics

NEW QUESTION # 97

With the implementation of EDC, which company Standard Operating Procedure (SOP) would require updates for new procedures of handling data?

- A. Coding Medical and Clinical Terms
- **B. Data Review and Validation**
- C. Handling External Data
- D. Data Backup, Recovery, and Contingency Plans

Answer: B

Explanation:

When a company transitions from paper-based data capture to Electronic Data Capture (EDC) systems, one of the most critical areas requiring procedural updates is the Data Review and Validation SOP. The introduction of EDC systems fundamentally changes how data is collected, reviewed, validated, and queried.

According to the Good Clinical Data Management Practices (GCDMP), the implementation of EDC introduces real-time data entry and review, automated edit checks, and electronic query management. These functionalities necessitate revised procedures to define how data validation, discrepancy management, and monitoring are conducted electronically. The SOP must specify roles, responsibilities, system access controls, and processes for electronic source verification (eSource), ensuring compliance with 21 CFR Part 11 and ICH E6 (R2) requirements.

Other SOPs such as Handling External Data or Data Backup may require minor updates, but the Data Review and Validation SOP undergoes the most extensive change because EDC technology shifts validation responsibilities from post-data entry review to real-time oversight within the system.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 6.3 - SOP Adaptation for EDC Implementation FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Handling and Validation

NEW QUESTION # 98

All of the following are preparation processes the data manager needs to take prior to database closure EXCEPT:

- **A. Ensuring study close out visits have been complete.**
- B. Performing SAE reconciliation between the clinical and safety databases.
- C. Ensuring all data expected for the study has been received.
- D. Checking for uncoded terms in all panels that are coded.

Answer: A

Explanation:

Before database lock, the Data Manager must confirm that all collected data are complete, validated, and reconciled across systems. This includes:

Ensuring data completeness (B) - confirming all expected forms and data files have been received.

Verifying coded data (A) - ensuring no pending terms remain in coding dictionaries like MedDRA or WHO Drug.

Performing SAE reconciliation (C) - cross-checking the clinical database against the safety system for accuracy.

However, ensuring study close-out visits (D) is not a data management function; it falls under clinical operations and monitoring responsibilities. While data management may review confirmation of site close-outs, the activity itself is not part of pre-database lock procedures.

Therefore, option D correctly identifies the exception-an activity outside the data manager's direct scope of responsibility before database closure.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.3 - Pre-Lock Validation and Reconciliation Activities ICH E6(R2) GCP, Section 5.5.3 - Data Handling and Quality Control Prior to Lock FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - Database Management and Lock Procedures

NEW QUESTION # 99

A Data Manager is asked to manage SOPs for a department. Given equal availability of the following systems, which of the following is the best choice for managing the organizational SOPs?

- A. Customized Excel spreadsheet
- B. Learning management system
- C. Existing paper filing system
- **D. Document management system**

Answer: D

Explanation:

The best choice for managing Standard Operating Procedures (SOPs) in a compliant and auditable manner is a Document Management System (DMS).

According to the GCDMP (Chapter: Regulatory Requirements and Compliance) and ICH E6 (R2), SOPs must be version-controlled, securely stored, retrievable, and auditable. A validated DMS supports controlled access, document lifecycle management (draft, review, approval, and archival), and electronic audit trails, ensuring full compliance with FDA 21 CFR Part 11 and Good Documentation Practices (GDP).

While Learning Management Systems (C) track training, they are not intended for document control. Spreadsheets (B) and paper systems (D) cannot provide adequate version tracking, access security, or audit capability required for regulatory inspection readiness.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Requirements and Compliance, Section 5.2 - SOP Management and Document Control ICH E6 (R2) GCP, Section 5.5.3 - Document and Record Management FDA 21 CFR Part 11 - Electronic Records and Signatures, Section 11.10 - System Validation and Document Controls

NEW QUESTION # 100

Which of the following statements would be BEST included in a data management plan describing the process for making self-evident corrections in a clinical database?

- A. No changes will be made in the database without a query response signed by the investigator.
- **B. Self-evident changes may be made per the listed conventions and documented to the investigative site.**
- C. Self-evident corrections made in the database will be reviewed and approved by a team leader or manager.
- D. A senior level data manager may make audited changes to the database without further documentation.

Answer: B

Explanation:

A self-evident correction (SEC) refers to a data correction that is obvious, logical, and unambiguous - such as correcting an impossible date (e.g., 31-APR-2024) or standardizing a known abbreviation (e.g., "BP" to "Blood Pressure"). According to the Good Clinical Data Management Practices (GCDMP), SECs can be applied by data management staff following pre-approved conventions defined in the Data Management Plan (DMP).

The DMP should explicitly describe the criteria for SECs, including the types of errors eligible for this correction method, the required documentation, and the communication procedure to inform the investigative site. The process must maintain audit trail transparency and ensure that all changes are traceable and justified.

Options A and B suggest unauthorized or informal change procedures, which violate audit and compliance standards. Option C is

too restrictive, as it prevents the efficient correction of non-clinical transcription or formatting errors.

Therefore, option D is correct: "Self-evident changes may be made per the listed conventions and documented to the investigative site." This approach aligns with CCDM expectations for balancing efficiency, accuracy, and regulatory compliance.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 6.2 - Self-Evident Corrections FDA 21 CFR Part 11 - Electronic Records; Audit Trails and Traceability Requirements

NEW QUESTION # 101

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