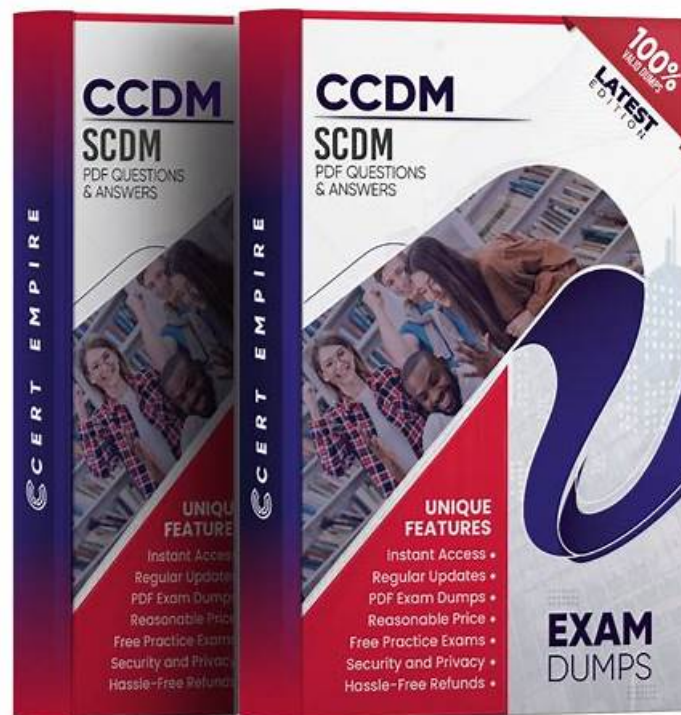


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SCDM Certified Clinical Data Manager Sample Questions (Q123-Q128):

NEW QUESTION # 123

Which method would best identify inaccuracies in safety data tables for an NDA?

- A. Compare counts of appropriate patients from line listings of CRF data to counts in table cells

- B. Compare counts of appropriate patients from manual CRFs to counts in table cells
- C. Review the tables to identify any values that look odd
- D. Review the line listings to identify any values that look odd

Answer: A

Explanation:

The best method for identifying inaccuracies in safety data tables prepared for a New Drug Application (NDA) is to compare counts of appropriate patients from line listings of CRF data to the counts in table cells.

According to the GCDMP (Chapter: Data Quality Assurance and Control), line listings represent raw, patient-level data extracted directly from the clinical database, whereas summary tables are aggregated outputs used for reporting and submission. Comparing these two sources ensures data traceability and accuracy, verifying that tabulated results correctly reflect the underlying patient data. Manual CRF checks (option A) are less efficient and error-prone, as data entry is typically already validated electronically. Simply reviewing tables or listings for "odd values" (options C and D) lacks the systematic verification necessary for regulatory data integrity. Thus, comparing line listings to tables (option B) provides a quantitative cross-check between the database and output deliverables, a standard practice in NDA data validation and statistical quality control.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 5.2 - Validation of Tables, Listings, and Figures (TLFs) FDA Guidance for Industry: Submission of NDA Safety Data, Section on Data Verification and Accuracy ICH E6 (R2) GCP, Section 5.5.3 - Validation of Derived Data Outputs

NEW QUESTION # 124

ePRO data are collected for a study using study devices given to subjects. Which is the most appropriate quality control method for the data?

- A. Programmed edit checks to detect out of range values upon data entry
- B. Manual review of data by the site study coordinator at the next visit
- C. Programmed edit checks to detect out of range values after submission to the database
- D. Data visualizations to look for site-to-site variation

Answer: A

Explanation:

When electronic patient-reported outcomes (ePRO) devices are used, data are captured directly by subjects through validated devices and transmitted electronically to the study database. To ensure real-time data quality control, programmed edit checks should be implemented at the point of data entry - that is, as subjects input data into the device.

According to Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), front-end programmed edit checks are the optimal method to prevent entry of invalid or out-of-range values in ePRO systems. This helps maintain data accuracy at the source, minimizing downstream queries and data cleaning workload.

Options A and B involve post-submission or manual review, which is less efficient and not compliant with the principle of first-pass data validation. Option C (visualization) is a valuable secondary QC method for trends, but not for immediate data validation.

Therefore, option D is correct - programmed edit checks upon data entry ensure immediate validation and higher data integrity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Automated Edit Checks and Front-End Validation ICH E6(R2) GCP, Section 5.5.3 - Computerized System Controls and Validation FDA Guidance for Industry: Electronic Source Data in Clinical Investigations (2013), Section 6 - Real-Time Data Quality Control

NEW QUESTION # 125

Who has primary responsibility for ensuring accurate completion of the CRF?

- A. Clinical Data Manager
- B. Clinical Research Associate
- C. Investigator
- D. Site Coordinator

Answer: C

Explanation:

The Investigator holds the primary responsibility for ensuring the accuracy, completeness, and timeliness of Case Report Form

(CRF) entries. This responsibility is mandated by regulatory requirements under ICH E6(R2) Good Clinical Practice (GCP). The investigator may delegate CRF completion to a qualified designee (e.g., site coordinator), but the ultimate accountability remains with the investigator. The investigator's signature (electronic or manual) on the CRF serves as certification that the data accurately reflect the source documents and the patient's participation.

The GCDMP (Chapter: CRF Design and Data Collection) reinforces this by stating that while data managers ensure design quality and CRAs verify consistency with source data, the investigator is legally responsible for CRF accuracy.

Thus, option D (Investigator) is correct, as it aligns with both GCP and CCDM standards.

Reference (CCDM-Verified Sources):

ICH E6(R2) GCP, Section 4.9 - Records and Reports (Investigator Responsibilities) SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 5.1 - Investigator's Role in Data Accuracy FDA 21 CFR Part 312.62 - Investigator Recordkeeping and Record Retention

NEW QUESTION # 126

In reviewing the adverse events for a subject, a data manager notices one recorded as "worsening of migraine." After reviewing the rest of the adverse events and finding no other migraine recordings, what is the data manager's next step?

- A. Query the site for the first adverse event occurrence of migraine.
- B. Look for any adverse event instance of headache and assume the events are similar.
- C. Check the medical history for recording of a history of migraines.
- **D. Query the site for more information on the adverse event, "worsening of migraine."**

Answer: D

Explanation:

When a data inconsistency arises - such as a record of "worsening of migraine" without prior documentation of a migraine episode - the Data Manager should query the site for clarification (Option D).

According to the GCDMP (Chapter: Data Validation and Cleaning), data managers must raise a clarification query whenever data appear incomplete, inconsistent, or ambiguous. The site must confirm whether "worsening of migraine" refers to a new event or an exacerbation of a preexisting condition. This clarification ensures accurate safety reporting and appropriate medical coding (e.g., MedDRA classification).

Checking the medical history (Option C) may help but does not resolve the inconsistency. Assuming a relationship (Option A or B) without verification would violate Good Clinical Data Management Practice and potentially misrepresent the adverse event.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.3 - Query Generation and Resolution ICH E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, Section II - Data Clarification Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Query Management

NEW QUESTION # 127

For clinical investigational sites on an EDC trial, which of the following archival options allows traceability of changes made to data?

- A. PDF images of the final eCRF screens for each patient
- B. Paper copies of the source documents
- **C. ASCII files of the site's data and related audit trails**
- D. Storing the computer used at the clinical investigational site

Answer: C

Explanation:

Regulatory agencies such as the FDA and ICH require that electronic data be retained in a format that preserves audit trails and traceability.

While PDF images (option C) provide a static representation of data, they do not preserve the underlying audit trail (i.e., who changed what, when, and why). The ASCII data files with corresponding audit trails (option D) provide complete transparency and comply with 21 CFR Part 11 and GCDMP archival standards.

Option A (storing computers) is unnecessary and impractical, and Option B (paper source documents) are site records, not system archives.

Hence, option D is correct - ASCII data files with audit trails meet traceability and compliance standards.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.4 - Archival Formats and Audit Trail Retention ICH E6(R2)

NEW QUESTION # 128

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