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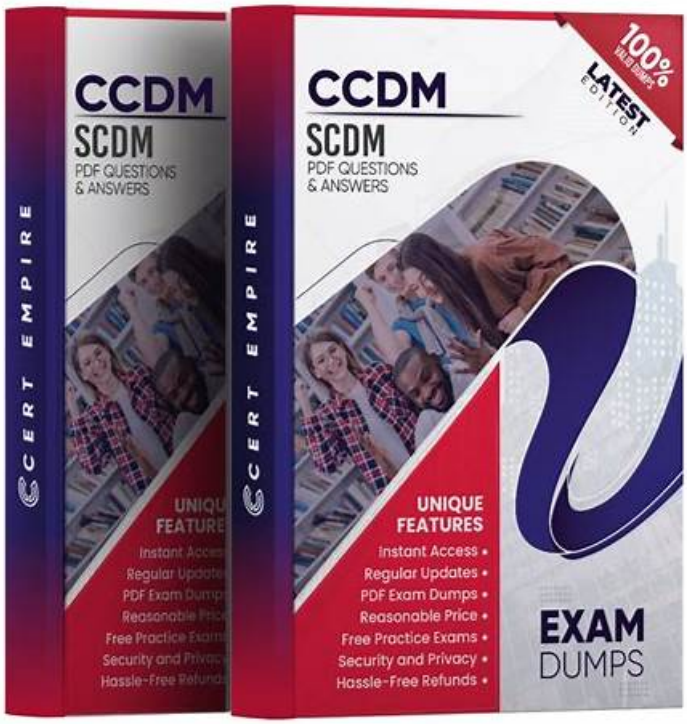

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SCDM Certified Clinical Data Manager Sample Questions (Q113-Q118):

NEW QUESTION # 113
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 all outstanding discrepancies to date and aging

- C. Identifying missing pages where visits have been completed to date
- 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 # 114
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. 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.
- C. The database set-up will need to be changed to allow for additional sites as they are added to the study.
- D. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.

Answer: B

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 # 115
Every database lock should follow documented approval of which stakeholders?

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

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 # 116
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 # 117
If database auditing is used for data quality control during a study, which is the optimal timing of the audits?

- A. Periodically throughout the study
- B. Immediately following database lock
- C. A week or two before database lock
- D. After the first few cases have been entered

Answer: A

Explanation:
Database audits are conducted to ensure ongoing data accuracy, completeness, and compliance throughout the lifecycle of a clinical trial. According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control), quality audits are most effective when performed periodically during study conduct, rather than waiting until study completion.
Performing audits periodically allows early detection of data entry errors, protocol deviations, and system inconsistencies, thereby reducing the risk of large-scale data issues before database lock. This proactive approach aligns with risk-based quality management principles outlined in ICH E6(R2) and ensures corrective actions are implemented in real time.
Options A and B represent reactive quality control, which occurs too late to prevent data issues. Option C (after first few cases) provides initial validation but does not ensure continuous oversight.
Therefore, option D - "Periodically throughout the study" - represents the optimal and compliant timing for quality audits of the database.

Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 5.3 - Ongoing Quality Control and Auditing ICH E6(R2) GCP, Section 5.1.1 - Quality Management System and Risk-Based Monitoring FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Review and Auditing Practices

NEW QUESTION # 118
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