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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• Review Tasks: This section measures the skills of Data Managers and involves reviewing protocols, CRFs, data tables, listings, figures, and clinical study reports (CSRs) for consistency, accuracy, and alignment with data handling definitions and regulatory requirements.
Topic 2	• Coordination and Project Management Tasks: This domain evaluates the skills of a Clinical Systems Analyst in coordinating data management workload, vendor selection, scheduling, cross-team communication, project timeline management, risk handling, metric tracking, and preparing for audits.
Topic 3	• Testing Tasks: This section measures the skills of Data Managers and involves creating test plans, generating test data, executing validation and user acceptance testing, and documenting results to ensure systems and processes perform reliably and according to specifications.
Topic 4	• Design Tasks: This section of the CCDM Exam measures skills of Data Managers and covers how to design and document data collection instruments, develop workflows and data flows, specify data elements, CRF forms, edit checks, reports, database structure, and define standards and procedures for traceability and auditability.
Topic 5	• Data Processing Tasks: This section measures skills of Clinical Systems Analysts and focuses on handling, transforming, integrating, reconciling, coding, querying, updating, and archiving study data while maintaining quality, consistency, and proper privileges over the data lifecycle.

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SCDM Certified Clinical Data Manager Sample Questions (Q10-Q15):

NEW QUESTION # 10

What method is used for quality control of the query resolution process?

- A. Perform random audits of the resolved query forms.
- B. Calculate the time from query sent to query resolution from the site.
- C. Tabulate the number of queries sent per site.
- D. Calculate the time from discrepancy identified to query sent.

Answer: A

Explanation:

The most effective method for quality control (QC) of the query resolution process is to perform random audits of resolved query forms. This ensures that queries are being appropriately raised, addressed, and resolved in accordance with the study protocol, data management plan (DMP), and standard operating procedures (SOPs).

According to the GCDMP (Chapter: Data Validation and Cleaning), QC activities should verify that the data review and query management process maintains high accuracy and consistency. Random auditing of resolved queries enables verification that:

Queries were raised for legitimate discrepancies,

The site's responses were appropriate, and

The resolution actions taken by data management were correct and well-documented.

Metrics such as turnaround time (options A and C) or query counts (option B) measure efficiency but do not assess quality. True quality control focuses on ensuring that data corrections preserve accuracy, auditability, and traceability - the fundamental principles of data integrity in clinical research.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.4 - Query Management and Quality Control ICH E6 (R2) GCP, Section 5.5.3 - Data Integrity and Validation Procedures

NEW QUESTION # 11

Which of the following scenarios requires a query to be sent to the central lab first when there is a discrepancy between the final lab data transfer and the CRF?

- A. Both the central lab and the CRF have data present for a visit
- B. The CRF has data for a visit but the central lab has missing data for the visit
- C. The central lab has data for a visit but the CRF has missing data for the visit
- D. Both the central lab and the CRF data have missing data for a visit

Answer: C

Explanation:

During data reconciliation between a central laboratory and CRF data, the source of truth is typically the central lab database, as it provides directly measured, vendor-generated results.

When the central lab has data but the CRF does not (option C), the Data Manager must first query the central lab to confirm that the result was transmitted correctly, since discrepancies may stem from data processing or timing issues. Once confirmed, a secondary query may be issued to the site to ensure CRF completion and alignment.

Conversely, if the CRF contains data but the central lab is missing results (option B), the issue is site-level, not vendor-level.

According to the GCDMP (Chapter: External Data Transfers and Reconciliation), priority for querying depends on the authoritative source - for lab data, the central lab is considered the source of record.

Therefore, option C is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers and Reconciliation, Section 6.1 - Reconciliation of Central Lab and CRF Data ICH E6(R2) GCP, Section 5.5.3 - Source Data Verification and Vendor Reconciliation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Data Reconciliation and Traceability

NEW QUESTION # 12

When reviewing local lab data from a paper study, a Data Manager notices there are lab values not entered. What should the Data Manager request data-entry personnel do?

- A. Nothing
- B. Issue a query
- C. Flag the module for review

- D. Call the patient to verify the information

Answer: B

Explanation:
When laboratory data are missing from a paper-based clinical study, the Data Manager should direct data-entry personnel to issue a query to the investigative site for clarification or correction.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), every missing, inconsistent, or out-of-range data point must be reviewed and, if necessary, resolved through the formal query management process. This ensures that all discrepancies between the source documents and database entries are properly documented, traceable, and auditable.
Data-entry staff are not authorized to infer or fill in missing information. They must escalate such discrepancies to the site via query, preserving data integrity and regulatory compliance with ICH E6 (R2) and FDA 21 CFR Part 11. Calling the patient directly (option B) would violate confidentiality and site communication protocol, while simply flagging or ignoring the issue (options A and D) would not meet GCDMP query resolution standards.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.2 - Query Management and Resolution ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication of Data Discrepancies FDA 21 CFR Part 11 - Electronic Records; Query Audit Trails Requirements

NEW QUESTION # 13
An organization has completed a study and wants to submit the data to the FDA using CDISC SDTM. Which of the following must be done?

- A. Re-enter the data into an SDTM compliant system
- B. Provide a letter of intent to use SDTM to the FDA
- C. SDTM cannot be used in this situation
- D. Map and transform the study data to SDTM

Answer: D

Explanation:
To submit study data to the FDA in CDISC SDTM format, the sponsor must map and transform the collected data from the study's operational database (e.g., EDC) into SDTM-compliant domains.
According to GCDMP (Chapter: Standards and Data Integration) and CDISC SDTM Implementation Guide, this process includes:
Mapping raw data elements from the clinical database to SDTM domains (e.g., DM, AE, VS).
Transforming data to comply with SDTM structural and naming conventions.
Validating the output using CDISC compliance tools (e.g., Pinnacle 21).
Re-entering data (B) is unnecessary, and a letter of intent (C) is not required. SDTM is explicitly accepted by FDA for both retrospective and prospective submissions, so (D) is incorrect.
Thus, option A is correct - map and transform existing data to SDTM format for regulatory submission.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.3 - Data Transformation and CDISC Mapping CDISC SDTM Implementation Guide, Version 3.4 - Data Conversion and Submission Requirements FDA Study Data Technical Conformance Guide, Section 2.2 - SDTM Mapping and Validation

NEW QUESTION # 14
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. 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.
- B. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- C. The database set-up will need to be changed to allow for additional sites as they are added to the study.
- D. Additional sites will likely have increased query rates since site training is occurring closer to study close.

Answer: A

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 # 15

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