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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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 3	• 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 4	• 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.
Topic 5	• 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.

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It is quite clear that let the facts speak for themselves is more convincing than any word, therefore, we have prepared free demo in

SCDM Certified Clinical Data Manager Sample Questions (Q12-Q17):

NEW QUESTION # 12
A study team member states that data entry can be done by clerical personnel at sites. Which are important considerations?

- A. It is possible that clerical personnel could be hired by sites because data entry requires little training and use of clerical personnel would reduce burden on sites
- B. The person at the sites who enters the data usually also understands which data in the medical record are needed for the study, where to find them and which value to choose
- C. Data entry at sites requires study-specific training on how to use the EDC system to enter data and respond to data discrepancies identified by the system
- D. Historically in clinical research site study coordinator roles have been filled by people with clinical or clinical research experience

Answer: C

Explanation:
Although clerical staff can technically perform data entry, data entry in clinical research requires study-specific training, particularly in the use of the Electronic Data Capture (EDC) system and understanding data discrepancy resolution procedures.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection) and ICH E6 (R2), individuals responsible for data entry at clinical sites must be qualified by education, training, and experience. This includes understanding how to navigate the EDC system, enter data according to CRF Completion Guidelines, and appropriately respond to queries or system-generated edit checks.
Untrained clerical personnel may inadvertently introduce errors, violate Good Clinical Practice (GCP) standards, or fail to recognize protocol-relevant data. Therefore, the Data Manager must ensure that site users receive study-specific and system training before gaining access to the EDC environment.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.2 - Investigator Site Training and Data Entry Requirements ICH E6 (R2) Good Clinical Practice, Section 4.1.5 - Qualified Personnel and Training Requirements FDA 21 CFR Part 11 - User Access and Training Provisions for Electronic Records

NEW QUESTION # 13
What method is used for quality control of the query resolution process?

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

Answer: D

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):

NEW QUESTION # 14

Which metric reveals the timeliness of the site-work dimension of site performance?

- A. Time from Last Patient Last Visit to database lock
- B. Median and range of time from query generation to resolution
- C. Time from site contract execution to first patient enrolled
- D. Time from final protocol to first patient enrolled

Answer: B

Explanation:
The site-work dimension of site performance evaluates how efficiently sites manage and resolve data-related tasks - particularly query resolution, data entry, and correction timelines. Among the given metrics, the median and range of time from query generation to resolution (D) directly measures the site's responsiveness and data management efficiency.
According to the GCDMP (Chapter on Metrics and Performance Measurement), this indicator helps identify sites that delay query resolution, which can impact overall study timelines and data quality. Tracking this metric allows the data management team to proactively provide additional training or communication to underperforming sites.
Other options measure different aspects of project progress:
A reflects overall database closure speed.
B and C relate to study startup and enrollment readiness, not ongoing data work.
Thus, option D accurately represents a site performance timeliness metric, aligning with CCDM principles for operational performance measurement.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Metrics and Performance Management, Section 5.4 - Site Query Resolution Metrics ICH E6(R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Performance Oversight

NEW QUESTION # 15

Data from two sites are combined. One site coded gender as 1 and 2 (for Male and Female, respectively) while the other stored the data as M and F. Which term best describes the mapping?

- A. Two-to-two
- B. One-to-one
- C. One-to-many
- D. Many-to-one

Answer: B

Explanation:
When combining data from two datasets where one uses numeric codes (1 = Male, 2 = Female) and another uses text codes (M, F), each unique value in one dataset corresponds exactly to one unique value in the other.
This relationship is a one-to-one mapping, where each element in one dataset maps directly to a single corresponding element in the other.
$1 \rightarrow M$
$2 \rightarrow F$
Such mappings ensure consistent data harmonization during data integration and standardization phases, as outlined in the GCDMP (Chapter: Database Design and Integration).
Many-to-one (C) mapping would occur if multiple values (e.g., "Male," "M," "Man") mapped to a single standardized value, which isn't the case here.
Thus, the mapping is one-to-one, ensuring precise correspondence between both representations of gender data.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.4 - Data Mapping and Harmonization CDISC SDTM Implementation Guide, Section 5.2 - Controlled Terminology and Mapping Rules ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Integration Principles

NEW QUESTION # 16

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. Flag the module for review
- B. Issue a query
- C. Call the patient to verify the information
- D. Nothing

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 # 17

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