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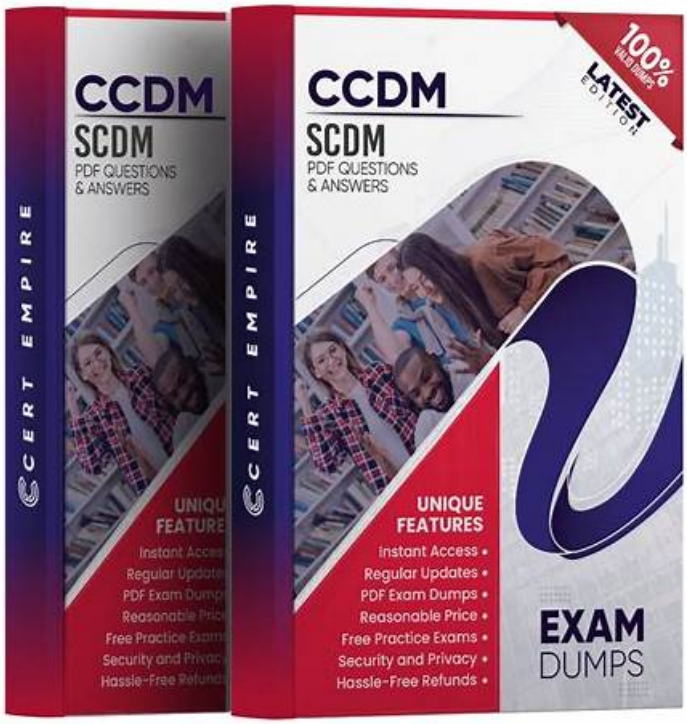

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SCDM CCDM Exam Syllabus Topics:

Topic	Details

Topic 1	• 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 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	• 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 4	• 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 5	• 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.

SCDM Certified Clinical Data Manager Sample Questions (Q16-Q21):

NEW QUESTION # 16
A study is using blood pressure as an efficacy measure. Which is the best way to collect the data?

- A. Measurement using study-provisioned equipment
- B. Asking the study subjects what their blood pressure usually runs
- C. Collecting the data from the medical record
- D. Measurement using existing equipment at sites

Answer: A

Explanation:
When a clinical study uses blood pressure (BP) as an efficacy endpoint, the most reliable and standardized method of data collection is through study-provisioned equipment.
According to the GCDMP (Chapter: CRF Design and Data Collection), data collected for primary efficacy endpoints must be consistent, accurate, and standardized across all investigative sites. Using study-provided calibrated equipment ensures that measurements are taken under uniform conditions, eliminating inter-site variability due to differences in devices, calibration, or measurement methods.
Collecting BP data from medical records (option A) risks inconsistent timing and techniques. Using each site's own equipment (option B) introduces variability, while patient self-reports (option D) lack reliability and objectivity.
Thus, the best practice is to provision and standardize all equipment used to collect endpoint-related physiological data, ensuring regulatory-quality results suitable for analysis.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.1 - Standardization of Clinical Measurements ICH E6 (R2) GCP, Section 5.5.3 - Data Accuracy and Equipment Standardization FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Data Capture and Standardization Requirements

NEW QUESTION # 17
A site study coordinator attempts to make an update in a study database in an EDC system after lock. What occurs?

- A. The change is logged as occurring after lock
- B. The old value is replaced in all locations by the new value
- C. The change is approved by the Data Manager before it is applied
- D. The site study coordinator is not able to make the change

Answer: D

Explanation:
Once a clinical database is locked, it becomes read-only - no further data modifications can be made by any users, including site personnel. This ensures that the data are finalized, consistent, and auditable for statistical analysis and regulatory submission.
According to the GCDMP (Chapter: Database Lock and Archiving), the lock process involves freezing the database to prevent accidental or unauthorized changes. After lock, access permissions are restricted, and all edit and update functions are disabled. If any corrections are required post-lock, the database must be unlocked under controlled procedures (with full audit trail documentation).
Thus, option C - The site study coordinator is not able to make the change - correctly reflects standard EDC functionality and regulatory compliance.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.2 - Database Lock Procedures and Controls ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Audit Trail Requirements FDA 21 CFR Part 11 - Controls for Electronic Records and System Lock Functions

NEW QUESTION # 18
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. The CRF has data for a visit but the central lab has missing data for the visit
- B. Both the central lab and the CRF data have missing data for a visit
- C. Both the central lab and the CRF have data present for a visit
- D. The central lab has data for a visit but the CRF has missing data for the visit

Answer: D

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 # 19
It has been identified that ten adverse events were not reported in the trial prior to the database lock. What action should be taken to determine the next step?

- A. Check the data from all sites again before relocking the database.
- B. Get the AE data entered immediately so the database can be locked again.
- C. Evaluate the potential effect of the omission on the validity of the safety and efficacy analysis.
- D. Notify upper management immediately so the monitor can contact the site.

Answer: C

Explanation:
When adverse events (AEs) are discovered after a database lock, the appropriate first step is to evaluate the impact of the missing data on the integrity, safety analysis, and regulatory validity of the study results.
According to GCDMP (Chapter: Data Quality Assurance and Control), any post-lock data discovery requires a root cause assessment and impact analysis before deciding whether to unlock the database. The key question is whether the missing AEs:

Affect primary safety endpoints,
Introduce bias in safety reporting, or
Alter efficacy conclusions.
Based on the assessment, the Data Management and Biostatistics teams determine if unlocking and correction are justified. Simply entering data immediately (A) or repeating checks (D) without analysis may violate data control procedures.
Hence, option B is correct - the first step is to assess the impact on data validity and analysis.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 5.5 - Post-Lock Findings and Impact Assessment ICH E6(R2) GCP, Section 5.1.1 - Quality Management and Risk Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Post-Lock Data Management

NEW QUESTION # 20
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. Determining CRF data entry status of received pages
- B. Identifying all outstanding discrepancies to date and aging
- C. Identifying the number of discrepancies resolved to date
- D. Identifying missing pages where visits have been completed to date

Answer: C

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 # 21
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