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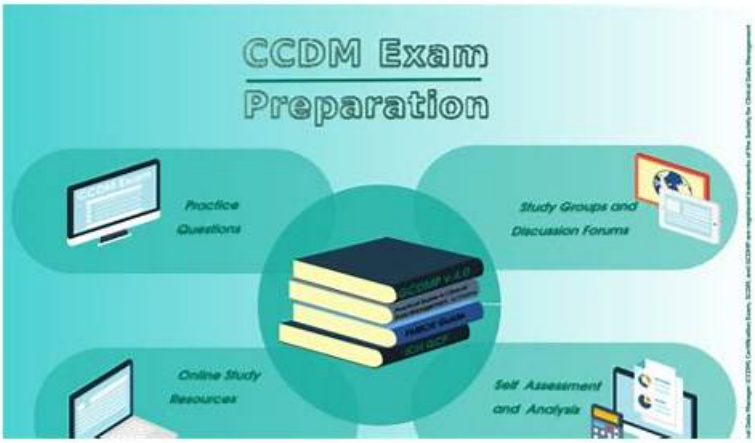

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SCDM CCDM Exam Syllabus Topics:

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 (Q147-Q152):

NEW QUESTION # 147
Which mode of data entry is most commonly used in EDC systems?

- A. Single entry
- B. Double entry
- C. Third party compare
- D. Blind verification

Answer: A

Explanation:
The most common mode of data entry in Electronic Data Capture (EDC) systems is single data entry.
According to the GCDMP (Chapter: Electronic Data Capture Systems), EDC systems have built-in edit checks, validation rules, and audit trails that ensure data accuracy and integrity at the point of entry. These real-time validation capabilities make double data entry (a legacy practice from paper studies) unnecessary.
EDC systems automatically verify data as they are entered by site staff, generating queries for inconsistencies or out-of-range values immediately. Blind verification (option B) and third-party comparisons (option D) are not standard data entry modes but may be used for specialized reconciliation or external data imports.
Thus, single data entry (Option C) is the industry standard approach, ensuring both efficiency and compliance with FDA 21 CFR Part 11 and ICH E6 (R2) data integrity requirements.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 5.4 - Data Entry and Verification Processes ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Computerized Systems and Data Validation FDA 21 CFR Part 11 - Electronic Records and Electronic Signatures: Validation and Data Entry Requirements

NEW QUESTION # 148
Every database lock should follow documented approval of which stakeholders?

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

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 # 149
For clinical investigational sites on an EDC trial, which of the following archival options allows traceability of changes made to data?

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

Answer: B

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) GCP, Section 5.5.3 - Data Integrity, Audit Trails, and Record Retention FDA 21 CFR Part 11 - Electronic Records; Audit Trail and Retention Requirements

NEW QUESTION # 150
A study uses commercially available activity monitors and collects data for each patient weekly by selecting and downloading the data from the manufacturer's website. There are 100 patients in the study and it takes the Data Manager 20 minutes per file to download, import, and process the dat a. Assuming that the distribution of work is uniform over the six-month trial, how many Data Managers are needed for the activity data alone?

- A. Fifty percent of a Data Manager per month
- B. Ten percent of a Data Manager per month
- C. Two Data Managers per month
- D. One Data Manager per month

Answer: D

Explanation:
This question tests workload estimation and resource planning, which are fundamental competencies outlined in the Good Clinical Data Management Practices (GCDMP, Chapter on Project Management in Data Management). The task is to determine the Data Manager effort required based on the frequency and duration of data collection and processing activities.
Let's calculate step by step:
Number of patients: 100
Frequency: Weekly (once per week)
Duration: 6 months ≈ 26 weeks
Time per file: 20 minutes
Total time per week:
100 patients × 20 minutes = 2,000 minutes per week
= 2,000 ÷ 60 = 33.3 hours per week
Total hours over 6 months:
33.3 hours/week × 26 weeks = 866 hours total
A full-time Data Manager typically works ~160 hours per month, so over six months:
160 × 6 = 960 hours total full-time capacity.
Therefore, the workload of 866 hours is approximately equivalent to one full-time Data Manager working across the six-month period:
866 ÷ 960 ≈ 0.9 FTE (Full-Time Equivalent).
This aligns most closely with Option D: One Data Manager per month (i.e., a full-time resource is required throughout the duration of the trial).
According to the GCDMP Project Management chapter, accurate resource estimation is critical in ensuring data management

timelines are met without overloading staff or compromising data quality. The estimation process must consider not just the raw data download time but also associated data processing, verification, and upload into the clinical database.
Other options underestimate the effort significantly:
A (10%) and B (50%) do not account for cumulative weekly workload across multiple patients.
C (Two Data Managers) overestimates, as one Data Manager working full-time can manage the load efficiently.
Therefore, Option D is correct - approximately one full-time Data Manager (1.0 FTE) is required for the activity data alone during the six-month trial.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Project Management in Data Management, Section 5.3 - Workload Estimation and Resource Allocation SCDM GCDMP, Chapter: Data Handling and Processing - Effort Estimation for Repetitive Data Tasks ICH E6 (R2) Good Clinical Practice, Section 5.1 - Quality Management and Resource Planning FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Operational Considerations for Data Management Activities

NEW QUESTION # 151
Which document contains the details of when, to whom, and in what manner the vendor data will be sent?

- A. Communication Plan
- B. Data Transfer Agreement
- C. Project Plan
- D. Data Management Plan

Answer: B

Explanation:
A Data Transfer Agreement (DTA) defines the operational and technical details for transferring data between a sponsor and an external vendor (e.g., central lab, ECG vendor). It is a formalized, controlled document specifying what data will be sent, when transfers will occur, the transfer method, file structure, encryption or security protocols, and the recipients of the data.
The DTA is developed jointly by the sponsor and vendor before production data transfers begin. According to the GCDMP, Chapter on External Data Transfers, this agreement ensures both parties share a clear understanding of timing, responsibility, and data content to minimize errors and ensure regulatory compliance.
The Data Management Plan (DMP) outlines general data handling processes but does not capture the technical specifics of vendor data transfer logistics. The Project Plan (A) and Communication Plan (B) are broader operational tools and not specific to data transfer protocols.
Hence, option C (Data Transfer Agreement) is the correct answer, as it precisely governs the procedural and technical framework of vendor data exchange.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers, Section 4.1 - Data Transfer Agreements and Specifications ICH E6(R2) Good Clinical Practice, Section 5.5 - Trial Management, Data Handling, and Record Keeping

NEW QUESTION # 152
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