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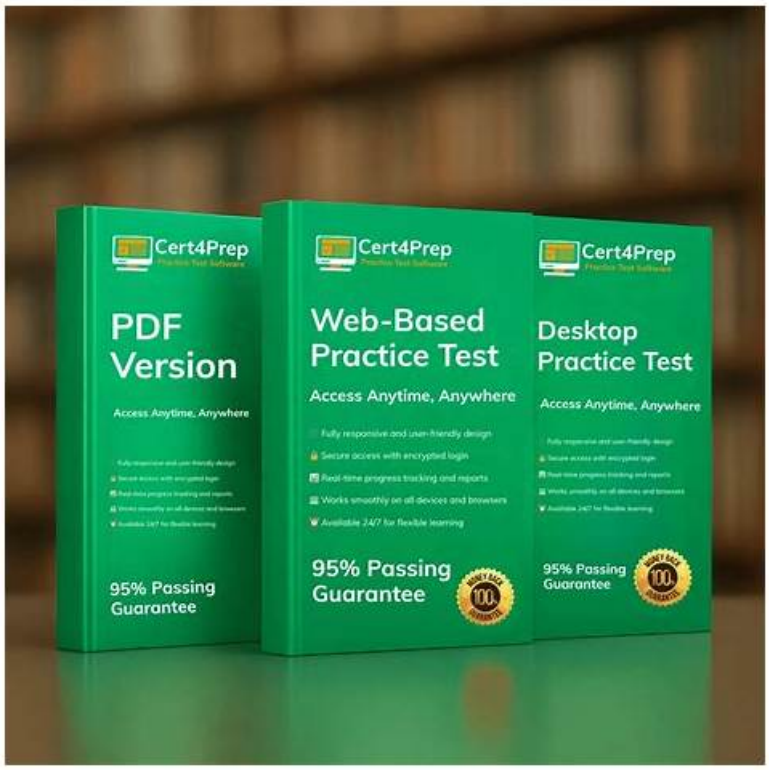

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SCDM CCDM Exam Syllabus Topics:

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

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CCDM Latest Practice Questions, CCDM Actual Test

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SCDM Certified Clinical Data Manager Sample Questions (Q50-Q55):

NEW QUESTION # 50
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. Two Data Managers per month
- B. Fifty percent of a Data Manager per month
- C. One Data Manager per month
- D. Ten percent of a Data Manager per month

Answer: C

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 # 51
A study is collecting pain levels three times a day. Which is the best way to collect the data?

- A. Study subjects calling into an IVRS three times a day to enter pain levels
- B. Using ePRO with reminders for data collection at each time point
- C. Using paper pain diary cards completed by study subjects
- D. Sites calling patients daily and administering a pain questionnaire

Answer: B

Explanation:
The optimal method for collecting frequent patient-reported pain data is through electronic Patient-Reported Outcomes (ePRO) with built-in reminder functionality.
According to the GCDMP (Chapter: Electronic Data Capture Systems), ePRO systems provide a validated, real-time, and user-friendly interface for subjects to record time-sensitive data accurately. The use of automated reminders ensures compliance with protocol-specified data collection times, improving data completeness and accuracy.
Paper diaries (option A) are prone to recall bias and backfilling, while daily site calls (option B) are resource-intensive and introduce human error. IVRS systems (option C) are acceptable but less efficient and user-friendly than modern ePRO applications, which can integrate timestamp validation, compliance monitoring, and real-time alerts.
ePRO systems also comply with FDA 21 CFR Part 11 and ICH E6 (R2) for audit trails, authentication, and validation, making them the preferred solution for repeated PRO data collection.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 6.1 - Use of ePRO for Repeated Measures FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 5 - ePRO Compliance and Validation ICH E6 (R2) GCP, Section 5.5.3 - Electronic Data Systems and Recordkeeping

NEW QUESTION # 52
For a study, body mass index is calculated from weight and height. Which information is needed to document the transformation?

- A. Algorithm and algorithm version associated with the calculated value
- B. Algorithm documented in the Data Management Plan
- C. Algorithm associated with the calculated value
- D. User ID making the change and reason for change

Answer: A

Explanation:
When derived or calculated variables (like Body Mass Index) are created, it is essential to document the algorithm used and its version to ensure full data traceability and reproducibility.
According to GCDMP (Chapter: Database Design and Derived Data), every derived field must include metadata describing:
The derivation algorithm (e.g., BMI = weight [kg] / height² [m²])
The version of the algorithm (if updates or revisions occur)
Any associated data sources or transformation rules
This ensures consistent calculation across systems, prevents discrepancies during regulatory submissions, and aligns with FDA and CDISC documentation expectations.
Option B lacks version control, which is critical for traceability. Option C describes audit trail data (not derivation metadata), and option D refers to broader documentation, not specific algorithm traceability.
Hence, option A (Algorithm and algorithm version associated with the calculated value) is the correct and compliant answer.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Derived Data and Algorithms, Section 5.3 - Documentation and Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Derived Data and Validation Traceability FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Data Definitions (Define.xml)

NEW QUESTION # 53
When a data manager runs a report on resolution types of discrepancy status, which of the following would NOT be a part of resolution types?

- A. Resolved with data/confirmed as is (non problematic)
- B. Cannot be resolved (but data incorrect)
- C. Data management - self evident corrections
- D. Received from site and not yet reviewed

Answer: D

Explanation:
In a discrepancy management workflow, "Received from site and not yet reviewed" is not a resolution type - it represents a status, not a final resolution outcome.
According to the GCDMP (Chapter: Data Validation and Cleaning), resolution types describe how a data discrepancy was finalized or addressed, such as:
Resolved with data correction,
Confirmed as correct (no change required),
Self-evident correction applied by data management, or
Unresolvable discrepancies documented.
In contrast, statuses describe the stage of the query (e.g., open, sent, answered, pending review, closed). "Received from site and not yet reviewed" indicates an intermediate workflow state where the response awaits validation by data management.
Proper classification of resolution types is essential for performance reporting, audit readiness, and ensuring the traceability of query management actions under ICH E6 (R2) and FDA 21 CFR Part 11.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.3 - Discrepancy Resolution Lifecycle ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Handling and Record Management FDA 21 CFR Part 11 - Electronic Records; Audit Trails and Discrepancy Tracking Requirements

NEW QUESTION # 54
A study uses and collects pacemaker interrogation data for each patient weekly by selecting and downloading the data from the manufacturer's website. There are 200 patients in the study and it takes the Data Manager 30 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. Two Data Managers per month
- B. Fifty percent of a Data Manager per month
- C. Two and a half Data Managers per month
- D. One Data Manager per month

Answer: B

Explanation:
Let's calculate the workload:
200 patients × 30 minutes = 6,000 minutes/week
6,000 minutes ÷ 60 = 100 hours/week
Over 6 months (~26 weeks): 100 × 26 = 2,600 hours total
Assuming a full-time Data Manager works approximately 160 hours/month, over 6 months (960 hours) per full-time equivalent (FTE):
2,600 ÷ 960 ≈ 2.7 FTEs total for the entire study period
To find the average per month, we divide evenly over 6 months:
2.7 ÷ 6 ≈ 0.45 FTE per month, or approximately 50% of a Data Manager per month.
Thus, the correct answer is B. Fifty percent of a Data Manager per month.
This estimate follows GCDMP best practices in resource planning, ensuring adequate data management capacity for ongoing external data handling activities.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management, Section 5.3 - Resource Estimation and Workload Planning ICH E6(R2) GCP, Section 5.1.1 - Quality Systems and Adequate Staffing

NEW QUESTION # 55

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