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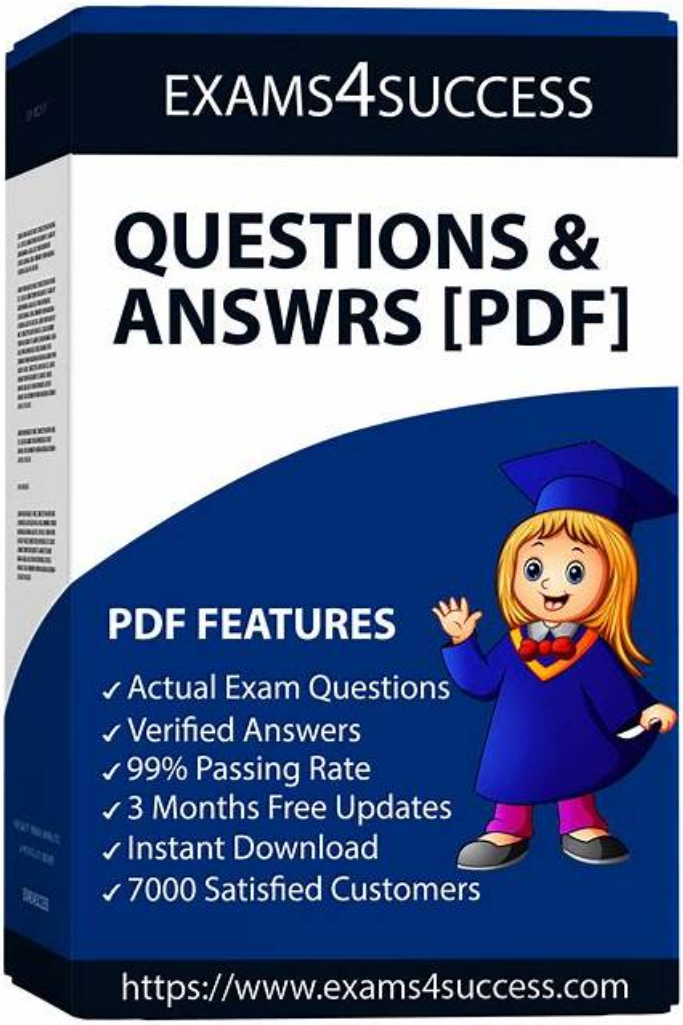

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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 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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SCDM Certified Clinical Data Manager Sample Questions (Q144-Q149):

NEW QUESTION # 144
A study team member suggests that data for a small, 50-patient, 2-year study can be entered and cleaned in two weeks before lock. Which are important other considerations?

- A. Processing the data in two weeks after the study is over would save money because the data manager would not be involved until the end
- B. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study
- C. Processing the data in two weeks after the study is over would save money because the EDC system would only be needed for a month
- D. It would take more than two weeks to get second iteration queries generated and resolved

Answer: D

Explanation:
The most critical consideration is that data cleaning is an iterative process, and completing all necessary steps - including query generation, site resolution, and second-pass validation - cannot realistically be accomplished within two weeks after study close.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), data cleaning must occur continuously throughout the study, not only at the end. Post-database lock activities typically include running final validation checks, resolving outstanding queries, performing reconciliation (e.g., SAEs, labs, coding), and conducting final quality review.
Even in small studies, query turnaround and response cycles from sites take time - typically 2-4 weeks per iteration - making a two-week total cleaning period unrealistic.
Therefore, Option D is correct: it would take more than two weeks to handle second-round (follow-up) queries and confirm final resolutions prior to database lock.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.4 - Ongoing vs. End-of-Study Data Cleaning ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Quality and Timeliness FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Management and Cleaning

NEW QUESTION # 145

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

Answer: B

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 # 146
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. Two Data Managers per month
- C. Ten percent of a Data Manager 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 # 147
The Medical Dictionary for Regulatory Activities (MedDRA) structure is in which of the following hierarchical orders, from most specific to least specific?

- A. LLT, HLGT, PT, HLT, SOC
- B. LLT, PT, HLGT, HLT, SOC
- C. LLT, HLGT, HLT, PT, SOC
- D. LLT, PT, HLT, HLGT, SOC

Answer: D

Explanation:
The MedDRA (Medical Dictionary for Regulatory Activities) is a standardized medical terminology used for coding and analyzing adverse event (AE) and medical history data in clinical trials. Its hierarchical structure supports aggregation, analysis, and reporting across varying levels of medical specificity.
From most specific to least specific, the hierarchy is as follows:
Lowest Level Term (LLT): The most granular term, often reflecting the verbatim text reported by the investigator.
Preferred Term (PT): The standardized medical concept representing one or more LLTs describing the same condition.
High Level Term (HLT): A grouping of related PTs describing similar medical conditions.
High Level Group Term (HLGT): A broader grouping of related HLTs.
System Organ Class (SOC): The highest level of classification, grouping HLGTs by body system or etiology (e.g., cardiac disorders, infections).
Thus, the correct order - from most specific to least specific - is:
LLT → PT → HLT → HLGT → SOC, which corresponds to option D.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Medical Coding and Dictionaries, Section 5.2 - MedDRA Hierarchical Structure ICH M1 MedDRA Terminology Guide, Version 26.0 - Hierarchy Overview ICH E2B(R3) Guidelines - Clinical Safety Data Management

NEW QUESTION # 148
Which list should be provided to support communication with sites regarding late data and queries?

- A. List of entered and clean data by site
- B. List of outstanding data and queries by site
- C. List of user account activity by site
- D. List of subjects screened and enrolled by site

Answer: B

Explanation:
Effective site communication in data management relies on transparent reporting of pending issues such as open queries, missing data, and overdue updates. According to the Good Clinical Data Management Practices (GCDMP, Chapter: Communication and Metrics), the list of outstanding data and queries by site provides a direct, actionable overview of what each site needs to address, supporting accountability and timely resolution.
This list typically includes subject identifiers, query types, dates generated, and status of resolution, allowing data managers to prioritize site follow-ups. Regular distribution of this report fosters efficient collaboration between the data management team,

monitors, and site staff, ultimately improving database cleanliness and timeline adherence.
Options A and B reflect general study status but do not target data issue resolution. Option C pertains to user access oversight, not data progress. Hence, option D is the correct and most operationally relevant answer.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Communication and Metrics, Section 5.2 - Site Reporting and Query Management Metrics ICH E6(R2) GCP, Section 5.18 - Site Oversight and Communication Requirements

NEW QUESTION # 149
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