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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 3	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.

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ActualTorrent is one of the trusted and reliable platforms that is committed to offering quick CCDM exam preparation. To achieve this objective ActualTorrent is offering valid, updated, and Real CCDM Exam Questions. These ActualTorrent Certified Clinical Data Manager (CCDM) exam dumps will provide you with everything that you need to prepare and pass the final CCDM exam with flying colors.

SCDM Certified Clinical Data Manager Sample Questions (Q21-Q26):

NEW QUESTION # 21

Which metrics report listed below would best help identify trends in the clinical data?

- A. Query frequency counts per data element
- B. Number of subjects screened/enrolled
- C. Percent of data/visits cleaned
- D. Last patient/last visit date to data lock date

Answer: A

Explanation:

The Query frequency counts per data element (Option D) is the best metric for identifying data trends and potential systemic data issues in clinical trials.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control), trend analysis involves identifying recurring data issues across subjects, sites, or variables to detect training gaps, protocol misinterpretation, or CRF design flaws. A high number of queries generated for specific fields (e.g., visit date, lab values, or dosing information) may indicate systemic problems such as unclear CRF instructions or site-level misunderstandings.

While metrics such as percent of data cleaned (A) and time to database lock (B) reflect overall progress and efficiency, they do not identify specific data pattern issues. The number of subjects screened/enrolled (C) pertains to recruitment rather than data quality. Therefore, query frequency per data element provides actionable insights for quality improvement, process refinement, and early identification of potential risks.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.3 - Metrics and Trend Analysis ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Risk-Based Quality Review and Data Trends FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section 6 - Data Metrics and Trend Evaluation

NEW QUESTION # 22

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 data. 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. One Data Manager per month
- B. Two and a half Data Managers per month
- C. Fifty percent of a Data Manager per month
- D. Two Data Managers per month

Answer: C

Explanation:

Let's calculate the workload:

$200 \text{ patients} \times 30 \text{ minutes} = 6,000 \text{ minutes/week}$

$6,000 \text{ minutes} \div 60 = 100 \text{ hours/week}$

Over 6 months (~26 weeks): $100 \times 26 = 2,600 \text{ hours total}$

Assuming a full-time Data Manager works approximately 160 hours/month, over 6 months (960 hours) per full-time equivalent (FTE):

$2,600 \div 960 \approx 2.7 \text{ FTEs total for the entire study period}$

To find the average per month, we divide evenly over 6 months:

$2.7 \div 6 \approx 0.45 \text{ FTE per month, or approximately 50\% of a Data Manager per month.}$

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 # 23

The Scope of Work would answer which of the following information needs?

- A. To look up which visit PK samples are taken
- B. To look up the date of the next clinical monitoring visit for a specific site
- C. To find the name and contact information of a specific clinical data associate
- **D. To determine the number of data transfers budgeted for a project**

Answer: D

Explanation:

The Scope of Work (SOW) is a project management document that defines what services are included in the work agreement between the sponsor and the CRO or vendor. It outlines deliverables, responsibilities, timelines, and budget allocations.

According to the GCDMP (Chapter: Project Management in Data Management), the SOW includes specifications such as:

The number and frequency of data transfers,

Database build and lock milestones,

Quality control deliverables, and

Resource allocation for data management tasks.

The SOW does not cover operational site-level details such as monitoring schedules (B), protocol sampling details (C), or personnel contact lists (D).

Therefore, option A (number of data transfers budgeted for a project) correctly identifies a use case directly addressed in the SOW.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Project Management, Section 4.1 - Scope of Work and Resource Planning ICH E6(R2) GCP, Section 5.5 - Sponsor Oversight and Data Management Responsibilities PMI Project Management Framework - Scope Definition and Deliverable Specifications

NEW QUESTION # 24

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

Answer: A

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 # 25

Which of the following data verification checks would most likely be included in a manual or visual data review step?

- A. Checking a value against a reference range
- B. Checking an entered value against a valid list of values
- C. Checking mandatory fields for missing values
- **D. Checking adverse event treatments against concomitant medications**

Answer: D

Explanation:

Manual or visual data review is used to identify complex clinical relationships and contextual inconsistencies that cannot be detected by automated edit checks.

According to the GCDMP (Chapter: Data Validation and Cleaning), automated edit checks are ideal for structured validations, such as missing fields (option C), reference ranges (option D), or predefined value lists (option A). However, certain clinical cross-checks—such as verifying adverse event treatments against concomitant medication records—require clinical judgment and contextual understanding.

For example, if an adverse event of "severe headache" was reported but no analgesic appears in the concomitant medication log, the data may warrant manual review and query generation. These context-based checks are best performed by trained data reviewers or medical data managers during manual data review cycles.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.3 - Manual Review and Clinical Data Consistency Checks ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Clinical Data Review Responsibilities FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Verification Principles

NEW QUESTION # 26

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