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SCDM CCDM Exam Syllabus Topics:

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

SCDM Certified Clinical Data Manager Sample Questions (Q88-Q93):

NEW QUESTION # 88

A Data Manager receives an audit finding of missing or undocumented training for two database developers according to the organization's training SOP and matrix. Which is the best response to the audit finding?

- A. Remove the training items from the training matrix
- B. Send the two developers to the required training
- C. Identify the root cause and improve the process to prevent it
- D. Reprimand the person responsible for maintaining training documentation

Answer: C

Explanation:

When an audit identifies missing or undocumented training, the most appropriate and compliant response is to identify the root cause of the issue and implement corrective and preventive actions (CAPA) to ensure that similar findings do not recur.

According to Good Clinical Data Management Practices (GCDMP, Chapter: Quality Management and Auditing), effective quality systems require root cause analysis (RCA) for all audit findings. The process involves:

Investigating why the documentation gap occurred (e.g., poor tracking, outdated SOP, or lack of oversight).

Correcting the immediate issue (e.g., ensuring the developers complete or document training).

Updating processes, training systems, or oversight mechanisms to prevent recurrence.

While sending the two developers to training (D) addresses the symptom, it does not resolve the systemic issue identified by the audit. Options B and C are non-compliant and do not address quality system improvement.

Therefore, option A (Identify the root cause and improve the process) is the best and CCDM-compliant response.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Quality Management and Auditing, Section 6.2 - Corrective and Preventive Actions (CAPA) ICH

E6(R2) GCP, Section 5.1.1 - Quality Management and Continuous Process Improvement FDA 21 CFR Part 820.100 - Corrective and Preventive Action (CAPA) Requirements

NEW QUESTION # 89

Which is the best way to see site variability in eligibility screening?

- A. Plot eligibility rate by site
- B. List eligibility waivers by site
- C. Summarize screening rate by site
- D. Graph enrollment by site

Answer: A

Explanation:

To identify site variability in eligibility screening, the most effective approach is to plot eligibility rate by site. This allows visual detection of differences in how well each site screens subjects according to protocol-defined inclusion and exclusion criteria.

The GCDMP (Chapter: Data Quality Assurance and Metrics) emphasizes the importance of graphical analysis for identifying anomalies and site-level performance variability. By plotting the eligibility rate by site, data managers and clinical operations teams can quickly identify outliers-sites that screen too many or too few eligible subjects-indicating potential training issues,

misunderstanding of inclusion/exclusion criteria, or even possible protocol deviations.

While summarizing screening rate (B) provides useful numeric data, it lacks visual comparability. Listing waivers (A) or enrollment counts (C) provide limited insights into eligibility consistency.

Therefore, option D-Plot eligibility rate by site-is the best analytic and visualization practice to assess site variability in screening outcomes.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.1 - Use of Metrics and Graphical Review for Site Performance ICH E6(R2) GCP, Section 5.18.4 - Identification of Systematic or Site-Specific Issues

NEW QUESTION # 90

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

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

Answer: C

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 # 91

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

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

Answer: A

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 -

NEW QUESTION # 92

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

Answer: A

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 # 93

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All of the traits above are available in this web-based Certified Clinical Data Manager (CCDM) practice test of ValidBrainDumps. The main distinction is that the Certified Clinical Data Manager (CCDM) online practice test works with not only Windows but also Mac, Linux, iOS, and Android. Above all, taking the Certified Clinical Data Manager (CCDM) web-based practice test while preparing for the examination does not need any software installation.

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