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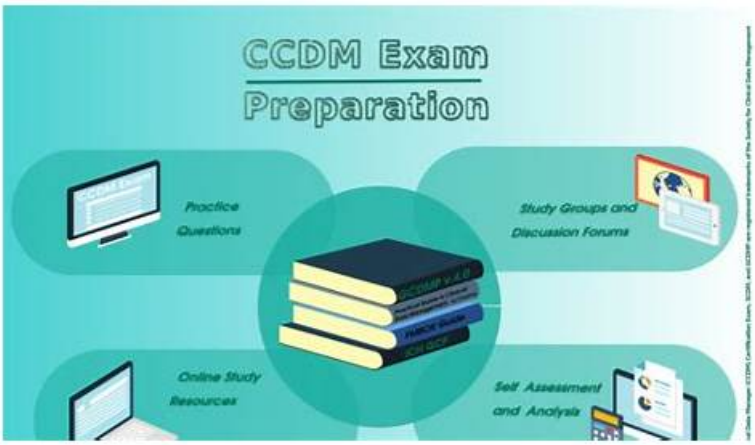

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SCDM CCDM Exam Syllabus Topics:

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	• 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	• 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	• 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.

>> CCDM Current Exam Content <<

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fortune and better opportunities have access to realize their life value. Our CCDM practice questions, therefore, is bound to help you pass though the CCDM Exam and win a better future. We will also continuously keep a pioneering spirit and are willing to tackle any project that comes your way. Our CCDM training materials will never let you down for its wonderful quality.

SCDM Certified Clinical Data Manager Sample Questions (Q146-Q151):

NEW QUESTION # 146
When implementing a study utilizing an EDC application, it would be appropriate to use free text fields for which of the following?

- A. Urine sedimentation rate
- B. Body Mass Index
- C. Date of birth
- D. Adverse event verbatim term

Answer: D

Explanation:
In Electronic Data Capture (EDC) systems, free text fields should be used only when a predefined list of acceptable responses cannot accommodate the full variability of input data - most notably for Adverse Event (AE) verbatim terms.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), AE verbatim terms are initially entered as free text by site staff to accurately capture the investigator's exact medical description of the event. These verbatim terms are later coded using standardized dictionaries such as MedDRA during medical coding, ensuring both flexibility and standardization in reporting.
Conversely, fields such as urine sedimentation rate (A), date of birth (C), and Body Mass Index (D) require structured numeric or date formats to enable validation, range checks, and consistency across datasets. Free text would compromise data integrity, accuracy, and validation efficiency for these structured data elements.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.3 - Use of Free Text and Coded Fields ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Structure and Validation MedDRA Introductory Guide, Section 2.3 - Verbatim Entry and Coding Requirements

NEW QUESTION # 147
What should be done if the site continues to provide inconsistent data after several re-queries?

- A. Escalate the issue to the appropriate site contact personnel
- B. Gently lead the site to the correct response
- C. Do nothing, the data will remain inconsistent
- D. Continue to re-query until the site changes the data

Answer: A

Explanation:
If a clinical site continues to provide inconsistent or illogical data after multiple queries, the correct course of action is to escalate the issue to the appropriate site contact personnel, typically the Clinical Research Associate (CRA) or Site Monitor.
According to the Good Clinical Data Management Practices (GCDMP), persistent data discrepancies often indicate a misunderstanding of the protocol, CRF instructions, or data entry procedures at the site level. Repeatedly re-querying the same data without escalation wastes time and risks introducing bias or error. By escalating through formal communication channels, the issue can be clarified through re-training, documentation review, or site monitoring visits.
The GCDMP emphasizes that escalation ensures data accuracy, site accountability, and protocol adherence, maintaining both data quality and regulatory compliance. Data managers must document the escalation process in the Data Management Plan (DMP) and ensure proper follow-up resolution is achieved.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 4.2 - Handling Persistent Data Discrepancies ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Communication FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Issue Escalation

NEW QUESTION # 148
Which statement applies to the CRF Completion Guidelines (CCGs) for a multinational study?

- A. CCGs can instruct sites to use any abbreviations if they are documented in the subject source notes
- B. CCGs must be translated and back-translated in each local language used in the study
- C. CCGs can instruct sites to write in their local language as long as the CRA is fluent in this language
- D. CCGs must contain the list of acceptable abbreviations to be used in the CRF

Answer: D

Explanation:
The Case Report Form (CRF) Completion Guidelines (CCGs) are critical documents that guide site staff on how to accurately and consistently record data on CRFs across all participating sites, especially in multinational trials.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), one of the key components of the CCGs is a list of acceptable abbreviations and conventions to be used during CRF entry. This standardization ensures data consistency across languages and countries, reduces ambiguity during data review, and facilitates database design and coding accuracy.
While translation (A) may be useful for training materials, it is not required for CCGs unless specified by regulatory bodies. Options C and D are incorrect because data collection should adhere to standardized terms in English (or the study's official language) - allowing free use of local languages or arbitrary abbreviations introduces inconsistencies.
Hence, option B - "CCGs must contain the list of acceptable abbreviations to be used in the CRF" - is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 5.3 - CRF Completion Guidelines and Standardization ICH E6(R2) GCP, Section 5.5.3 - Consistency and Data Recording Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.2 - Data Entry Conventions and Documentation

NEW QUESTION # 149
In a study conducted using paper CRFs, a discrepancy is discovered in a CRF to database QC audit. What is the reason why this discrepancy would be considered an audit finding?

- A. Discrepancy not explained by the data handling conventions
- B. Discrepancy not explained by the data quality control audit plan
- C. Discrepancy not explained by the protocol
- D. Discrepancy not explained by the CRF completion guidelines

Answer: A

Explanation:
In a CRF-to-database quality control (QC) audit, auditors compare data recorded on the paper Case Report Form (CRF) with data entered in the electronic database. If discrepancies exist that cannot be explained by documented data handling conventions, they are classified as audit findings.
Per GCDMP (Chapter: Data Quality Assurance and Control), data handling conventions define acceptable data entry practices, transcription rules, and allowable transformations. These conventions ensure that CRF data are consistently interpreted and entered. If a discrepancy deviates from these established rules, it indicates a process gap or error in data entry, validation, or training. Discrepancies justified by protocol design or CRF guidelines would not constitute findings.
Therefore, option C (Discrepancy not explained by the data handling conventions) correctly identifies the criterion for a true QC audit finding.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.1 - Data Handling Conventions and QC Auditing ICH E6(R2) GCP, Section 5.1 - Quality Management and Documentation of Deviations FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Verification and Audit Findings

NEW QUESTION # 150
A study collects blood pressure. Which is the best way to collect the data?

- A. Two continuous variables
- B. Coding a verbatim field with a MedDRA diagnosis
- C. High/Low radio button
- D. Check boxes for twenty-point increments

Answer: A

Explanation:
Blood pressure is a quantitative physiological measurement, typically consisting of two continuous numeric values: systolic and diastolic pressure. Therefore, the most appropriate and scientifically valid method of data collection is to use two continuous variables (e.g., systolic = 120 mmHg, diastolic = 80 mmHg).
According to the GCDMP (Chapter: CRF Design and Data Collection), data fields must be designed to capture the most precise, accurate, and analyzable form of clinical data. Numeric data should be collected using numeric data types to allow for range checks, calculations (e.g., mean arterial pressure), and statistical analysis.
Options such as categorical representations (radio buttons or check boxes) introduce rounding, data loss, and analytic limitations. Coding a verbatim diagnosis (option A) is inappropriate for numeric vital sign data and violates the principle of capturing data at the most granular level.
Thus, the correct and validated method per CCDM standards is two continuous variables, ensuring accuracy, traceability, and analytical flexibility.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.2 - Best Practices for Quantitative Data Capture ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Accuracy and Collection Standards FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Data Format and Structure Requirements

NEW QUESTION # 151
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