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SCDM CCDM

Certified Clinical Data Manager Exam

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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">• 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 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"> • 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q96-Q101):

NEW QUESTION # 96

A sponsor may transfer responsibility for any or all of their obligations to a contract research organization. Which of the following statements is true?

- A. A description of each of the obligations being transferred to the contract research organization is not required.
- B. Any written description is not transferred to the contract research organization.
- **C. A description of each of the obligations being assumed by the contract research organization is required.**
- D. A general statement that all obligations have been transferred is acceptable.

Answer: C

Explanation:

Under ICH E6 (R2) Good Clinical Practice and 21 CFR Part 312.52, when a sponsor delegates or transfers obligations for a clinical trial to a Contract Research Organization (CRO), there must be a written description of each specific obligation being assumed by the CRO.

According to the Good Clinical Data Management Practices (GCDMP), while sponsors may outsource responsibilities such as data management, monitoring, or biostatistics, ultimate accountability remains with the sponsor. The documentation of the transfer of responsibilities ensures regulatory transparency and compliance.

This written agreement, often referred to as a Transfer of Obligations (TOO) document, defines exactly which duties the CRO is responsible for (e.g., CRF design, data cleaning, database lock), as well as any retained sponsor oversight. A general statement that "all obligations are transferred" (option D) is insufficient per regulatory expectations, as sponsors must retain traceability of responsibility.

Therefore, Option B is correct - a detailed written description of transferred obligations is required.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Compliance and Oversight, Section 5.2 - Sponsor and CRO Responsibilities ICH E6 (R2) Good Clinical Practice, Section 5.2.1 - Transfer of Trial-Related Duties and Functions FDA 21 CFR 312.52 - Transfer of Obligations to a Contract Research Organization

NEW QUESTION # 97

During a database audit, it was determined that there were more errors than expected. Who is responsible for assessing the overall

impact on the analysis of the data?

- **A. Statistician**
- B. Investigator
- C. Data Manager
- D. Quality Auditor

Answer: A

Explanation:

The Statistician is responsible for assessing the overall impact of data errors on the analysis and study results.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control) and ICH E9 (Statistical Principles for Clinical Trials), while the Data Manager ensures data accuracy and completeness through cleaning and validation, the Statistician determines whether the observed data discrepancies are statistically significant or if they may affect the validity, power, or interpretability of the study's outcomes.

The Quality Auditor (C) identifies and reports issues but does not quantify analytical impact. The Investigator (D) is responsible for clinical oversight, not statistical assessment. Thus, after a database audit, the Statistician (B) performs a formal evaluation to determine whether the magnitude and nature of the errors could bias results or require reanalysis.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Data Audit and Impact Assessment ICH E9 - Statistical Principles for Clinical Trials, Section 3.2 - Data Quality and Analysis Impact Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Validation and Analysis Review

NEW QUESTION # 98

A study collects blood pressure. Which is the best way to collect the data?

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

Answer: C

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 # 99

What is the primary benefit of using a standard dictionary for medications?

- A. To identify differences in medication components based on country of source
- B. To improve safety monitoring of patients in a clinical trial setting
- C. To facilitate the reporting and analysis of possible drug interactions
- **D. To standardize recording of medications taken by patients across sites**

Answer: D

Explanation:

The primary benefit of using a standard medical dictionary (such as WHO Drug Dictionary, WHO-DD Enhanced, or RxNorm) in clinical data management is to standardize the recording and representation of medications taken by study participants across all sites, countries, and data sources (Option A).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Medical Coding and Dictionaries), standardized coding ensures that all variations of drug names - including brand names, generic names, abbreviations, and misspellings - are consistently mapped to a uniform dictionary term. This harmonization allows for accurate aggregation, analysis, and regulatory reporting of concomitant medications and investigational products across multiple studies and global sites.

For example, "Paracetamol" and "Acetaminophen" are the same compound but are known by different names in different regions. Coding both to the same preferred term (PT) in the WHO Drug Dictionary ensures that all references are analyzed consistently in safety summaries and pharmacovigilance reports.

While other options describe secondary benefits:

Option B: Facilitating drug interaction analysis is an important downstream benefit, but it depends on having standardized coding first.

Option C: Identifying differences in medication components by country is a feature of dictionary metadata but not the primary goal.

Option D: Safety monitoring relies on consistent adverse event and drug data but is an overarching objective, not the direct function of dictionary coding.

Thus, the primary benefit lies in ensuring consistency, clarity, and interoperability of medication data across all clinical sites and systems, forming the foundation for reliable safety and efficacy analysis.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Medical Coding and Dictionaries, Section 6.1 - Purpose and Principles of Coding WHO Drug Dictionary (WHO-DD) User Manual, Section 2.3 - Standardization of Medicinal Product Terminology ICH E2B (R3) Clinical Safety Data Management - Data Elements for Transmission of Individual Case Safety Reports FDA Study Data Technical Conformance Guide, Section 3.2 - Use of Controlled Terminology in Drug and Event Coding

NEW QUESTION # 100

In a cross-functional team meeting, a monitor mentions performing source data verification (SDV) on daily diary data entered by patients on mobile devices. Which of the following is the best response?

- A. The diary data should not be source data verified
- B. Diary data to be source data verified should be randomly selected
- **C. Diary data to be source data verified should be selected using a risk-based approach**
- D. All diary data should be source data verified

Answer: C

Explanation:

The best response is that diary data to be source data verified should be selected using a risk-based approach.

According to the GCDMP (Chapter: Data Quality Assurance and Control) and FDA Guidance on Risk-Based Monitoring (RBM), not all data require full SDV. Electronic patient-reported outcome (ePRO) or mobile diary data are typically direct electronic source data (eSource) captured at the time of entry, which already ensures authenticity and traceability.

A risk-based SDV approach focuses verification efforts on data critical to subject safety and primary efficacy endpoints, as defined in the study's Risk Assessment Plan or Monitoring Plan. Random or full verification of low-risk data (like diary compliance metrics) adds unnecessary effort and cost.

Thus, Option C aligns with current regulatory expectations and data management best practices.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Risk-Based Monitoring and SDV ICH E6 (R2) Good Clinical Practice, Section 5.18 - Risk-Based Quality Management FDA Guidance for Industry: Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring (2013)

NEW QUESTION # 101

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