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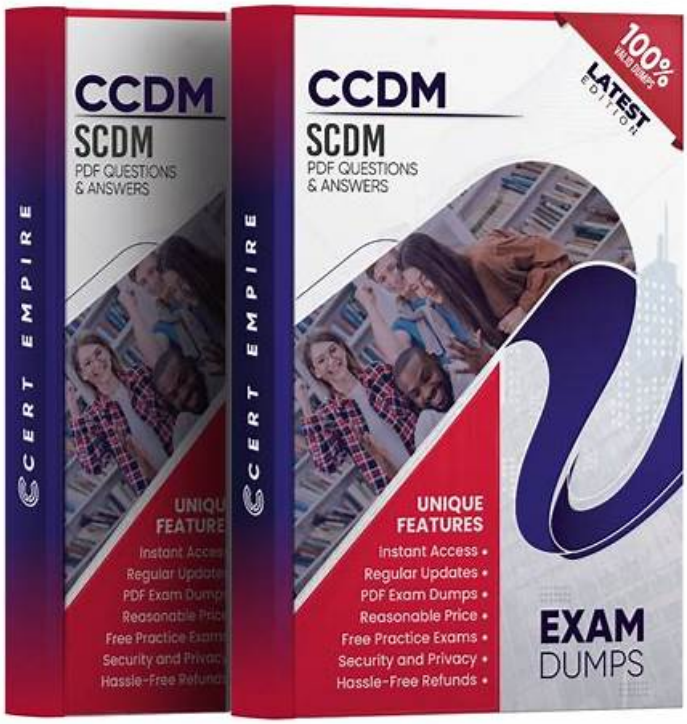

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SCDM Certified Clinical Data Manager Sample Questions (Q17-Q22):

NEW QUESTION # 17
For a study, body mass index is calculated from weight and height. Which information is needed to document the transformation?

- A. Algorithm documented in the Data Management Plan
- B. Algorithm associated with the calculated value
- C. User ID making the change and reason for change
- D. Algorithm and algorithm version associated with the calculated value

Answer: D

Explanation:
When derived or calculated variables (like Body Mass Index) are created, it is essential to document the algorithm used and its version to ensure full data traceability and reproducibility.
According to GCDMP (Chapter: Database Design and Derived Data), every derived field must include metadata describing:
The derivation algorithm (e.g., BMI = weight [kg] / height² [m²])
The version of the algorithm (if updates or revisions occur)
Any associated data sources or transformation rules
This ensures consistent calculation across systems, prevents discrepancies during regulatory submissions, and aligns with FDA and CDISC documentation expectations.
Option B lacks version control, which is critical for traceability. Option C describes audit trail data (not derivation metadata), and option D refers to broader documentation, not specific algorithm traceability.
Hence, option A (Algorithm and algorithm version associated with the calculated value) is the correct and compliant answer.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Derived Data and Algorithms, Section 5.3 - Documentation and Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Derived Data and Validation Traceability FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Data Definitions (Define.xml)

NEW QUESTION # 18
Which protocol section most concisely conveys timing of data collection throughout a study?

- A. Protocol synopsis
- B. Study endpoints section
- C. Study schedule of events
- D. ICH essential documents

Answer: C

Explanation:
The Study Schedule of Events (SoE) section in the protocol is the most concise and comprehensive representation of the timing of data collection throughout a study.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Management Planning and Study Start-up) and ICH E6 (R2) GCP, the SoE outlines what assessments, procedures, and data collections occur at each study visit (e.g., screening, baseline, treatment visits, follow-up). This table is a foundational tool for CRF design, database structure, and edit-check development, ensuring alignment between the protocol and data management systems.
While the study endpoints section (A) defines what is measured, and the protocol synopsis (C) summarizes the design, only the schedule of events (B) specifies when data collection occurs for each parameter. The ICH essential documents (D) pertain to regulatory documentation, not study visit timing.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.1 - Using the Schedule of Events for Database Design ICH E6 (R2) GCP, Section 6.3 - Trial Design and Schedule of Assessments FDA Guidance for Industry: Protocol Design and Data Collection Standards

NEW QUESTION # 19
On a dose escalation study, the Data Manager notices one site has a much higher number of queries than other sites and most are older than 30 days. The Data Safety Monitoring Board will meet in three weeks. What should the Data Manager providing CRO oversight do?

- A. Notify the CRO's Clinical Leader about the concerns
- B. Ignore it for now and check back next week
- C. Consult the CRO's Lead Data Manager and the CRO's Project Leader
- D. Call the site directly and ask the study coordinator about the concerns

Answer: C

Explanation:
The correct action is to consult the CRO's Lead Data Manager and CRO's Project Leader (Option C) to ensure the issue is addressed through the appropriate oversight and escalation process.

According to the GCDMP (Chapter: Project Management and Communication), when a sponsor Data Manager identifies significant data management issues under CRO oversight - such as aging queries or site performance disparities - communication must follow the established governance and escalation pathway defined in the Scope of Work (SOW) and Data Management Plan (DMP). Directly contacting the site (Option B) bypasses the CRO's chain of command and violates communication protocols. Notifying only the Clinical Leader (Option A) is insufficient, and ignoring the issue (Option D) jeopardizes the Data Safety Monitoring Board (DSMB) review timeline.
Therefore, Option C ensures a documented, collaborative approach to problem resolution within the contractual oversight structure.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 7.1 - Oversight of CRO Data Management Activities ICH E6 (R2) GCP, Section 5.2 - Contract Research Organization Responsibilities FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Roles and Communication Pathways

NEW QUESTION # 20
When a data manager runs a report on resolution types of discrepancy status, which of the following would NOT be a part of resolution types?

- A. Resolved with data/confirmed as is (non problematic)
- B. Data management - self evident corrections
- C. Received from site and not yet reviewed
- D. Cannot be resolved (but data incorrect)

Answer: C

Explanation:
In a discrepancy management workflow, "Received from site and not yet reviewed" is not a resolution type - it represents a status, not a final resolution outcome.
According to the GCDMP (Chapter: Data Validation and Cleaning), resolution types describe how a data discrepancy was finalized or addressed, such as:
Resolved with data correction,
Confirmed as correct (no change required),
Self-evident correction applied by data management, or
Unresolvable discrepancies documented.
In contrast, statuses describe the stage of the query (e.g., open, sent, answered, pending review, closed). "Received from site and not yet reviewed" indicates an intermediate workflow state where the response awaits validation by data management.
Proper classification of resolution types is essential for performance reporting, audit readiness, and ensuring the traceability of query management actions under ICH E6 (R2) and FDA 21 CFR Part 11.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.3 - Discrepancy Resolution Lifecycle ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Handling and Record Management FDA 21 CFR Part 11 - Electronic Records; Audit Trails and Discrepancy Tracking Requirements

NEW QUESTION # 21
Which Clinical Study Report section would be most useful for a Data Manager to review?

- A. Description of statistical analysis methods
- B. Rationale for the study design
- C. Description of how data were processed
- D. Clinical narratives of adverse events

Answer: C

Explanation:
The section of the Clinical Study Report (CSR) most useful for a Data Manager is the description of how data were processed.
According to the GCDMP (Chapter: Data Quality Assurance and Control), this section details the data handling methodology - including data cleaning, coding, transformation, and derivation procedures - all of which are core responsibilities of data management. Reviewing this section ensures that the data processing methods documented in the CSR align with the Data Management Plan (DMP), Data Validation Plan (DVP), and database specifications.
The statistical methods section (option A) is primarily for biostatistics, and the rationale for study design (option B) pertains to clinical and regulatory affairs. Clinical narratives (option D) are used by medical reviewers, not data managers.

By reviewing how data were processed, the Data Manager verifies that the study data lifecycle-from collection to analysis-was conducted in compliance with regulatory and GCDMP standards.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.3 - Documentation of Data Processing in Clinical Study Reports ICH E3 - Structure and Content of Clinical Study Reports, Section 11.3 - Data Handling and Processing FDA Guidance for Industry: Clinical Study Reports and Data Submission - Data Traceability and Handling Documentation

NEW QUESTION # 22
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