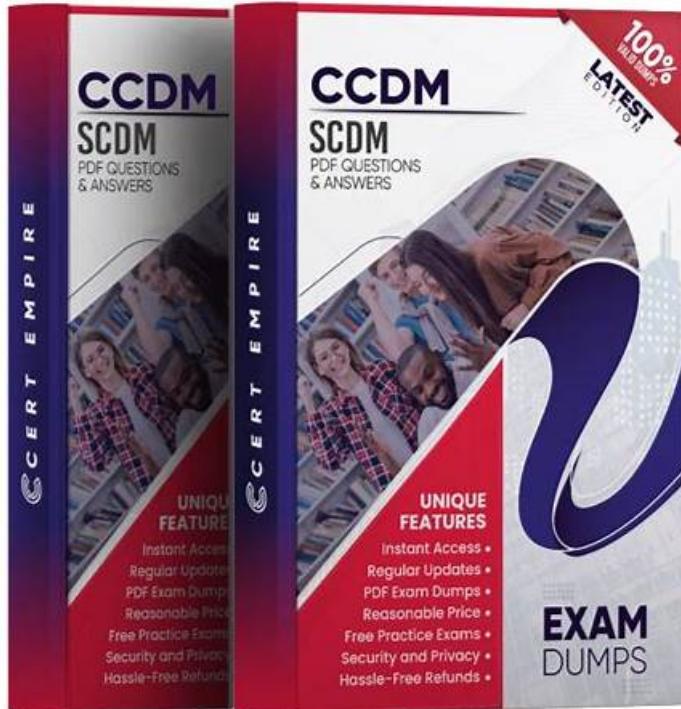


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SCDM Certified Clinical Data Manager Sample Questions (Q97-Q102):

NEW QUESTION # 97

What significant difference is there in the DM role when utilizing an EDC application?

- A. Metrics generation is required
- B. Data updates are implemented by the sites
- C. Database validation is not required
- D. Tracking of eCRFs is a monitor's responsibility

Answer: B

Explanation:

The most significant difference in the Data Manager's role when using an Electronic Data Capture (EDC) system is that data updates are implemented directly by site personnel (Option A).

According to the GCDMP (Chapter: Electronic Data Capture Systems), EDC technology shifts responsibility for data entry and correction from the sponsor or CRO to the investigator site, enabling real-time data entry and validation. This eliminates the need for double entry or remote data transcription, allowing Data Managers to focus on system validation, query management, and data quality oversight rather than physical data handling.

However, the EDC system still requires full validation (contrary to Option B). Metrics generation (Option C) and CRF tracking (Option D) are important but not unique to EDC-based workflows.

Thus, the correct answer is Option A - Data updates are implemented by the sites, reflecting the most fundamental operational shift introduced by EDC systems.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 4.1 - Role of the Data Manager in EDC ICH E6 (R2) GCP, Section 5.5.3 - Electronic Data Entry and Responsibilities FDA 21 CFR Part 11 - Electronic Records and Signatures: Data Entry Responsibilities

NEW QUESTION # 98

What action should be taken regarding the clinical database when MedDRA releases a new version of its dictionary?

- A. Upgrade the version immediately and recode.
- B. Evaluate the extent and impact of the changes.
- C. Identify an alternative dictionary.
- D. Continue using the existing version to code.

Answer: B

Explanation:

When a new version of MedDRA (Medical Dictionary for Regulatory Activities) is released, the correct action is to evaluate the extent and impact of the changes before implementation.

According to the GCDMP (Chapter: Medical Coding and Dictionaries), MedDRA updates are published twice yearly (March and September). Each release may introduce new terms, modify hierarchies, or retire old ones. Prior to adopting a new version, the Data Manager and Medical Coder must:

Assess the number and type of term changes,

Determine the potential effect on ongoing coding consistency, and

Decide whether migration to the new version is warranted mid-study or deferred until database lock.

Immediate recoding (option C) without evaluation may cause inconsistencies and require additional validation. Continuing with the existing version (option B) may be acceptable short-term but must be justified. Using an alternative dictionary (option D) is noncompliant, as MedDRA is the regulatory standard for safety reporting.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Medical Coding and Dictionaries, Section 6.3 - Version Control and Impact Assessment MedDRA Term Selection: Points to Consider (MSSO, Latest Version), Section 3 - Versioning and Maintenance ICH E2B(R3) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

NEW QUESTION # 99

Which competency is necessary for EDC system use in a study using the medical record as the source?

- A. Resolving discrepant data
- B. Screening study subjects
- C. Using ePRO devices
- D. Training on how to log into Medical Records system

Answer: D

Explanation:

In studies where the medical record serves as the source document, the Electronic Data Capture (EDC) system users (typically study coordinators or site personnel) must have appropriate training on how to access and log into the medical record system. This competency ensures that data abstracted from the electronic medical record (EMR) are complete, accurate, and verifiable in

compliance with Good Clinical Practice (GCP) and Good Clinical Data Management Practices (GCDMP).

According to the GCDMP (Chapter: EDC Systems and Data Capture) and ICH E6(R2), all personnel involved in data entry and verification must be trained in both the EDC and the primary source systems (e.g., EMR). This ensures that the integrity of data flow-from source to EDC-is maintained, and that personnel understand system access controls, audit trails, and proper documentation of source verification.

While resolving discrepant data (C) and screening subjects (A) are part of study operations, the competency directly related to EDC system use in EMR-based studies is the ability to properly log into and navigate the medical records system to extract source data. Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC), Section 5.1 - Source Data and System Access Requirements ICH E6(R2) Good Clinical Practice, Section 4.9 - Source Documents and Data Handling FDA Guidance: Use of Electronic Health Record Data in Clinical Investigations, Section 3 - Investigator Responsibilities

NEW QUESTION # 100

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

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

Answer: C

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 # 101

According to the FDA Guidance for Industry, Providing Regulatory Submissions in Electronic Format (April 2006) and Good Clinical Data Management Practices (GCDMP, May 2007), which of the following is the most acceptable for a derived field?

- A. Providing CRF annotation AVE next to the average score
- **B. Providing the algorithm for calculating the average score in the dataset definition file**
- C. Providing CRF annotation "not entered in the database" next to the average score
- D. Providing the algorithm for calculating the average score on the CRF

Answer: B

Explanation:

In clinical data management, a derived field refers to any variable that is not directly collected from the Case Report Form (CRF) but is instead calculated or inferred from one or more collected variables (for example, calculating an average blood pressure from multiple readings). Proper documentation of derived fields is essential for ensuring data traceability, transparency, and compliance with both FDA and SCDM guidelines.

According to the Good Clinical Data Management Practices (GCDMP, May 2007), all derivations and transformations applied to clinical data must be clearly defined and documented in metadata such as the dataset definition file (also referred to as data specifications, variable definition tables, or Define.xml files). The derivation algorithm should be explicitly stated in this documentation to allow independent verification, regulatory review, and reproducibility of results.

The FDA Guidance for Industry (April 2006) on electronic submissions further emphasizes that derived fields must be supported by comprehensive metadata that defines the computational method used. This documentation enables the FDA or any regulatory body

to audit and reproduce analytical results without ambiguity. Annotating or describing derivations directly on the CRF (as in options A, B, or D) is not sufficient, as CRFs represent data collection instruments-not analytical documentation.

Therefore, the correct and regulatory-compliant practice is to provide the derivation algorithm for a calculated field within the dataset definition file, aligning with both FDA and GCDMP expectations for data integrity and auditability.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Handling and Processing - Derived and Calculated Data Fields, Section 5.3.3 FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006, Section 3.2 on Dataset Documentation Requirements CDISC Define.xml Implementation Guide - Metadata and Algorithm Documentation for Derived Variables

NEW QUESTION # 102

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