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Exam : **CCDM**

Title : Certified Clinical Data Manager

Version : DEMO

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

2.A study numbers subjects sequentially within each site and does not reuse site numbers.
Which information is required when joining data across tables?
A. Subject number and site number
B. Subject number
C. Study number and subject number
D. Site number
Answer: A
Explanation:
When subjects are numbered sequentially within each site, it means that the subject identification numbers (Subject IDs) restart from 001 at each site. For example, Site 101 may have Subject 001, and

Site 102 may also have a Subject 001. In such cases, the subject number alone is not globally unique across the entire study. Therefore, when integrating or joining data across multiple database tables (for example, linking demographic, adverse event, and laboratory data), both the site number and the subject number are required to create a unique key that accurately identifies each record. According to the Good Clinical Data Management Practices (GCDMP, Chapter on CRF Design and Data Collection), every data record in a clinical trial database must be uniquely and unambiguously identified. This is typically achieved through a composite key, combining identifiers such as site number, subject number, and sometimes study number. The GCDMP specifies that a robust data structure must prevent duplication or mislinking of records across domains or tables.
Furthermore, FDA and CDISC standards (SDTM model) also emphasize the importance of unique subject identifiers (USUBJID), which are derived from concatenating the study ID, site ID, and subject ID. This ensures traceability, integrity, and accuracy of subject-level data during database joins, data exports, and regulatory submissions.
Thus, in the described scenario, since subject numbering restarts at each site, both the site number and subject number are required to uniquely identify and correctly join subject data across different datasets or tables.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.1 – Unique Subject Identification
CDISC SDTM Implementation Guide, Section 5.2 – Subject and Site Identification (Variable: USUBJID)
FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 – Data Integrity and Record Identification

3.Which of the following factors can be tested through a second test transfer?
A. Change management
B. File format
C. Transfer method
D. Transfer frequency
Answer: B
Explanation:
In the context of database design and external data management, a test data transfer (or trial data load) is performed to ensure the proper configuration, structure, and integrity of data imported from an external vendor or system. The second test transfer is specifically useful to confirm that data structures and formats are consistently aligned between the sending and receiving systems after initial adjustments have been made from the first test.
According to the Good Clinical Data Management Practices (GCDMP), the file format — including variables, data types, field lengths, delimiters, and encoding — must be validated during test transfers to confirm compatibility and ensure accurate loading into the target database. Once the initial test identifies and corrects errors (e.g., mismatched variable names or data types), the second transfer verifies that the corrections have been implemented correctly and that the file structure functions as intended.
Testing change management (A) involves procedural controls, not data transfers. The transfer method (C) and transfer frequency (D) are validated during initial process setup, not during subsequent test transfers.
Therefore, option B (File format) is correct, as the second test transfer verifies the technical integrity of

the file structure before live production transfers begin. Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers and Data Integration, Section 5.2 – Test Transfers and File Validation
FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 – Data Import and Validation Controls

4.Which of the following statements would be BEST included in a data management plan describing the process for making self-evident corrections in a clinical database?
A. A senior level data manager may make audited changes to the database without further documentation.
B. Self-evident corrections made in the database will be reviewed and approved by a team leader or manager.
C. No changes will be made in the database without a query response signed by the investigator.
D. Self-evident changes may be made per the listed conventions and documented to the investigative site.
Answer: D
Explanation:
A self-evident correction (SEC) refers to a data correction that is obvious, logical, and unambiguous — such as correcting an impossible date (e.g., 31-APR-2024) or standardizing a known abbreviation (e.g., “BP” to “Blood Pressure”). According to the Good Clinical Data Management Practices (GCDMP), SECs can be applied by data management staff following pre-approved conventions defined in the Data Management Plan (DMP).
The DMP should explicitly describe the criteria for SECs, including the types of errors eligible for this correction method, the required documentation, and the communication procedure to inform the investigative site. The process must maintain audit trail transparency and ensure that all changes are traceable and justified.
Options A and B suggest unauthorized or informal change procedures, which violate audit and compliance standards.
Option C is too restrictive, as it prevents the efficient correction of non-clinical transcription or formatting errors.
Therefore, option D is correct: “Self-evident changes may be made per the listed conventions and documented to the investigative site.” This approach aligns with CCDM expectations for balancing efficiency, accuracy, and regulatory compliance.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 6.2 – Self-Evident Corrections FDA 21 CFR Part 11 – Electronic Records; Audit Trails and Traceability Requirements

5.Which document contains the details of when, to whom, and in what manner the vendor data will be sent?
A. Project Plan
B. Communication Plan
C. Data Transfer Agreement
D. Data Management Plan
Answer: C

Explanation:
A Data Transfer Agreement (DTA) defines the operational and technical details for transferring data between a sponsor and an external vendor (e.g., central lab, ECG vendor). It is a formalized, controlled document specifying what data will be sent, when transfers will occur, the transfer method, file structure, encryption or security protocols, and the recipients of the data.
The DTA is developed jointly by the sponsor and vendor before production data transfers begin. According to the GCDMP, Chapter on External Data Transfers, this agreement ensures both parties share a clear understanding of timing, responsibility, and data content to minimize errors and ensure regulatory compliance.
The Data Management Plan (DMP) outlines general data handling processes but does not capture the technical specifics of vendor data transfer logistics. The Project Plan (A) and Communication Plan (B) are broader operational tools and not specific to data transfer protocols.
Hence, option C (Data Transfer Agreement) is the correct answer, as it precisely governs the procedural and technical framework of vendor data exchange. Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers, Section 4.1 – Data Transfer Agreements and Specifications
ICH E6(R2) Good Clinical Practice, Section 5.5 – Trial Management, Data Handling, and Record Keeping