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Practice Materials & Tests

DEMO VERSION

SCDM

CCDM Exam

Certified Clinical Data Manager Exam

Exam Latest Version: 6.0

Question 1. (Single Select)

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

Correct 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

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Question 2. (Single Select)

Which metric reveals the timeliness of the site-work dimension of site performance?

A: Time from Last Patient Last Visit to database lock
B: Time from final protocol to first patient enrolled
C: Time from site contract execution to first patient enrolled
D: Median and range of time from query generation to resolution

Correct Answer: D

Explanation:

The site-work dimension of site performance evaluates how efficiently sites manage and resolve data-related tasks — particularly query resolution, data entry, and correction timelines. Among the given metrics, the median and range of time from query generation to resolution (D) directly measures the site's responsiveness and data management efficiency.

According to the GCDMP (Chapter on Metrics and Performance Measurement), this indicator helps identify sites that delay query resolution, which can impact overall study timelines and data quality. Tracking this metric allows the data management team to proactively provide additional training or communication to underperforming sites.

Other options measure different aspects of project progress:

A reflects overall database closure speed.

B and C relate to study startup and enrollment readiness, not ongoing data work.

Thus, option D accurately represents a site performance timeliness metric, aligning with CCDM principles for operational performance measurement.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Metrics and Performance Management, Section 5.4 – Site Query Resolution Metrics

ICH E6(R2) Good Clinical Practice, Section 5.18 – Monitoring and Site Performance Oversight

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Question 3. (Single Select)

What is the main reason 21 CFR Part 11 requires that EDC systems maintain an audit trail?

A: To preserve data integrity
B: To preserve the ability for modifications
C: To preserve source document verifications
D: To preserve data availability

Correct Answer: A

Explanation:

The primary purpose of maintaining an audit trail as required under 21 CFR Part 11 is to preserve data integrity. According to the U.S. FDA's regulation on electronic records and signatures, every change to electronic data must be traceable, including information about who made the change, when it was made, and what the change entailed.

The Good Clinical Data Management Practices (GCDMP) outlines that an audit trail provides a permanent, chronological record of all modifications to clinical data. This ensures transparency and allows the reconstruction of the course of data entry and modification. The regulation aims to prevent unauthorized or undocumented data manipulation, thereby maintaining the accuracy, reliability, and validity of electronic records.

The FDA 21 CFR Part 11, Section 11.10(e) explicitly mandates that systems must use secure,

computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. This ensures the data remains trustworthy and defensible in regulatory reviews or inspections.

Therefore, the main reason for requiring an audit trail is to preserve data integrity — ensuring that all data captured, modified, or transmitted is authentic, accurate, and complete throughout the study lifecycle.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Compliance and Data Integrity

FDA 21 CFR Part 11 – Electronic Records; Electronic Signatures, Section 11.10(e)

ICH E6 (R2) Good Clinical Practice, Section 5.5.3 – Data Integrity and System Validation

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Question 4. (Single Select)

Electronic submission standards require that an individual subject's complete CRF should be provided as what type of file:

A: Portable Document Format (.pdf)
B: Rich Text Format (.rtf)
C: Microsoft Word (.docx)
D: Statistical Analysis System (.sas)

Correct Answer: A

Explanation:

Electronic submission standards, as established by FDA, CDISC, and ICH, require that an individual subject’s complete Case Report Form (CRF) be submitted as a Portable Document Format (.pdf) file. The PDF format is universally recognized and accepted because it ensures that the structure, format, and visual fidelity of the CRF are preserved exactly as originally designed, regardless of software or hardware environment.

According to the FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format (2006) and CDISC SDTM standards, sponsors must include a subject-level CRF in PDF form for each participant in the submission dataset. This requirement ensures that reviewers can trace data points from analysis datasets back to their source entries in the CRF, fulfilling the principles of data traceability and transparency.

The Good Clinical Data Management Practices (GCDMP) also support this requirement, emphasizing that CRF archiving should maintain readability and regulatory accessibility. Formats like RTF, DOCX, or SAS datasets are not acceptable substitutes for regulatory CRF submission because they may alter formatting, structure, or introduce modifiable content, violating FDA data integrity principles.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Archiving and Submission

FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006

CDISC SDTM Implementation Guide, Section 5.3 – CRF Representation and Traceability

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Question 5. (Single Select)

Which document describes what study subjects expect with respect to data disclosure during and after a study?

A: Study data sharing plan
B: ICH essential documents
C: Informed consent form
D: Study protocol

Correct Answer: C

Explanation:

The Informed Consent Form (ICF) is the document that explicitly describes what study subjects can expect regarding data disclosure, privacy, and confidentiality during and after participation in

a clinical trial. According to ICH E6 (R2) Good Clinical Practice and FDA Human Subject Protection Regulations (21 CFR Parts 50 and 56), participants must be fully informed about how their personal and clinical data will be collected, used, stored, and shared — both during the study and in any subsequent data-sharing or publication activities.

The GCDMP reiterates that clinical data managers must ensure that all data handling practices align with the privacy commitments made in the ICF. This includes compliance with data protection regulations such as HIPAA (in the U.S.) and GDPR (in the EU). The ICF defines the permissible scope of data use, ensuring ethical management and subject protection.

Documents like the protocol or data sharing plan may outline procedures and responsibilities but do not directly inform participants of their rights and data use expectations. Only the ICF is designed for that ethical communication purpose.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Ethics, Privacy, and Data Security

ICH E6 (R2) Good Clinical Practice, Sections 4.8.10 & 4.8.12

FDA 21 CFR Part 50 – Protection of Human Subjects, Informed Consent Requirements

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