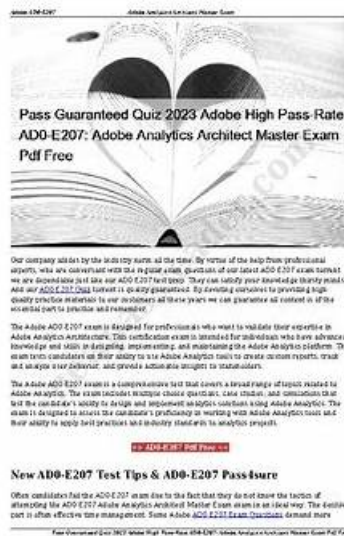


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## SCDM Certified Clinical Data Manager Sample Questions (Q150-Q155):

### NEW QUESTION # 150

ePRO data are collected for a study using study devices given to subjects. Which is the most appropriate quality control method for the data?

- A. Data visualizations to look for site-to-site variation
- B. Programmed edit checks to detect out of range values after submission to the database
- C. Programmed edit checks to detect out of range values upon data entry
- D. Manual review of data by the site study coordinator at the next visit

**Answer: C**

Explanation:

When electronic patient-reported outcomes (ePRO) devices are used, data are captured directly by subjects through validated devices and transmitted electronically to the study database. To ensure real-time data quality control, programmed edit checks should be implemented at the point of data entry - that is, as subjects input data into the device.

According to Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), front-end programmed edit checks are the optimal method to prevent entry of invalid or out-of-range values in ePRO systems. This helps maintain data accuracy at the source, minimizing downstream queries and data cleaning workload.

Options A and B involve post-submission or manual review, which is less efficient and not compliant with the principle of first-pass data validation. Option C (visualization) is a valuable secondary QC method for trends, but not for immediate data validation.

Therefore, option D is correct - programmed edit checks upon data entry ensure immediate validation and higher data integrity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Automated Edit Checks and Front-End Validation ICH E6(R2) GCP, Section 5.5.3 - Computerized System Controls and Validation FDA Guidance for Industry: Electronic Source Data in Clinical Investigations (2013), Section 6 - Real-Time Data Quality Control

### NEW QUESTION # 151

An organization has completed a study and wants to submit the data to the FDA using CDISC SDTM. Which of the following must be done?

- A. Provide a letter of intent to use SDTM to the FDA
- B. Map and transform the study data to SDTM
- C. Re-enter the data into an SDTM compliant system
- D. SDTM cannot be used in this situation

**Answer: B**

Explanation:

To submit study data to the FDA in CDISC SDTM format, the sponsor must map and transform the collected data from the study's operational database (e.g., EDC) into SDTM-compliant domains.

According to GCDMP (Chapter: Standards and Data Integration) and CDISC SDTM Implementation Guide, this process includes: Mapping raw data elements from the clinical database to SDTM domains (e.g., DM, AE, VS).

Transforming data to comply with SDTM structural and naming conventions.

Validating the output using CDISC compliance tools (e.g., Pinnacle 21).

Re-entering data (B) is unnecessary, and a letter of intent (C) is not required. SDTM is explicitly accepted by FDA for both retrospective and prospective submissions, so (D) is incorrect.

Thus, option A is correct - map and transform existing data to SDTM format for regulatory submission.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.3 - Data Transformation and CDISC Mapping CDISC SDTM Implementation Guide, Version 3.4 - Data Conversion and Submission Requirements FDA Study Data Technical Conformance Guide, Section 2.2 - SDTM Mapping and Validation

### NEW QUESTION # 152

A Data Manager is importing lab data for a study. The lab data and the associated audit trail is kept at the central lab. What is necessary to maintain traceability of the transferred data at the Data Manager's location?

- A. Maintaining a copy of the data as received

- B. Making changes only on the copy of the received data
- C. Making changes only after data have been imported
- D. Making changes only for exceptions

**Answer: A**

Explanation:

Maintaining traceability of external data imports (such as laboratory results) is a fundamental principle of clinical data management. According to the GCDMP (Chapter: External Data Transfers and Integration), Data Managers must retain an unaltered copy of the raw data exactly as received from the vendor.

This archived version serves as a reference for:

Data provenance verification,

Audit trail review, and

Discrepancy resolution between vendor and study database.

Since the central lab maintains its own audit trail, the Data Manager's responsibility is to preserve the original data transmission file before applying transformations, merges, or validations.

Options A, C, and D describe procedural safeguards but do not meet the regulatory requirement of traceable data lineage. Only option B (Maintaining a copy of the data as received) ensures compliance with ICH E6(R2) and FDA 21 CFR Part 11 standards for data traceability and integrity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers and Integration, Section 5.2 - Data Traceability and Version Control ICH

E6(R2) GCP, Section 5.5.3 - Data Integrity and Source Data Verification FDA Guidance for Industry: Computerized Systems

Used in Clinical Investigations, Section 6.4 - Source Data Traceability and Archiving

#### NEW QUESTION # 153

In the transfer of obligations for a double-blind, multi-center trial, a sponsor has maintained the task of creating the randomization schedule. Who at the sponsor company should create the randomization schedule?

- A. A sponsor's biostatistician not on the project
- B. The sponsor's project biostatistician
- C. The CRO biostatistician
- D. The sponsor's project statistical programmer

**Answer: A**

Explanation:

In a double-blind clinical trial, the randomization schedule must be generated by an independent biostatistician not directly involved in study operations or data management to preserve study blinding and integrity.

According to ICH E9 and the GCDMP (Chapter: Regulatory Requirements and Compliance), randomization generation and blinding must be handled in a way that prevents bias or unintentional unblinding of study personnel. The sponsor's biostatistician not assigned to the project (Option C) is the appropriate person because they have the necessary statistical expertise but remain operationally independent from study execution.

A project biostatistician (Option D) or programmer (Option A) directly involved in data analysis could inadvertently compromise blinding. The CRO biostatistician (Option B) should not perform this function if the sponsor retains randomization responsibility.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Requirements and Compliance, Section 6.4 -

Randomization and Blinding ICH E9 - Statistical Principles for Clinical Trials, Section 5.4 - Randomization Procedures and Blinding

FDA Guidance for Industry: Adaptive Design Clinical Trials for Drugs and Biologics, Section 4.3 - Maintaining Blinding Integrity

#### NEW QUESTION # 154

What is the purpose of providing the central laboratory vendor with a complete listing of subjects' demographic data?

- A. To assure that lab data for screening failure subjects have not been included in the lab data transmission
- B. To assure that all subjects have lab data for valid visits
- C. To provide for an independent reconciliation of the patient and remote databases after database lock
- D. To provide for an independent reconciliation of the patient and remote databases during study conduct

**Answer: D**

Explanation:

Providing the central laboratory vendor with a complete subject demographic listing allows ongoing reconciliation between the sponsor's EDC system and the vendor's laboratory database during study conduct.

The GCDMP (Chapter: External Data Transfers and Integration) emphasizes that subject reconciliation ensures that all laboratory data correspond to valid enrolled subjects and visits. Regular reconciliation throughout the study prevents data mismatches, missing results, or misassigned lab reports.

This proactive measure supports timely query resolution and data integrity across systems. Waiting until after database lock (as in option A) would delay corrections and risk inconsistencies. Options B and D address secondary benefits but not the primary purpose-ongoing subject-level reconciliation.

Thus, option C is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers, Section 4.4 - Reconciliation and Vendor Communication ICH E6(R2) GCP, Section 5.5.3 - Data Management, Reconciliation, and Integration FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - External Data Management

## NEW QUESTION # 155

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