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## SCDM CCDM Desktop Practice Exam Questions Software

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## SCDM Certified Clinical Data Manager Sample Questions (Q84-Q89):

### NEW QUESTION # 84

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

**Answer: B**

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 # 85

Which is the most important reason for why a data manager would review data before a monitor reviews it?

- A. Data managers have access to programming tools to identify discrepancies.
- B. Data managers write the Data Management Plan that specifies the data cleaning workflow.
- **C. Data can be viewed and discrepancies highlighted prior to a monitor's review.**
- D. The GCDMP recommends that data managers review data prior to a monitor's review.

**Answer: C**

Explanation:

The primary reason data managers review data before a monitor's review is to identify and flag discrepancies or inconsistencies so that site monitors can focus their efforts more efficiently during on-site or remote source data verification (SDV).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), proactive data review by data management staff ensures data completeness and accuracy by identifying missing, inconsistent, or out-of-range values. This pre-review helps streamline the monitoring process, reduces the volume of open queries, and enhances data quality.

Option A is true but not the main reason for pre-monitor review. Option C highlights a capability rather than a rationale. Option D is partially correct, but the GCDMP emphasizes process purpose, not prescriptive order. Thus, option B correctly captures the practical and process-oriented reason for early data review-to ensure data are ready and accurate for the monitor's review phase.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Data Review Timing and Purpose ICH E6(R2) GCP, Section 5.18 - Monitoring and Data Verification Requirements

### NEW QUESTION # 86

The serious adverse event (SAE) database should be reconciled against the clinical trial database prior to which occasion?

- **A. Database closure or locking**
- B. Case report form data entry
- C. Database quality audit
- D. Expedited safety reporting

**Answer: A**

Explanation:

SAE reconciliation must be completed before database lock or closure to ensure all safety data are consistent between the clinical database and the pharmacovigilance (safety) database.

According to the GCDMP (Chapter: Safety Data Handling and Reconciliation), SAE reconciliation involves verifying that all adverse events reported in the clinical trial database are also captured and accurately recorded in the safety system (and vice versa). This is essential to confirm that no SAE is missing, misclassified, or inconsistently dated or coded between the two systems.

Performing this reconciliation before database lock ensures that any discrepancies are corrected, and both databases reflect consistent, verified information for regulatory submission. Conducting this after closure (or only at audit time) would risk data inconsistencies in the final submission datasets.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: SAE Reconciliation, Section 6.1 - Timing and Procedures for Reconciliation ICH E2A/E2F - Clinical Safety Data Management: Definitions and Standards FDA Guidance for Industry: E2A - Clinical Safety Data Management: Processing Standards for Safety Reports

### NEW QUESTION # 87

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

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

**Answer: C**

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 # 88

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

**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 # 89

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