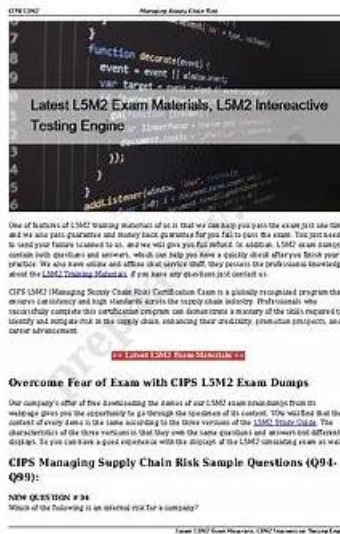


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## SCDM Certified Clinical Data Manager Sample Questions (Q120-Q125):

### NEW QUESTION # 120

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

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

**Answer: C**

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 # 121

A statistician analyzes data from a randomized, double-blind, placebo-controlled study and finds that the placebo outperformed the investigational product. Which of the following is a plausible explanation for this?

- A. Sites appropriately dispensed the investigational product to the subjects.
- B. The treatment codes were incorrectly entered into the database.
- C. The placebo was intended to contain medicinal properties.
- D. The investigational product performed well in this study population.

**Answer: B**

Explanation:

In a randomized, double-blind, placebo-controlled study, if statistical analysis shows that the placebo appears to outperform the investigational product, a likely cause is a data management or coding error, particularly in treatment code entry or mapping.

According to the GCDMP (Chapter: Database Design and Build), treatment assignment data - typically stored in randomization or code-break files - must be accurately integrated into the clinical database. Any mismatch between randomization codes, subject identifiers, or treatment arms can lead to incorrect grouping during analysis, producing false conclusions such as placebo superiority.

The Data Manager should initiate a root cause review of randomization data integration and treatment mapping. The placebo is never designed to have active medicinal effects (option A). Option D is incorrect because the described scenario implies a data inconsistency, not true efficacy differences. Proper verification of randomization coding and reconciliation between data management and statistical programming systems are essential.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Build, Section 6.1 - Randomization and Treatment Code Management ICH E6 (R2) GCP, Section 5.5.3 - Data Verification and Coding Accuracy FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Mapping and Validation Requirements

### NEW QUESTION # 122

What does 21 CFR Part 11 dictate in regards to a minimum expectation of EDC training prior to access?

- A. Training must be face to face

- B. Training must be in the user's native language
- C. Training must include an exam
- **D. Training must be performed**

**Answer: D**

Explanation:

Under FDA 21 CFR Part 11, organizations using electronic systems must ensure that all system users are trained to perform their assigned functions before gaining access to the system. The regulation requires documented evidence of training but does not specify how it should be conducted (e.g., exam-based, in person, or language-specific).

The GCDMP (Chapter: Computerized Systems and Compliance) further clarifies that personnel training should include instruction on system functionality, audit trails, data entry procedures, and electronic signatures to maintain compliance and data integrity. Training must be performed and documented but does not require a specific format or delivery method.

Therefore, option A-Training must be performed-is correct, as it reflects the minimum regulatory expectation per FDA and SCDM standards.

Reference (CCDM-Verified Sources):

FDA 21 CFR Part 11, Section 11.10(i) - Personnel Training Requirements

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 5.4 - System Training and Documentation ICH

E6(R2) GCP, Section 2.8 - Qualified Personnel and Training Requirements

### NEW QUESTION # 123

A study has an expected enrollment period of one year but has subject recruitment issues. Twelve new sites are added toward the end of the expected enrollment period to help boost enrollment. What is the most likely impact on data flow?

- A. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- B. Additional sites will likely have increased query rates since site training is occurring closer to study close.
- C. The database set-up will need to be changed to allow for additional sites as they are added to the study.
- **D. A bolus of CRFs at the end of the study will result in the need to increase data entry and cleaning rates to meet existing timelines.**

**Answer: D**

Explanation:

Adding multiple new sites late in the enrollment period creates a concentrated influx of new data near the end of the study. These sites typically start enrolling patients later, resulting in a "bolus" of Case Report Forms (CRFs) that must be entered, validated, and cleaned within a shorter timeframe to meet database lock deadlines.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Data Flow), late site activation compresses the timeline for data management tasks, necessitating increased resources for data entry, query management, and cleaning. Data management teams must anticipate this surge and plan accordingly-either by increasing staffing or revising timelines to prevent bottlenecks and maintain quality.

While option D (increased query rates) can occur, it is a secondary effect. The most direct and consistent impact is the surge in data volume requiring expedited processing near study end.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Project Management, Section 5.3 - Managing Changes in Site Activation and Data Flow ICH E6(R2)

GCP, Section 5.1 - Quality Management and Oversight

### NEW QUESTION # 124

To ensure data quality and efficient integration of data, which of the following best describes the main topic that should be covered in initial discussions with a vendor providing the external data?

- A. Metrics that will be used to measure data quality
- B. Standard dictionary versioning and maintenance
- **C. Acceptable record, field, and file formats**
- D. Criteria to trigger audits based on performance-monitoring reports

**Answer: C**

Explanation:

In initial vendor discussions for external data integration (e.g., central lab, ECG, imaging vendors), the most critical and foundational

topic is defining the acceptable record, field, and file formats.

According to the GCDMP (Chapter: External Data Transfers and Integration), establishing the Data Transfer Specifications (DTS) early in the process ensures consistent structure, proper mapping, and compatibility between the vendor's system and the sponsor's database. These specifications define:

Data structure (variable names, formats, delimiters)

File naming conventions

Frequency of transfers

Methods of secure data transmission

Discussing formats first allows later alignment on data validation, quality metrics, and dictionary standards (which occur in subsequent stages). Without format agreement, all downstream processes risk misalignment, resulting in data incompatibility and rework.

Thus, option C (Acceptable record, field, and file formats) correctly represents the foundational focus of initial vendor discussions for ensuring data quality and integration efficiency.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers and Integration, Section 4.1 - Data Transfer Planning and Specification

Development ICH E6(R2) GCP, Section 5.5.3 - Data Handling and System Validation FDA Guidance: Computerized Systems

Used in Clinical Investigations, Section 6.3 - Data Import and Format Control

## NEW QUESTION # 125

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


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