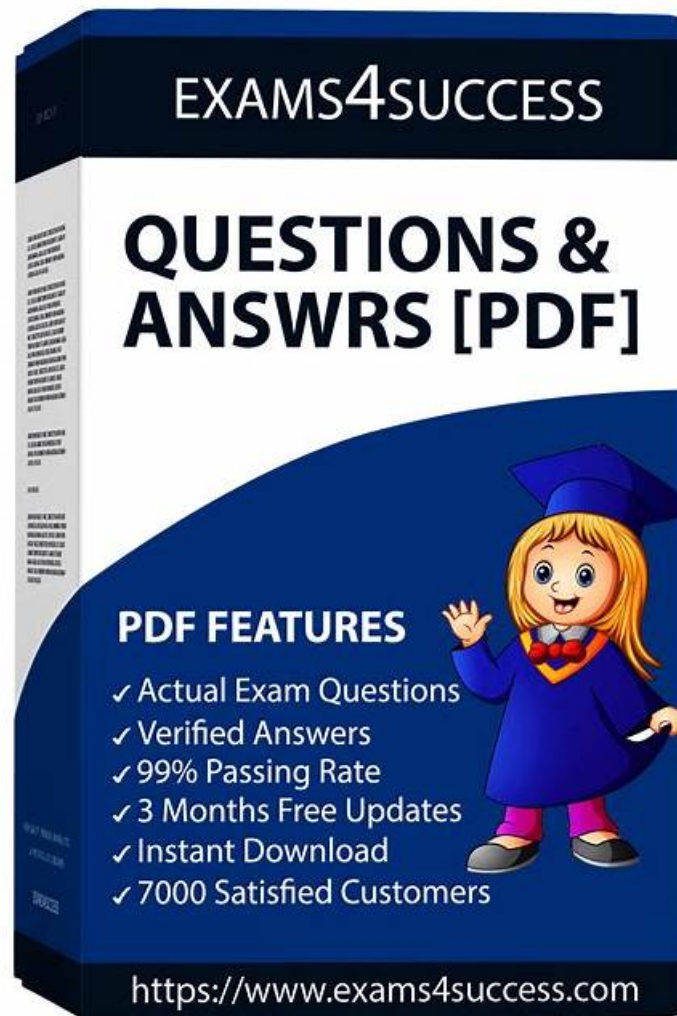


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## SCDM Certified Clinical Data Manager Sample Questions (Q104-Q109):

### NEW QUESTION # 104

A Data Manager is drafting a report for clinical operations staff for support in responding to questions about milestone-based site payments. Which is the most important information to display?

- A. Milestones met by month, by type
- B. Milestones included in the last payment by site, by patient
- C. Expected versus actual milestones met to date, by site
- D. Milestones met by month, by site

**Answer: C**

Explanation:

When reporting milestone-based site payment information, the most critical information to include is expected versus actual milestones met to date, by site.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), effective reporting must support operational and financial decision-making by presenting performance indicators in a clear, actionable format. Site payments in clinical studies are typically tied to specific milestones such as subject enrollment, visit completion, or data cleaning achievements.

By comparing expected (planned) versus actual (achieved) milestones per site, the Data Manager provides clinical operations staff with an accurate view of site progress and payment eligibility. This allows for identification of delayed sites, forecasting of upcoming payments, and early intervention for underperforming centers.

While milestone summaries by month or type (options A and B) may be useful for trend analysis, they lack the operational detail required for financial tracking. Milestone data by patient (option D) is overly granular for site-level payment management.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Data Reporting for Site Performance and Payments ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication and Monitoring Reports FDA Guidance for Industry: Oversight of Clinical Investigations - Site Management and Reporting

### NEW QUESTION # 105

Which type of edit check would be implemented to check the correctness of data present in a text box?

- A. Manual Check
- B. Programmed check
- C. Front-end check
- D. Back-end check

**Answer: C**

Explanation:

A front-end check is a type of real-time validation performed at the point of data entry-typically within an Electronic Data Capture (EDC) system or data entry interface-designed to ensure that the data entered in a text box (or any input field) is valid, logically correct, and within expected parameters before the user can proceed or save the record.

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), edit checks are essential components of data validation that ensure data accuracy, consistency, and completeness. Front-end checks are implemented within the data collection interface and are triggered immediately when data are entered. They prevent invalid entries (such as letters in numeric fields, out-of-range values, or improper date formats) from being accepted by the system.

Examples of front-end checks include:

Ensuring a numeric field accepts only numbers (e.g., weight cannot include text characters).

Validating that a date is within an allowable range (e.g., not before the subject's date of birth).

Requiring mandatory fields to be completed before moving forward.

This differs from back-end checks or programmed checks, which are typically run later in batch processes to identify data inconsistencies after entry. Manual checks are human-performed reviews, often for context or data that cannot be validated automatically (e.g., narrative assessments).

Front-end edit checks are preferred wherever possible because they prevent errors at the source, reducing the number of downstream data queries and cleaning cycles. They contribute significantly to data quality assurance, regulatory compliance, and

efficiency in data management operations.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.2 - Edit Checks and Real-Time Data Validation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Data Entry and Verification Controls ICH E6 (R2) Good Clinical Practice, Section 5.5 - Data Handling and Record Integrity CDISC Operational Data Model (ODM) Specification - Edit Check Implementation Standards

### NEW QUESTION # 106

A Data Manager is establishing a timeline for database lock for a 100-person study where the data have been maintained almost all clean throughout the study. All data from external labs have been received and reconciled. Which is the best estimate of the amount of time needed to lock the database after Last Patient Last Visit?

- A. A few months
- B. A few hours
- C. A few weeks
- **D. A few days**

**Answer: D**

Explanation:

For a well-maintained 100-subject study with ongoing data cleaning and completed reconciliations, the database lock process typically takes a few days after the Last Patient Last Visit (LPLV).

According to the GCDMP (Chapter: Database Lock and Archiving), the duration of the lock process depends on the level of data cleanliness at LPLV. If the study team has conducted continuous data cleaning, query resolution, and external data reconciliation throughout the trial, then the final lock steps (e.g., final data review, documentation, and approvals) can be completed in 2-5 days. However, if significant cleaning or reconciliation remains outstanding, lock may take several weeks. Since the question states that data are "maintained almost all clean," Option B - a few days - is the appropriate estimate.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Lock and Archiving, Section 6.2 - Database Lock Preparation and Timelines ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Quality and Lock Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Lock and Archiving Procedures

### NEW QUESTION # 107

A site study coordinator attempts to make an update in a study database in an EDC system after lock. What occurs?

- A. The old value is replaced in all locations by the new value
- **B. The site study coordinator is not able to make the change**
- C. The change is logged as occurring after lock
- D. The change is approved by the Data Manager before it is applied

**Answer: B**

Explanation:

Once a clinical database is locked, it becomes read-only - no further data modifications can be made by any users, including site personnel. This ensures that the data are finalized, consistent, and auditable for statistical analysis and regulatory submission.

According to the GCDMP (Chapter: Database Lock and Archiving), the lock process involves freezing the database to prevent accidental or unauthorized changes. After lock, access permissions are restricted, and all edit and update functions are disabled. If any corrections are required post-lock, the database must be unlocked under controlled procedures (with full audit trail documentation).

Thus, option C - The site study coordinator is not able to make the change - correctly reflects standard EDC functionality and regulatory compliance.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.2 - Database Lock Procedures and Controls ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Audit Trail Requirements FDA 21 CFR Part 11 - Controls for Electronic Records and System Lock Functions

### NEW QUESTION # 108

In the EDC database, which factors are considered when defining user roles?

- **A. Data Entry and Data Review**
- B. Protocol Review and Data Entry
- C. Data Review and Analysis Programming
- D. Patient Recruitment and Protocol Review

**Answer: A**

Explanation:

In Electronic Data Capture (EDC) systems, user roles are defined based on the functions and permissions required for specific study tasks. The most fundamental and universally applicable roles are Data Entry (performed by site staff) and Data Review (performed by monitors or data managers).

According to the GCDMP (Chapter: Technology and Electronic Data Capture Systems), defining user roles involves:

Assigning functional access levels (e.g., entry, review, query resolution).

Ensuring role-based security to protect data integrity.

Complying with 21 CFR Part 11 and ICH E6(R2) access control standards.

Options B, C, and D include functions (protocol review, analysis programming) not directly controlled within an EDC system.

Thus, option A (Data Entry and Data Review) correctly represents the two core factors considered when defining user roles.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Technology and Electronic Data Capture Systems, Section 4.3 - User Access, Roles, and Permissions

ICH E6(R2) GCP, Section 5.5.3 - System Access and Security Controls  
FDA 21 CFR Part 11 - Access Control and Audit Trail Requirements

## NEW QUESTION # 109

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