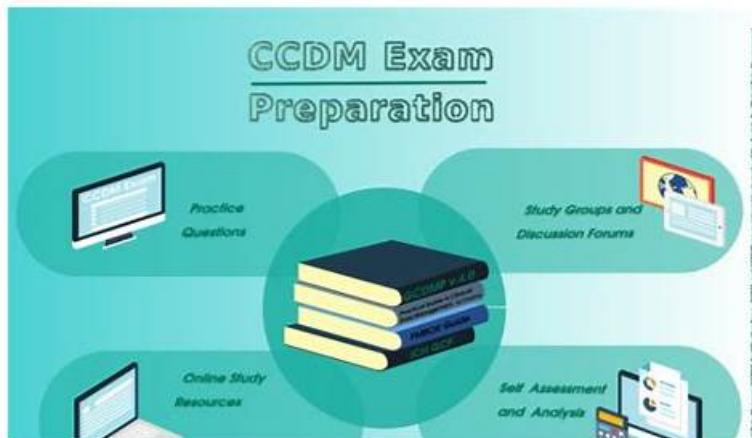


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## SCDM Certified Clinical Data Manager Sample Questions (Q66-Q71):

### NEW QUESTION # 66

During an inspection to determine appropriate documentation for use of a computerized system, what SOP might the inspector expect to find?

- A. Data management plan
- B. Statistical analysis plan
- C. Data backup plan
- D. Edit specifications

**Answer: C**

Explanation:

During a regulatory inspection, inspectors expect to find documented Standard Operating Procedures (SOPs) governing the use, validation, and maintenance of computerized systems, including data backup and recovery procedures.

According to the GCDMP (Chapter: Computerized Systems and Compliance) and FDA 21 CFR Part 11, organizations must

maintain an SOP that ensures data protection against loss, corruption, or unauthorized access. The SOP should describe backup frequency, secure storage, verification of backup integrity, and procedures for data restoration.

While the Data Management Plan (A) and Edit Specifications (D) are study-level documents, and the Statistical Analysis Plan (C) focuses on analysis procedures, only a Data Backup Plan (B) constitutes a required system-level SOP ensuring compliance and data continuity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 5.2 - Data Security, Backup, and Recovery SOPs  
FDA 21 CFR Part 11 - Subpart B, Controls for Closed Systems ICH E6(R2) GCP, Section 5.5.3 - System Security, Data Backup, and Recovery Requirements

## NEW QUESTION # 67

A Data Manager is designing a CRF for a study for which the efficacy data are not covered by the current SDTM domains. Which search should the Data Manager do?

- A. Use controlled terminology covering the needed concepts
- **B. Search for relevant data element standards**
- C. Advise the study team not to collect the data
- D. Work with the study team to define new data elements

**Answer: B**

Explanation:

When existing SDTM (Study Data Tabulation Model) domains do not cover specific efficacy data, the best practice is to first search for relevant data element standards that may be available through CDISC CDASH (Clinical Data Acquisition Standards Harmonization) or other recognized industry standards.

Per GCDMP (Chapter: Standards and Data Integration), Data Managers must ensure that new CRF elements are consistent with standardized definitions, controlled terminology, and data models to support interoperability, future analysis, and regulatory submission.

If no existing standards exist, only then should the Data Manager collaborate with the study team to define new elements - but standard searches always come first.

Thus, option C is correct - search for relevant data element standards ensures alignment with CDISC best practices and regulatory expectations.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.1 - Use of CDISC Standards in CRF Design CDISC CDASH Implementation Guide, Section 4.1 - Standardization of Data Collection Fields FDA Study Data Technical Conformance Guide (SDTCG), Section 2.4 - Use of Standard and Custom Domains

## NEW QUESTION # 68

When reviewing local lab data from a paper study, a Data Manager notices there are lab values not entered. What should the Data Manager request data-entry personnel do?

- **A. Issue a query**
- B. Nothing
- C. Call the patient to verify the information
- D. Flag the module for review

**Answer: A**

Explanation:

When laboratory data are missing from a paper-based clinical study, the Data Manager should direct data-entry personnel to issue a query to the investigative site for clarification or correction.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), every missing, inconsistent, or out-of-range data point must be reviewed and, if necessary, resolved through the formal query management process. This ensures that all discrepancies between the source documents and database entries are properly documented, traceable, and auditable.

Data-entry staff are not authorized to infer or fill in missing information. They must escalate such discrepancies to the site via query, preserving data integrity and regulatory compliance with ICH E6 (R2) and FDA 21 CFR Part 11. Calling the patient directly (option B) would violate confidentiality and site communication protocol, while simply flagging or ignoring the issue (options A and D) would not meet GCDMP query resolution standards.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.2 - Query Management and Resolution ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication of Data Discrepancies FDA 21 CFR Part 11 - Electronic Records; Query Audit Trails Requirements

### NEW QUESTION # 69

Who has primary responsibility for ensuring accurate completion of the CRF?

- A. Site Coordinator
- B. Clinical Research Associate
- C. Clinical Data Manager
- D. Investigator

**Answer: D**

Explanation:

The Investigator holds the primary responsibility for ensuring the accuracy, completeness, and timeliness of Case Report Form (CRF) entries. This responsibility is mandated by regulatory requirements under ICH E6(R2) Good Clinical Practice (GCP). The investigator may delegate CRF completion to a qualified designee (e.g., site coordinator), but the ultimate accountability remains with the investigator. The investigator's signature (electronic or manual) on the CRF serves as certification that the data accurately reflect the source documents and the patient's participation.

The GCDMP (Chapter: CRF Design and Data Collection) reinforces this by stating that while data managers ensure design quality and CRAs verify consistency with source data, the investigator is legally responsible for CRF accuracy.

Thus, option D (Investigator) is correct, as it aligns with both GCP and CCDM standards.

Reference (CCDM-Verified Sources):

ICH E6(R2) GCP, Section 4.9 - Records and Reports (Investigator Responsibilities) SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 5.1 - Investigator's Role in Data Accuracy FDA 21 CFR Part 312.62 - Investigator Recordkeeping and Record Retention

### NEW QUESTION # 70

On a dose escalation study, the Data Manager notices one site has a much higher number of queries than other sites and most are older than 30 days. The Data Safety Monitoring Board will meet in three weeks. What should the Data Manager providing CRO oversight do?

- A. Call the site directly and ask the study coordinator about the concerns
- B. Consult the CRO's Lead Data Manager and the CRO's Project Leader
- C. Notify the CRO's Clinical Leader about the concerns
- D. Ignore it for now and check back next week

**Answer: B**

Explanation:

The correct action is to consult the CRO's Lead Data Manager and CRO's Project Leader (Option C) to ensure the issue is addressed through the appropriate oversight and escalation process.

According to the GCDMP (Chapter: Project Management and Communication), when a sponsor Data Manager identifies significant data management issues under CRO oversight - such as aging queries or site performance disparities - communication must follow the established governance and escalation pathway defined in the Scope of Work (SOW) and Data Management Plan (DMP).

Directly contacting the site (Option B) bypasses the CRO's chain of command and violates communication protocols. Notifying only the Clinical Leader (Option A) is insufficient, and ignoring the issue (Option D) jeopardizes the Data Safety Monitoring Board (DSMB) review timeline.

Therefore, Option C ensures a documented, collaborative approach to problem resolution within the contractual oversight structure.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 7.1 - Oversight of CRO Data Management Activities ICH E6 (R2) GCP, Section 5.2 - Contract Research Organization Responsibilities FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Roles and Communication Pathways

### NEW QUESTION # 71

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