

# 100% Pass 2026 Efficient CCDM: Reliable Certified Clinical Data Manager Mock Test

## Certified Clinical Data Manager (CCDM) Practice Exam

**Question 1: What does Clinical Data Management primarily involve?**

- A. Developing clinical protocols
- B. Ensuring accurate and timely collection, validation, and reporting of trial data
- C. Marketing clinical research findings
- D. Overseeing patient recruitment processes

Answer: B

Explanation: Clinical Data Management focuses on collecting, validating, and reporting trial data accurately and on time, which is essential for reliable study outcomes.

**Question 2: Which stakeholder is primarily responsible for overseeing regulatory compliance of clinical trial data?**

- A. Clinical Data Manager
- B. Sponsor
- C. Regulatory Bodies
- D. Site Investigator

Answer: C

Explanation: Regulatory bodies, such as the FDA, are charged with ensuring that clinical trial data meets regulatory standards.

**Question 3: Which document outlines the procedures for data collection and management in clinical trials?**

- A. Informed Consent Form
- B. Data Management Plan
- C. Clinical Study Report
- D. Investigator Brochure

Answer: B

Explanation: The Data Management Plan (DMP) details the procedures for data collection, validation, cleaning, and reporting throughout the trial.

**Question 4: What is a key responsibility of a Clinical Data Manager?**

- A. Designing marketing strategies
- B. Managing data validation and query resolution
- C. Recruiting study participants
- D. Developing new drugs

Answer: B

Explanation: Clinical Data Managers are responsible for data validation, ensuring data integrity, and managing queries to resolve discrepancies.

**Question 5: Which guideline is commonly followed to ensure data quality in clinical trials?**

- A. ICH-GCP
- B. ISO 9001
- C. Six Sigma

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## SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none"> <li>• Design Tasks: This section of the CCDM exam measures skills of Data Managers and covers how to design and document data collection instruments, develop workflows and data flows, specify data elements, CRF forms, edit checks, reports, database structure, and define standards and procedures for traceability and auditability.</li> </ul>
Topic 2	<ul style="list-style-type: none"> <li>• Testing Tasks: This section measures the skills of Data Managers and involves creating test plans, generating test data, executing validation and user acceptance testing, and documenting results to ensure systems and processes perform reliably and according to specifications.</li> </ul>

Topic 3	<ul style="list-style-type: none"> <li>• <b>Data Processing Tasks:</b> This section measures skills of Clinical Systems Analysts and focuses on handling, transforming, integrating, reconciling, coding, querying, updating, and archiving study data while maintaining quality, consistency, and proper privileges over the data lifecycle.</li> </ul>
Topic 4	<ul style="list-style-type: none"> <li>• <b>Coordination and Project Management Tasks:</b> This domain evaluates the skills of a Clinical Systems Analyst in coordinating data management workload, vendor selection, scheduling, cross-team communication, project timeline management, risk handling, metric tracking, and preparing for audits.</li> </ul>
Topic 5	<ul style="list-style-type: none"> <li>• <b>Review Tasks:</b> This section measures the skills of Data Managers and involves reviewing protocols, CRFs, data tables, listings, figures, and clinical study reports (CSRs) for consistency, accuracy, and alignment with data handling definitions and regulatory requirements.</li> </ul>

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### SCDM Certified Clinical Data Manager Sample Questions (Q59-Q64):

#### NEW QUESTION # 59

Which of the following is the best reason for a statistician to review the case report form prior to using it in a study?

- A. To ensure the layout will make a logical, useful programming guide
- **B. To ensure the data from the CRF can be analyzed for safety and efficacy**
- C. To ensure the header fields will provide a unique key for each subject
- D. To ensure the variable names conform to statistical programming standards

**Answer: B**

Explanation:

The primary reason a statistician reviews the Case Report Form (CRF) is to ensure that the data being collected will support the planned statistical analyses for both safety and efficacy endpoints.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), CRF design should always align with the statistical analysis plan (SAP) to ensure that all necessary data elements are collected accurately and in analyzable formats. The statistician verifies that the CRF captures:

All endpoints specified in the protocol

Proper derivation or calculation fields

Timing of assessments

Consistency across visits and forms

Options B, C, and D address secondary or technical design considerations but not the primary analytical purpose. The review ensures that the CRF provides a complete and analyzable dataset for meeting study objectives, regulatory submissions, and statistical integrity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 4.4 - Role of Statistics in CRF Design ICH E9 - Statistical Principles for Clinical Trials, Section 5.2 - Data Collection and Analysis Alignment FDA Guidance for Industry: E6(R2) GCP, Section 5.1 - Quality Management and Design Input from Stakeholders

#### NEW QUESTION # 60

When a hospitalized subject in a cardiovascular trial experiences a repeated but mild episode of tachycardia, the physician decides to extend the subject's hospital stay for continued observation. How would this event be characterized?

- A. Adverse event
- **B. Serious adverse event**
- C. Spontaneous adverse event
- D. Severe adverse event

**Answer: B**

Explanation:

This event qualifies as a Serious Adverse Event (SAE) because it resulted in a prolonged hospitalization, even though the episode itself was mild.

According to ICH E2A and GCDMP (Chapter: Safety Data Handling and Reconciliation), an adverse event is considered "serious" if it results in any of the following outcomes:

Death,

Life-threatening situation,

Hospitalization or prolongation of existing hospitalization,

Persistent or significant disability/incapacity, or

Congenital anomaly/birth defect.

The severity (mild, moderate, severe) describes intensity, while seriousness describes regulatory significance and medical outcome.

Thus, a mild tachycardia episode leading to extended hospital stay meets the regulatory definition of an SAE.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Safety Data Handling and Reconciliation, Section 5.2 - Definition and Classification of Serious Adverse Events ICH E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, Section II - Seriousness Criteria FDA 21 CFR 312.32 - IND Safety Reporting: Serious Adverse Event Definitions

#### **NEW QUESTION # 61**

A Clinical Data Manager reads a protocol for a clinical trial to test the efficacy of an antiviral to counteract a new epidemic. The stated primary efficacy endpoint is 3-month survival. Which data element is needed for the primary efficacy endpoint?

- A. Birth date
- B. Date of autopsy
- **C. Death date**
- D. Cause of death

**Answer: C**

Explanation:

When the primary efficacy endpoint in a clinical trial is 3-month survival, the key data element required is the death date. This is because the survival endpoint is determined by calculating whether the subject lived or died within a defined time frame from study enrollment or randomization.

According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the Clinical Data Manager (CDM) must identify and ensure the capture of all critical data elements necessary to evaluate the study endpoints. For time-to-event analyses (e.g., survival studies), accurate event dates (death date) are essential for endpoint derivation and statistical analysis.

Other data elements such as cause of death or date of autopsy (options B and C) may support secondary analyses or safety reviews but are not necessary to determine the survival endpoint itself. Similarly, birth date (option D) contributes to demographic data but is unrelated to the primary efficacy outcome.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.4 - Critical Data Identification for Endpoints ICH E9 - Statistical Principles for Clinical Trials, Section 2.2.3 - Time-to-Event Data Considerations FDA Guidance for Industry: Clinical Trial Endpoints for Drug Development

#### **NEW QUESTION # 62**

Which data are needed to monitor site variability in eligibility screening?

- **A. Number of subjects screened and number of subjects enrolled**
- B. Number of sites with high enrollment
- C. Number of subjects enrolled
- D. Number of sites with low enrollment

**Answer: A**

Explanation:

To monitor site variability in eligibility screening, you must analyze the number of subjects screened versus the number of subjects enrolled at each site. This allows identification of sites that are over- or under-screening relative to their enrollment yield.

The GCDMP (Chapter: Data Quality Assurance and Metrics) emphasizes that screening-to-enrollment ratios are critical indicators of protocol compliance and data quality. Sites with unusually low conversion rates may have unclear understanding of inclusion/exclusion criteria, requiring targeted training or monitoring.

Other options (A, C, D) provide enrollment metrics but do not reveal screening efficiency or variability, which depend on both screening and enrollment data.

Thus, option B correctly identifies the data necessary for monitoring eligibility screening performance across sites.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Metrics, Section 5.4 - Site Performance Metrics ICH E6(R2) GCP, Section 5.18 - Monitoring and Site Oversight Requirements

### NEW QUESTION # 63

Which method would best identify clinical chemistry lab data affected by a blood draw taken distal to a saline infusion?

- A. Abnormally low urine glucose values in a dataset
- B. Abnormally high sodium values in a dataset
- C. Lab values from a blood draw with a very low sodium and very high other values
- **D. Lab values from a blood draw with a very high sodium and very low other values**

**Answer: D**

Explanation:

If a blood sample is drawn distal (downstream) from a saline infusion site, it may become contaminated with saline, leading to abnormal laboratory results. Saline contains a high concentration of sodium chloride, which artificially elevates sodium while diluting other blood components.

Therefore, such samples would display:

Very high sodium levels, and

Abnormally low levels of other analytes (e.g., proteins, glucose, potassium).

This abnormal pattern (option B) is a classic indicator of saline contamination.

Per the GCDMP (Chapter: Data Validation and Cleaning), cross-variable consistency checks are critical for identifying biologically implausible patterns, such as this one, which indicate pre-analytical errors rather than true physiological changes.

Hence, option B accurately describes the data signature of a contaminated blood draw.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 6.2 - Logical and Consistency Checks for Laboratory Data ICH E6(R2) GCP, Section 5.1.1 - Data Quality and Biological Plausibility Checks FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Detecting Laboratory Anomalies

### NEW QUESTION # 64

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