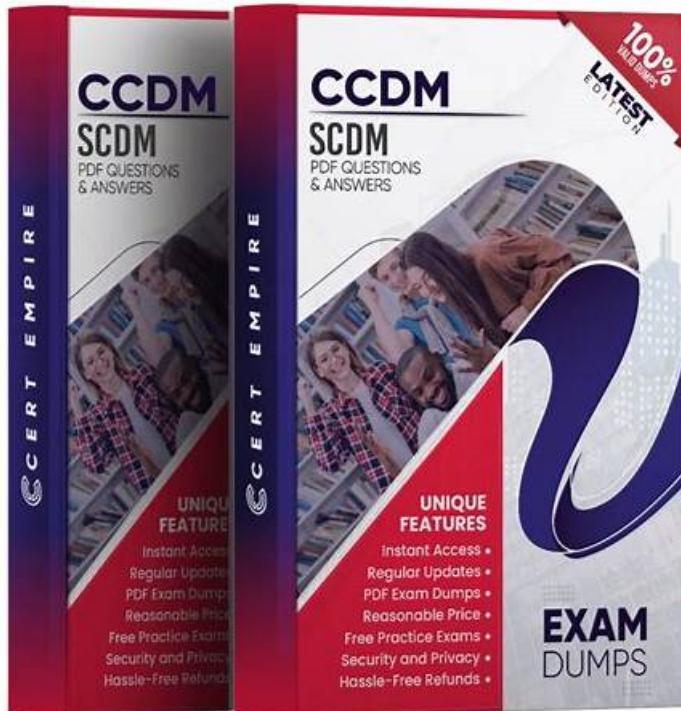


SCDM CCDM Exam Online - CCDM Valid Exam Test



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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">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.
Topic 2	<ul style="list-style-type: none">Coordination and Project Management Tasks: 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.
Topic 3	<ul style="list-style-type: none">Review Tasks: 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.
Topic 4	<ul style="list-style-type: none">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.

Topic 5	<ul style="list-style-type: none"> • Data Processing Tasks: 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.
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SCDM's Realistic CCDM Exam Questions with Accurate Answers Prepare You for Success

More and more people hope to enhance their professional competitiveness by obtaining CCDM certification. However, under the premise that the pass rate is strictly controlled, fierce competition makes it more and more difficult to pass the CCDM examination. In order to guarantee the gold content of the CCDM Certification, the official must also do so. However, it is an indisputable fact that a large number of people fail to pass the CCDM examination each year, some of them may choose to give it up while others may still choose to insist.

SCDM Certified Clinical Data Manager Sample Questions (Q83-Q88):

NEW QUESTION # 83

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

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

Answer: C

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 # 84

What should be done if the site continues to provide inconsistent data after several re-queries?

- A. Continue to re-query until the site changes the data
- B. Do nothing, the data will remain inconsistent
- **C. Escalate the issue to the appropriate site contact personnel**
- D. Gently lead the site to the correct response

Answer: C

Explanation:

If a clinical site continues to provide inconsistent or illogical data after multiple queries, the correct course of action is to escalate the issue to the appropriate site contact personnel, typically the Clinical Research Associate (CRA) or Site Monitor.

According to the Good Clinical Data Management Practices (GCDMP), persistent data discrepancies often indicate a misunderstanding of the protocol, CRF instructions, or data entry procedures at the site level. Repeatedly re-querying the same data without escalation wastes time and risks introducing bias or error. By escalating through formal communication channels, the issue

can be clarified through re-training, documentation review, or site monitoring visits.

The GCDMP emphasizes that escalation ensures data accuracy, site accountability, and protocol adherence, maintaining both data quality and regulatory compliance. Data managers must document the escalation process in the Data Management Plan (DMP) and ensure proper follow-up resolution is achieved.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 4.2 - Handling Persistent Data Discrepancies ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Communication FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Issue Escalation

NEW QUESTION # 85

A study team member wants to let sites enroll patients before the system is ready. Which are important considerations?

- A. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study
- B. If the study were audited, enrolling subjects prior to having the EDC system ready would become an audit finding
- C. There is no way to identify, report and track adverse events and serious adverse events without the EDC system in place
- D. Starting the study prior to the EDC system being ready will delay processing of milestone-based site payments

Answer: A

Explanation:

Enrolling subjects before the Electronic Data Capture (EDC) system is ready poses major data integrity and compliance risks. The primary issue is that data cannot be accurately captured, validated, or monitored without the system in place.

Per the GCDMP (Chapter: Data Management Planning and Study Start-up), data collection systems must be fully validated, tested, and released before enrollment begins to ensure:

Real-time data entry and quality control

Proper tracking of adverse events (AEs/SAEs)

Audit trails and traceability for regulatory compliance

Option A highlights the most critical consequence - without an operational EDC, data collection and verification processes cannot occur, compromising data quality and study oversight.

While options B, C, and D may be partially true, they are secondary effects. The fundamental consideration is data capture capability and monitoring control, making option A correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Management Planning and Study Start-up, Section 4.2 - EDC Readiness and System Validation ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation Before Use FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - System Qualification Prior to Data Entry

NEW QUESTION # 86

Which document describes what study subjects expect with respect to data disclosure during and after a study?

- A. Informed consent form
- B. Study data sharing plan
- C. Study protocol
- D. ICH essential documents

Answer: A

Explanation:

The Informed Consent Form (ICF) is the document that explicitly describes what study subjects can expect regarding data disclosure, privacy, and confidentiality during and after participation in a clinical trial. According to ICH E6 (R2) Good Clinical Practice and FDA Human Subject Protection Regulations (21 CFR Parts 50 and 56), participants must be fully informed about how their personal and clinical data will be collected, used, stored, and shared - both during the study and in any subsequent data-sharing or publication activities.

The GCDMP reiterates that clinical data managers must ensure that all data handling practices align with the privacy commitments made in the ICF. This includes compliance with data protection regulations such as HIPAA (in the U.S.) and GDPR (in the EU).

The ICF defines the permissible scope of data use, ensuring ethical management and subject protection.

Documents like the protocol or data sharing plan may outline procedures and responsibilities but do not directly inform participants of their rights and data use expectations. Only the ICF is designed for that ethical communication purpose.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Ethics, Privacy, and Data Security ICH E6 (R2) Good

NEW QUESTION # 87

Which Clinical Study Report section would be most useful for a Data Manager to review?

- A. Description of how data were processed
- B. Description of statistical analysis methods
- C. Clinical narratives of adverse events
- D. Rationale for the study design

Answer: A

Explanation:

The section of the Clinical Study Report (CSR) most useful for a Data Manager is the description of how data were processed. According to the GCDMP (Chapter: Data Quality Assurance and Control), this section details the data handling methodology - including data cleaning, coding, transformation, and derivation procedures - all of which are core responsibilities of data management. Reviewing this section ensures that the data processing methods documented in the CSR align with the Data Management Plan (DMP), Data Validation Plan (DVP), and database specifications.

The statistical methods section (option A) is primarily for biostatistics, and the rationale for study design (option B) pertains to clinical and regulatory affairs. Clinical narratives (option D) are used by medical reviewers, not data managers.

By reviewing how data were processed, the Data Manager verifies that the study data lifecycle - from collection to analysis - was conducted in compliance with regulatory and GCDMP standards.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.3 - Documentation of Data Processing in Clinical Study Reports ICH E3 - Structure and Content of Clinical Study Reports, Section 11.3 - Data Handling and Processing FDA Guidance for Industry: Clinical Study Reports and Data Submission - Data Traceability and Handling Documentation

NEW QUESTION # 88

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