

CCDM인기자격증최신시험덤프자료, CCDM합격보장 가능덤프공부



2026 PassTIP 최신 CCDM PDF 버전 시험 문제집과 CCDM 시험 문제 및 답변 무료 공유: <https://drive.google.com/open?id=1JNbcZGflB4yLnIyGYUJ78Xj6HoToIdrq>

SCDM인증 CCDM시험은 멋진 IT전문가로 거듭나는 길에서 반드시 넘어야 할 높은 산입니다. SCDM인증 CCDM시험 문제 패스가 어렵다 한들 PassTIP덤프만 있으면 패스도 간단한 일로 변경됩니다. PassTIP의 SCDM인증 CCDM덤프는 100% 시험패스율을 보장합니다. SCDM인증 CCDM시험문제가 업데이트되면 SCDM인증 CCDM덤프도 바로 업데이트하여 무료 업데이트서비스를 제공해드리기에 덤프유효기간을 연장하는 것으로 됩니다.

SCDM CCDM 시험요강:

주제	소개
주제 1	<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.
주제 2	<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.

주제 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.
주제 4	<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.
주제 5	<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.

>> CCDM인기자격증 최신시험 덤프자료 <<

시험준비에 가장 좋은 CCDM인기자격증 최신시험 덤프자료 덤프데모문제 다운

PassTIP는 완전히 여러분이 인증시험준비와 안전이 시험패스를 위한 완벽한 덤프제공사이트입니다.우리 PassTIP의 덤프들은 응시자에 따라, 시험, 시험방법에 따라 제품의 완성도도 다릅니다. 그 말은 즉 알맞춤 자료입니다. 여러분은 PassTIP의 알맞춤 덤프들로 아주 간단하고 편안하게 패스할 수 있습니다. 많은 SCDM인증관련 응시자들은 모두 우리PassTIP가 제공하는 CCDM문제와 답 덤프로 자격증 취득을 했습니다. 때문에 우리PassTIP또한 업계에서 아주 좋은 이미지를 가지고 있습니다

최신 Clinical Data Management CCDM 무료샘플문제 (Q113-Q118):

질문 # 113

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 site
- 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 type

정답: C

설명:

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

질문 # 114

The best example of a protocol compliance edit check is:

- A. An edit check that fires when a visit date is outside the specified window
- B. An edit check that fires when an invalid date is entered
- C. An edit check that fires when a value is outside of the normal range for vital signs
- D. An edit check that fires when a field is left blank

정답: A

설명:

A protocol compliance edit check is designed to ensure that the data collected adheres to the specific requirements defined in the study protocol, such as visit timing, procedure windows, and eligibility criteria.

The example in option A - an edit check that triggers when a visit date falls outside the protocol-specified window - directly verifies compliance with the study design. This type of check supports real-time monitoring of protocol adherence, a critical quality and regulatory requirement under GCDMP and ICH E6(R2).

Other options are examples of general data validation checks, not protocol compliance:

B: Ensures clinical plausibility (data range check).

C: Ensures completeness (missing data check).

D: Ensures format correctness (system validation check).

Thus, option A best represents a protocol compliance edit check, confirming that collected data conform to the visit schedule defined in the protocol.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.4 - Protocol Compliance Edit Checks ICH E6(R2) GCP, Section 5.1.1 - Quality Management and Compliance Controls FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Edit Check Design and Validation

질문 # 115

During testing of an ePRO system, a test fails. Which information should be found in the validation documentation?

- A. Expected and actual results
- B. Reconciliation datapoints
- C. Root cause analysis of the system errors
- D. Training requirements

정답: A

설명:

When a system validation test fails during Electronic Patient-Reported Outcome (ePRO) system testing, the validation documentation must record the expected results (what should have occurred) and the actual results (what occurred).

According to the GCDMP (Chapter: Database Validation and Testing), proper system validation documentation ensures traceability, reproducibility, and compliance with FDA 21 CFR Part 11 and ICH E6 (R2). Each test case must include:

Test objective,

Preconditions,

Test steps,

Expected results,

Actual results, and

Pass/fail status.

If a test fails, this documentation provides the objective evidence necessary for deviation handling, issue resolution, and re-testing.

While a separate root cause analysis may be performed later (option D), the validation record itself must focus on verifying outcomes against predefined expectations.

Therefore, the correct answer is B - Expected and actual results.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Validation and Testing, Section 4.4 - Documentation of Test Results FDA 21 CFR Part 11 - Validation Requirements (Section 11.10(a)) ICH E6 (R2) GCP, Section 5.5.3 - Computer System Validation and Documentation

질문 # 116

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

정답: A

설명:

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

질문 # 117

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

정답: D

설명:

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

질문 # 118

SCDM CCDM인증 시험은 현재IT업계에서 아주 인기 있는 시험입니다. 많은 IT인사들이 관련 자격증을 취득하려고 노력하고 있습니다. SCDM CCDM인증 시험에 대한 열기는 식지 않습니다. SCDM CCDM자격증은 여러분의 사회생활에 많은 도움이 될 것이며 연봉상승 등 생활보장에 업그레이드 될 것입니다.

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