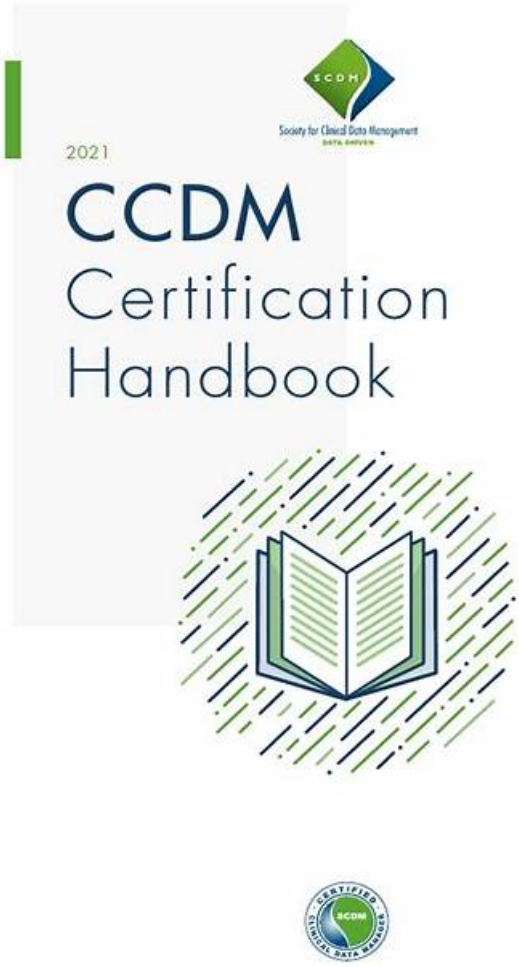
CCDM試験資料 & CCDM関連資格試験対応



P.S.PassTestがGoogle Driveで共有している無料の2026 SCDM CCDMダンプ：https://drive.google.com/open?id=1S2F2euFUH1FTdYQN4TzPNNQgogl0qpGi

PassTestは多くの認証業界の評判を持っています。それは我々はSCDMのCCDM問題集やCCDMスタディガイドやCCDM問題と解答がたくさんありますから。現在のサイトで最もプロなITテストベンダーとして我々は完璧なアフターサービスを提供します。全てのお客様に追跡サービスを差し上げますから、あなたが買ったあとの一年間で、弊社は全てのお客様に問題集のアップグレードを無料に提供します。その間で認定テストセンターのSCDMのCCDM試験問題は修正とか表示されたら、無料にお客様に保護して差し上げます。SCDMのCCDM試験問題集はPassTestのIT領域の専門家が心を込めて研究したものですから、PassTestのSCDMのCCDM試験資料を手に入れると、あなたが美しい明日を迎えることと信じています。

SCDM CCDM 認定試験の出題範囲：

トピック	出題範囲
トピック 1	• 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.
トピック 2	• 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.

トピック 3	• 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.
トピック 4	• 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.
トピック 5	• 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.

SCDM Certified Clinical Data Manager 認定 CCDM 試験問題 (Q137-Q142):

質問 # 137
During testing of an ePRO system, a test fails. Which information should be found in the validation documentation?

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

正解：B

解説：
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

質問 # 138
An organization is using an international data exchange standard and a new version is released. Which of the following should be assessed first?

- A. Existence of backwards compatibility
- B. Cost of migrating to the new version
- C. Content coverage of the new version
- D. Availability of other standards covering the same content

正解：A

解説：
When an updated version of a data exchange standard (such as CDISC SDTM, ADaM, or ODM) is released, the first factor that should be assessed is backwards compatibility. This determines whether the new version can interoperate with or accept data from prior versions without significant reconfiguration or data loss.
According to the Good Clinical Data Management Practices (GCDMP) and CDISC Implementation Guides, assessing backwards compatibility ensures that historical or ongoing study data remain valid and usable within the updated environment. If the new version introduces structural or semantic changes (such as variable name modifications or controlled terminology updates), it could impact mapping, validation, or regulatory submissions.
Once backward compatibility is confirmed, secondary assessments such as content coverage, availability of overlapping standards, and migration cost can be considered. However, ensuring that the new version supports existing infrastructure and data continuity is the first critical step before adoption.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Standards and Data Integration, Section 4.2 - Data Standards Updates and Compatibility Considerations CDISC SDTM Implementation Guide, Section 1.5 - Backward Compatibility and Version Control ICH E6(R2) GCP, Section 5.5 - Data Handling and Standardization

質問 # 139
Which data are needed to monitor site variability in eligibility screening?

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

正解：D

解説：
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

質問 # 140
In reviewing the adverse events for a subject, a data manager notices one recorded as "worsening of migraine." After reviewing the rest of the adverse events and finding no other migraine recordings, what is the data manager's next step?

- A. Look for any adverse event instance of headache and assume the events are similar.
- B. Check the medical history for recording of a history of migraines.
- C. Query the site for more information on the adverse event, "worsening of migraine."
- D. Query the site for the first adverse event occurrence of migraine.

正解：C

解説：
When a data inconsistency arises - such as a record of "worsening of migraine" without prior documentation of a migraine episode - the Data Manager should query the site for clarification (Option D).
According to the GCDMP (Chapter: Data Validation and Cleaning), data managers must raise a clarification query whenever data appear incomplete, inconsistent, or ambiguous. The site must confirm whether "worsening of migraine" refers to a new event or an exacerbation of a preexisting condition. This clarification ensures accurate safety reporting and appropriate medical coding (e.g., MedDRA classification).
Checking the medical history (Option C) may help but does not resolve the inconsistency. Assuming a relationship (Option A or B) without verification would violate Good Clinical Data Management Practice and potentially misrepresent the adverse event.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.3 - Query Generation and Resolution ICH E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, Section II - Data Clarification Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Query Management

質問 # 141
A study has an expected enrollment period of one year but has subject recruitment issues. Twelve new sites are added toward the end of the expected enrollment period to help boost enrollment. What is the most likely impact on data flow?

- A. The database set-up will need to be changed to allow for additional sites as they are added to the study.
- B. A bolus of CRFs at the end of the study will result in the need to increase data entry and cleaning rates to meet existing timelines.
- C. Additional sites will likely have increased query rates since site training is occurring closer to study close.
- D. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.

正解：B

解説：
Adding multiple new sites late in the enrollment period creates a concentrated influx of new data near the end of the study. These sites typically start enrolling patients later, resulting in a "bolus" of Case Report Forms (CRFs) that must be entered, validated, and cleaned within a shorter timeframe to meet database lock deadlines.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Data Flow), late site activation compresses the timeline for data management tasks, necessitating increased resources for data entry, query management, and cleaning. Data management teams must anticipate this surge and plan accordingly-either by increasing staffing or revising timelines to prevent bottlenecks and maintain quality.
While option D (increased query rates) can occur, it is a secondary effect. The most direct and consistent impact is the surge in data volume requiring expedited processing near study end.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management, Section 5.3 - Managing Changes in Site Activation and Data Flow ICH E6(R2) GCP, Section 5.1 - Quality Management and Oversight

質問 # 142
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- SCDM CCDM試験資料: いい加減CCDM関連資格試験対応 □ ウェブサイト➽ www.goshiken.com □を開き、➽ CCDM □を検索して無料でダウンロードしてくださいCCDM関連資料
- SCDM CCDM試験資料: いい加減CCDM関連資格試験対応 □ 「 www.japancert.com 」にて限定無料の《 CCDM 》問題集をダウンロードせよCCDM技術問題
- 効果的なSCDM CCDM試験資料 - 合格スムーズCCDM関連資格試験対応 | 実用的なCCDMテスト問題集 □ 【 www.goshiken.com 】で[CCDM]を検索して、無料で簡単にダウンロードできますCCDM認定資格試験問題集
- CCDM模擬解説集 □ CCDM資格受験料 □ CCDM関連資料 □ 検索するだけで➽ www.passtest.jp □から（ CCDM ）を無料でダウンロードCCDM資格受験料
- CCDM認定資格試験問題集 □ CCDM問題無料 □ CCDM技術問題 □□ ➤ www.goshiken.com □で➤ CCDM □を検索して、無料でダウンロードしてくださいCCDMミシュレーション問題
- 効果的なSCDM CCDM試験資料 - 合格スムーズCCDM関連資格試験対応 | 実用的なCCDMテスト問題集 □ □ CCDM □の試験問題は➥ www.goshiken.com □で無料配信中CCDM実際試験
- 素敵なCCDM試験資料一回合格-高品質なCCDM関連資格試験対応 □ ☀ www.goshiken.com □☀□サイトにて最新➠ CCDM □問題集をダウンロードCCDM資格受験料
- 完璧なCCDM丨権威のあるCCDM試験資料試験丨試験の準備方法Certified Clinical Data Manager関連資格試験対応 □ ウェブサイト➽ www.it-passports.com □を開き、➽ CCDM □を検索して無料でダウンロードしてくださいCCDM試験情報
- lilygwvj957966.tusblogos.com, www.stes.tyc.edu.tw, montyvgle814850.glifeblog.com, thebookmarkid.com, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, gogogobookmarks.com, www.stes.tyc.edu.tw, www.stes.tyc.edu.tw, dianeibsw157270.thenerdsblog.com, mattiepwfg010629.theblogfairy.com, Disposable vapes

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