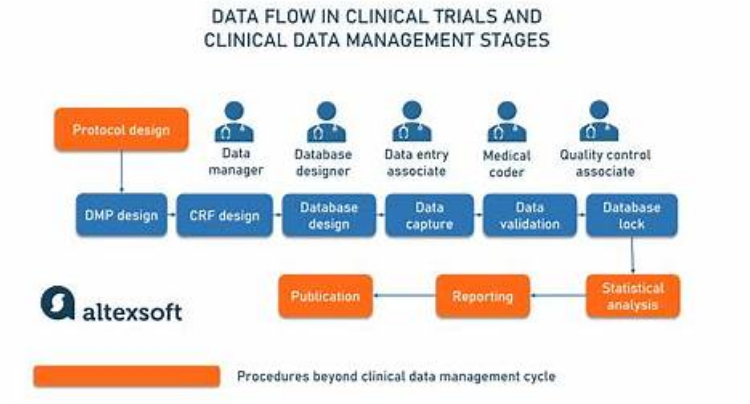
CCDM試験の準備方法｜素晴らしいCCDM学習資料試験｜検証するCertified Clinical Data Manager模試エンジン



P.S.JPNTest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=1Sp1J_FyX3U172vviOhF3tbf7Pxwn7lBe

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SCDM CCDM 認定試験の出題範囲：

トピック	出題範囲
トピック 1	• 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 2	• 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.
トピック 3	• 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 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	• 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.

>> CCDM学習資料 <<

SCDM CCDM模試エンジン、CCDM試験問題解説集

SCDM才能の新しい時代に次第に飽和して彼ら自身の利点を獲得し、あなたの能力をどのように反映しますか？ おそらく最も直感的な方法は、テストCCDM認定を取得して、JPNTest対応する資格を取得することです。ただし、CCDM認定試験はそれほど単純ではないため、レビューには多大な労力が必要です。 テスト認定を効果的に取得する方法について説明します。CCDM試験に短時間で合格することは空想ではないことを伝えるCCDM学習教材です。 何万人もの受験者が99％の合格率でCertified Clinical Data Manager試験に合格するのを支援しました。

SCDM Certified Clinical Data Manager 認定 CCDM 試験問題 (Q57-Q62):

質問 # 57
Which is a minimum prerequisite that should be in place before choosing an EDC system?

- A. Updated governance documentation
- B. Knowledge of functional requirements
- C. Completed installation qualification
- D. Draft validation plan

正解：B

解説：
Before selecting an Electronic Data Capture (EDC) system for a clinical trial, it is essential to have a clear understanding of the functional requirements. This serves as the minimum prerequisite to guide system selection, ensuring that the EDC solution aligns with the protocol needs, data workflow, security requirements, and regulatory compliance.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Computerized Systems and Compliance), functional requirements describe what the system must do-such as data entry capabilities, edit checks, query management, user roles, audit trails, and integration with external systems (e.g., labs, ePRO). This understanding allows sponsors and CROs to evaluate vendor systems effectively during the selection and qualification phase.
Other options:
B . Installation qualification and D. Validation plan occur after system selection.
C . Governance documentation supports operations but is not required before choosing the system.
Hence, option A is correct - the first and most essential prerequisite before EDC selection is a solid understanding of the functional requirements.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 4.2 - Requirements Gathering and System Selection
FDA 21 CFR Part 11 - System Validation and Intended Use Requirements ICH E6(R2) GCP, Section 5.5.3 - Computerized System Selection and Qualification

質問 # 58
In a study conducted using paper CRFs, a discrepancy is discovered in a CRF to database QC audit. What is the reason why this discrepancy would be considered an audit finding?

- A. Discrepancy not explained by the data quality control audit plan
- B. Discrepancy not explained by the CRF completion guidelines
- C. Discrepancy not explained by the protocol
- D. Discrepancy not explained by the data handling conventions

正解：D

解説：
In a CRF-to-database quality control (QC) audit, auditors compare data recorded on the paper Case Report Form (CRF) with data entered in the electronic database. If discrepancies exist that cannot be explained by documented data handling conventions, they are classified as audit findings.
Per GCDMP (Chapter: Data Quality Assurance and Control), data handling conventions define acceptable data entry practices, transcription rules, and allowable transformations. These conventions ensure that CRF data are consistently interpreted and entered. If a discrepancy deviates from these established rules, it indicates a process gap or error in data entry, validation, or training. Discrepancies justified by protocol design or CRF guidelines would not constitute findings.
Therefore, option C (Discrepancy not explained by the data handling conventions) correctly identifies the criterion for a true QC audit finding.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.1 - Data Handling Conventions and QC Auditing ICH

E6(R2) GCP, Section 5.1 - Quality Management and Documentation of Deviations FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Verification and Audit Findings

質問 # 59
For a study, body mass index is calculated from weight and height. Which information is needed to document the transformation?

- A. Algorithm and algorithm version associated with the calculated value
- B. Algorithm associated with the calculated value
- C. User ID making the change and reason for change
- D. Algorithm documented in the Data Management Plan

正解：A

解説：
When derived or calculated variables (like Body Mass Index) are created, it is essential to document the algorithm used and its version to ensure full data traceability and reproducibility.
According to GCDMP (Chapter: Database Design and Derived Data), every derived field must include metadata describing:
The derivation algorithm (e.g., BMI = weight [kg] / height² [m²])
The version of the algorithm (if updates or revisions occur)
Any associated data sources or transformation rules
This ensures consistent calculation across systems, prevents discrepancies during regulatory submissions, and aligns with FDA and CDISC documentation expectations.
Option B lacks version control, which is critical for traceability. Option C describes audit trail data (not derivation metadata), and option D refers to broader documentation, not specific algorithm traceability.
Hence, option A (Algorithm and algorithm version associated with the calculated value) is the correct and compliant answer.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Derived Data and Algorithms, Section 5.3 - Documentation and Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Derived Data and Validation Traceability FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Data Definitions (Define.xml)

質問 # 60
According to ICH E6, developing a Monitoring Plan is the responsibility of whom?

- A. CRO
- B. Monitor
- C. Sponsor
- D. Data Manager

正解：C

解説：
According to ICH E6(R2) Good Clinical Practice (GCP), Section 5.18.1, the Sponsor is ultimately responsible for developing and implementing the Monitoring Plan.
The Monitoring Plan defines:
The extent and nature of monitoring (e.g., on-site, remote, risk-based).
The responsibilities of monitors.
The communication and escalation procedures for data quality and protocol compliance.
While the CRO (B) or Monitor (D) may perform monitoring activities under delegation, the Sponsor retains legal accountability for ensuring a compliant and effective plan is developed and maintained. The Data Manager (C) may contribute by outlining data review workflows, but is not responsible for authoring or owning the plan.
Therefore, option A (Sponsor) is the correct answer.
Reference (CCDM-Verified Sources):
ICH E6(R2) GCP, Section 5.18.1 - Purpose and Responsibilities for Monitoring SCDM GCDMP, Chapter: Regulatory Compliance and Oversight, Section 5.3 - Sponsor Responsibilities in Monitoring and Quality Assurance FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor Responsibilities (2013)

質問 # 61

An international study collects lab values. Sites use different units in the source documents. Which of the following data collection strategies will have fewer transcription errors?

- A. Allow values to be entered as they are in the source document and derive the units based on the magnitude of the value
- B. Use a structured field and print standard units on the data collection form
- C. Allow values to be entered as they are in the source and the selection of units on the data collection form
- D. Have all sites convert the values to the same unit system on the data collection form

正解：C

解説：
In international or multicenter clinical studies, laboratory data often originate from different laboratories that use varying measurement units (e.g., mg/dL vs. mmol/L). The Good Clinical Data Management Practices (GCDMP, Chapter on CRF Design and Data Collection) provides clear guidance on managing this variability to ensure data consistency, traceability, and minimized transcription errors.
The approach that results in fewer transcription errors is to allow sites to enter lab values exactly as recorded in the source document (original lab report) and to require explicit selection of the corresponding unit from a predefined list on the data collection form or within the electronic data capture (EDC) system. This method (Option B) preserves the original source data integrity while enabling centralized or automated unit conversion later during data cleaning or statistical processing.
Option B also supports compliance with ICH E6 (R2) Good Clinical Practice (GCP), which mandates that transcribed data must remain consistent with the source documents. Attempting to derive units automatically (Option A) can lead to logical errors, while forcing sites to manually convert units (Option D) introduces unnecessary complexity and increases the risk of miscalculation or inconsistent conversions. Printing only standard units on the CRF (Option C) ignores local lab practices and can lead to discrepancies between CRF entries and source records, triggering numerous data queries.
The GCDMP emphasizes that CRF design must account for local variations in measurement systems and ensure that unit selection is structured (dropdowns, controlled lists) rather than free-text to prevent typographical errors and facilitate standardization during data transformation.
Therefore, Option B-"Allow values to be entered as they are in the source and the selection of units on the data collection form"-is the most compliant, accurate, and efficient strategy for minimizing transcription errors in international lab data collection.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.4 - Laboratory Data Management and Unit Handling ICH E6 (R2) Good Clinical Practice, Section 5.18 - Data Handling and Record Retention CDISC SDTM Implementation Guide, Section 6.3 - Handling of Laboratory Data and Standardized Units FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Source Data and Accuracy of Data Entry

質問 # 62
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JPNTestのSCDMのCCDM試験トレーニング資料は最高のトレーニング資料です。あなたはIT職員としたら、JPNTestはあなたが選ばなくてはならないトレーニング資料です。JPNTestのSCDMのCCDM試験トレーニング資料は絶対に信頼できるもので、IT認証を受ける受験生を対象として特別に研究された問題と解答に含まれているう資料です。 SCDMのCCDM試験に受かるのはIT職員の皆さんの目標です。JPNTestの合格率は信じられないほど高いです。JPNTestはあなたの成功にずっと力を尽くしています。

CCDM模試エンジン: https://www.jpntest.com/shiken/CCDM-mondaishu

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