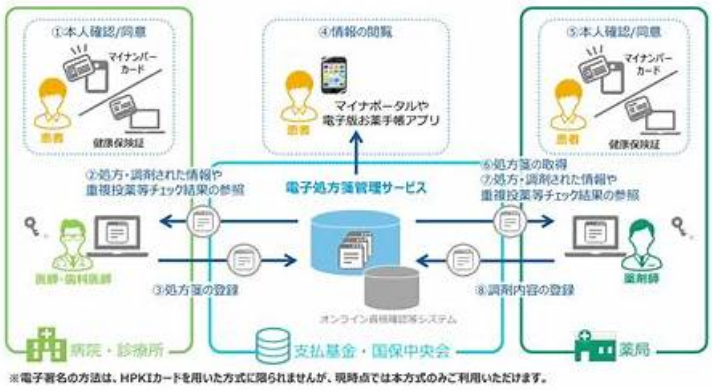
CCDMオンライン試験、CCDMテスト資料



さらに、It-Passports CCDMダンプの一部が現在無料で提供されています：https://drive.google.com/open?id=15CGNHRr6fDDEneNMXTueYd1Hh3MzfiTx

CCDM認定試験はずっと人気があるのです。最近IT試験を受けて認証資格を取ることは一層重要になりました。たとえばSCDM、IBM、Cisco、VMware、SAPなどのいろいろな試験は今では全部非常に重要な試験です。より多くの人々は複数の資格を取得するために多くのCCDM試験を受験したいと思っています。もちろん、このようにすればあなたがすごい技能を身につけていることが証明されることができます。しかし、仕事しながら試験の準備をすることはもともと大変で、複数の試験を受験すれば非常に多くの時間が必要です。いまこのようなことで悩んいるのでしょうか。それは問題ではないですよ。It-Passportsあなたを時間を節約させことができますから。It-Passportsのさまざまなit試験の問題集はあなたを受験したい任意の試験に合格させることができます。CCDM認定試験などの様々な認定試験で、受験したいなら躊躇わずに申し込んでください。心配する必要はないです。

SCDM CCDM 認定試験の出題範囲：

トピック	出題範囲
トピック 1	• 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	• 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	• 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 4	• 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 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.

>> CCDMオンライン試験 <<

CCDMテスト資料 & CCDM試験感想

あなたに安心にSCDMのCCDMソフトを購入させるために、我々は最も安全的な支払手段を提供します。PayPalは国際的に最大の安全的な支払システムです。そのほかに、我々はあなたの個人情報の安全性を保証します。SCDMのCCDM試験の資料についてあなたは何か問題があったら、それとも、ほかの試験ソフトに興味があったら、直ちにオンラインで我々を連絡したり、メールで問い合わせたりすることができます。我々は尽力してあなたにSCDMのCCDM試験に合格させます。

SCDM Certified Clinical Data Manager 認定 CCDM 試験問題 (Q115-Q120):

質問 # 115
If database auditing is used for data quality control during a study, which is the optimal timing of the audits?

- A. Periodically throughout the study
- B. A week or two before database lock
- C. Immediately following database lock
- D. After the first few cases have been entered

正解：A

解説：
Database audits are conducted to ensure ongoing data accuracy, completeness, and compliance throughout the lifecycle of a clinical trial. According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control), quality audits are most effective when performed periodically during study conduct, rather than waiting until study completion.
Performing audits periodically allows early detection of data entry errors, protocol deviations, and system inconsistencies, thereby reducing the risk of large-scale data issues before database lock. This proactive approach aligns with risk-based quality management principles outlined in ICH E6(R2) and ensures corrective actions are implemented in real time.
Options A and B represent reactive quality control, which occurs too late to prevent data issues. Option C (after first few cases) provides initial validation but does not ensure continuous oversight.
Therefore, option D - "Periodically throughout the study" - represents the optimal and compliant timing for quality audits of the database.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 5.3 - Ongoing Quality Control and Auditing ICH E6(R2) GCP, Section 5.1.1 - Quality Management System and Risk-Based Monitoring FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Review and Auditing Practices

質問 # 116
A study team member suggests that data for a small, 50-patient, 2-year study can be entered and cleaned in two weeks before lock. Which are important other considerations?

- A. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study
- B. It would take more than two weeks to get second iteration queries generated and resolved
- C. Processing the data in two weeks after the study is over would save money because the data manager would not be involved until the end
- D. Processing the data in two weeks after the study is over would save money because the EDC system would only be needed for a month

正解：B

解説：
The most critical consideration is that data cleaning is an iterative process, and completing all necessary steps - including query generation, site resolution, and second-pass validation - cannot realistically be accomplished within two weeks after study close.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), data cleaning must occur continuously throughout the study, not only at the end. Post-database lock activities typically include running final validation checks, resolving outstanding queries, performing reconciliation (e.g., SAEs, labs, coding), and conducting final quality review.
Even in small studies, query turnaround and response cycles from sites take time - typically 2-4 weeks per iteration - making a two-week total cleaning period unrealistic.
Therefore, Option D is correct: it would take more than two weeks to handle second-round (follow-up) queries and confirm final resolutions prior to database lock.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.4 - Ongoing vs.

End-of-Study Data Cleaning ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Quality and Timeliness FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Management and Cleaning

質問 # 117
A Data Manager is importing lab data for a study. The lab data and the associated audit trail is kept at the central lab. What is necessary to maintain traceability of the transferred data at the Data Manager's location?

- A. Making changes only for exceptions
- B. Making changes only on the copy of the received data
- C. Maintaining a copy of the data as received
- D. Making changes only after data have been imported

正解：C

解説：
Maintaining traceability of external data imports (such as laboratory results) is a fundamental principle of clinical data management. According to the GCDMP (Chapter: External Data Transfers and Integration), Data Managers must retain an unaltered copy of the raw data exactly as received from the vendor.
This archived version serves as a reference for:
Data provenance verification,
Audit trail review, and
Discrepancy resolution between vendor and study database.
Since the central lab maintains its own audit trail, the Data Manager's responsibility is to preserve the original data transmission file before applying transformations, merges, or validations.
Options A, C, and D describe procedural safeguards but do not meet the regulatory requirement of traceable data lineage. Only option B (Maintaining a copy of the data as received) ensures compliance with ICH E6(R2) and FDA 21 CFR Part 11 standards for data traceability and integrity.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: External Data Transfers and Integration, Section 5.2 - Data Traceability and Version Control ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Source Data Verification FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Source Data Traceability and Archiving

質問 # 118
What significant difference is there in the DM role when utilizing an EDC application?

- A. Data updates are implemented by the sites
- B. Database validation is not required
- C. Tracking of eCRFs is a monitor's responsibility
- D. Metrics generation is required

正解：A

解説：
The most significant difference in the Data Manager's role when using an Electronic Data Capture (EDC) system is that data updates are implemented directly by site personnel (Option A).
According to the GCDMP (Chapter: Electronic Data Capture Systems), EDC technology shifts responsibility for data entry and correction from the sponsor or CRO to the investigator site, enabling real-time data entry and validation. This eliminates the need for double entry or remote data transcription, allowing Data Managers to focus on system validation, query management, and data quality oversight rather than physical data handling.
However, the EDC system still requires full validation (contrary to Option B). Metrics generation (Option C) and CRF tracking (Option D) are important but not unique to EDC-based workflows.
Thus, the correct answer is Option A - Data updates are implemented by the sites, reflecting the most fundamental operational shift introduced by EDC systems.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 4.1 - Role of the Data Manager in EDC ICH E6 (R2) GCP, Section 5.5.3 - Electronic Data Entry and Responsibilities FDA 21 CFR Part 11 - Electronic Records and Signatures: Data Entry Responsibilities

質問 # 119
A study takes body-composition measurements at baseline using a DEXA scanner. Which information is needed to correctly associate the body-composition data to the rest of the study data?

- A. Study number and subject number
- B. Subject number and visit number
- C. Study number and visit number
- D. Subject number

正解：B

解説：
To properly associate body-composition data (from a DEXA scanner) with other study data, both the subject number and the visit number are required.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), every clinical data record must be uniquely identifiable and linkable to a specific subject and study event. The subject number identifies the participant, while the visit number defines the temporal context in which the measurement was taken.
Without both identifiers, data integration becomes ambiguous-especially if multiple assessments occur over time (e.g., baseline, week 12, end of study). Including both ensures data traceability, integrity, and alignment with the protocol-defined schedule of events.
Study number (option A) alone does not distinguish between visits or subjects, and visit number alone (option C) lacks linkage to the individual participant.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.4 - Data Linking and Identification Requirements ICH E6 (R2) GCP, Section 5.5.3 - Data Traceability Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Identification Requirements

質問 # 120
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- CCDM参考書 □ CCDM参考書 ➡□ CCDM復習対策 □ □ www.passtest.jp □は、☀ CCDM □☀□を無料でダウンロードするのに最適なサイトですCCDM復習対策
- 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, www.stes.tyc.edu.tw, www.stes.tyc.edu.tw, www.stes.tyc.edu.tw, www.stes.tyc.edu.tw, www.stes.tyc.edu.tw, myportal.utt.edu.tt, Disposable vapes