CCDM최신인증시험기출자료, CCDM최고품질인증시험기출문제

SCDM CCDM덤프의 유효성을 보장해드릴수 있도록 저희 기술팀은 오랜시간동안SCDM CCDM시험에 대하여 분석하고 연구해 왔습니다. SCDM CCDM 덤프를 한번 믿고SCDM CCDM시험에 두려움없이 맞서보세요. 만족할수 있는 좋은 성적을 얻게 될것입니다.

Fast2test는 믿을 수 있는 사이트입니다. IT업계에서는 이미 많이 알려져 있습니다. 그리고 여러분에 신뢰를 드리기 위하여 SCDM 인증CCDM 관련자료의 일부분 문제와 답 등 샘플을 무료로 다운받아 체험해볼 수 있게 제공합니다. 아주 만족할 것이라고 믿습니다. Fast2test제품에 대하여 아주 자신이 있습니다. SCDM 인증CCDM 도 여러분의 무용지물이 아닌 아주 중요한 자료가 되리라 믿습니다. 여러분께서는 아주 순조로이 시험을 패스하실 수 있을 것입니다.

>> CCDM최신 인증시험 기출자료 <<

시험대비 CCDM최신 인증시험 기출자료 최신버전 덤프데모 문제

여러분이 우리SCDM CCDM문제와 답을 체험하는 동시에 우리Fast2test를 선택여부에 대하여 답이 나올 것입니다. 우리는 백프로 여러분들한테 편리함과 통과 율은 보장 드립니다. 여러분이 안전하게SCDM CCDM시험을 패스할 수 있는 곳은 바로 Fast2test입니다.

SCDM CCDM 시험요강:

주제	소개
주제 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.
주제 2	• 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	• 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 4	• 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.
주제 5	• 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.

최신 Clinical Data Management CCDM 무료샘플문제 (Q25-Q30):

질문 # 25
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. 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
- B. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study
- C. It would take more than two weeks to get second iteration queries generated and resolved
- D. 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

정답：C

설명:
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

질문 # 26
During testing of an ePRO system, a test fails. Which information should be found in the validation documentation?

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

정답：B

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 # 27
Every database lock should follow documented approval of which stakeholders?

- A. Clinical/Scientific Representative, Biostatistician
- B. Clinical/Scientific Representative, Data Manager
- C. Clinical/Scientific Representative, Data Manager, Biostatistician
- D. Clinical/Scientific Representative, Biostatistician, Programmer

정답：C

설명：
According to the Good Clinical Data Management Practices (GCDMP), the database lock (DBL) process signifies the formal closure of the clinical trial database, ensuring that no further changes can be made to the data before statistical analysis. This process must be documented, controlled, and approved by key study stakeholders to ensure data accuracy, completeness, and readiness for analysis.
The GCDMP specifies that database lock should occur only after all data cleaning, discrepancy resolution, and reconciliation activities are complete. The lock authorization typically requires the approval of the Clinical/Scientific Representative (to confirm clinical completeness), the Data Manager (to confirm data integrity and query closure), and the Biostatistician (to confirm readiness for statistical analysis).
This tri-party approval ensures that the database reflects final, verified data consistent with the clinical protocol, and that the statistical analysis dataset derived from the database is accurate and auditable. The approval process is documented via a Database Lock Authorization Form or Sign-off Log, which becomes part of the permanent trial master file (TMF).
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Lock and Archiving, Section 7.1 - Lock Procedures and Approvals ICH E6 (R2) GCP, Section 5.5.3 - Data Handling and Record Keeping FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Database Closure

질문 # 28
Which of the following ensures that the trials are conducted and the data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)?

- A. CRFs

- B. Data Management Plan (DMP)
- C. Standard Operating Procedures (SOP)
- D. Statistical Analysis Plan (SAP)

정답：C

설명：
Standard Operating Procedures (SOPs) are formal, controlled documents that define standardized processes to ensure clinical trials are conducted in compliance with Good Clinical Practice (GCP), the study protocol, and regulatory requirements (such as ICH and FDA).
According to Good Clinical Data Management Practices (GCDMP) and ICH E6(R2) GCP, SOPs are fundamental to quality management systems. They describe how tasks are performed, ensuring consistency, accountability, and traceability across all studies and team members. Proper adherence to SOPs guarantees that data are accurately generated, documented, and reported in compliance with ethical and regulatory standards.
Other options serve different purposes:
SAP (B) defines statistical methodology, not compliance control.
DMP (C) focuses on study-specific data handling, not organizational compliance.
CRFs (D) are tools for data collection but do not enforce compliance by themselves.
Therefore, option A (SOP) is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Quality Management and Compliance, Section 5.1 - Role of SOPs in Regulatory Compliance ICH E6(R2) GCP, Section 2.13 and 5.1.1 - Quality Management Systems and SOP Requirements FDA 21 CFR Part 312.50 - Sponsor Responsibilities and Compliance Systems

질문 # 29
Which is the MOST appropriate flow for EDC set-up and implementation?

- A. CRF "wire-frames" created, CRFs reviewed, CRFs printed, CRFs distributed to sites
- B. Database created, Database tested, Sites trained, Protocol finalized, Database released
- C. Protocol finalized, Database created, Edit Checks created, Database tested, Sites trained
- D. Database created, Subjects enrolled, Database tested, Sites trained, Database released

정답：C

설명：
The correct and compliant sequence for EDC system setup and implementation begins only after the study protocol is finalized, as all case report form (CRF) designs, database structures, and validation rules derive directly from the finalized protocol.
According to GCDMP (Chapter: EDC Systems Implementation), the proper order is:
Protocol finalized - defines endpoints and data requirements.
Database created - built according to the protocol and CRFs.
Edit checks created - programmed to validate data entry accuracy.
Database tested (UAT) - ensures functionality, integrity, and compliance.
Sites trained and system released - only then can data entry begin.
Option B follows this logical and regulatory-compliant sequence. Other options (A, C, D) are either paper-based workflows or violate GCP-compliant timelines (e.g., enrolling subjects before database validation).
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.2 - System Setup and Implementation Flow ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation and User Training Before Use FDA 21 CFR Part 11 - Validation and System Release Requirements

질문 # 30
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