

# 최신업데이트버전CCDM퍼펙트덤프최신샘플덤프공부자료



BONUS!!! PassTIP CCDM 시험 문제집 전체 버전을 무료로 다운로드하세요: <https://drive.google.com/open?id=1JNbcZGflB4yLnlyGYUJ78Xj6HoToIdrq>

PassTIP선택으로SCDM CCDM시험을 패스하도록 도와드리겠습니다. 우선 우리PassTIP 사이트에서SCDM CCDM 관련자료의 일부 문제와 답 등 샘플을 제공함으로 여러분은 무료로 다운받아 체험해보실 수 있습니다. 체험 후 우리의PassTIP에 신뢰감을 느끼게 됩니다. PassTIP에서 제공하는SCDM CCDM덤프로 시험 준비하세요. 만약 시험에서 떨어진다면 덤프전액환불을 약속 드립니다.

PassTIP의 제품들은 모두 우리만의 거대한IT업계엘리트들로 이루어진 그룹 즉 관련업계에서 권위가 있는 전문가들이 자기만의 지식과 지금까지의 경험으로 최고의 IT인증관련자료를 만들어냅니다. PassTIP의 문제와 답은 정확도 적중률이 아주 높습니다. 우리의 덤프로 완벽한SCDM인증CCDM시험대비를 하시면 되겠습니다. 이렇게 어려운 시험은 우리SCDM인증CCDM덤프로 여러분의 고민과 꿈을 한방에 해결해드립니다.

>> CCDM퍼펙트 덤프 최신 샘플 <<

## CCDM유효한 덤프자료 & CCDM최신 덤프문제보기

PassTIP는SCDM CCDM시험을 패스할 수 있는 아주 좋은 사이트입니다. PassTIP은 아주 알맞게 최고의SCDM CCDM시험문제와 답 내용을 만들어 냅니다. 덤프는 기존의 시험문제와 답과 시험문제분석 등입니다. PassTIP에서 제공하는SCDM CCDM시험자료의 문제와 답은 실제시험의 문제와 답과 아주 비슷합니다.

### SCDM CCDM 시험요강:

주제	소개
주제 1	<ul style="list-style-type: none"><li>• 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.</li></ul>
주제 2	<ul style="list-style-type: none"><li>• 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.</li></ul>
주제 3	<ul style="list-style-type: none"><li>• 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.</li></ul>

주제 4	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
주제 5	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

## 최신 Clinical Data Management CCDM 무료샘플문제 (Q86-Q91):

### 질문 # 86

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

정답: A

#### 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 # 87

An external organization has been hired to manage SAE follow-up for a large study. Which of the following would be used as guidance for exchange of the SAE data between the EDC system and the vendor's safety management system?

- A. Biomedical Research Domain Model
- B. Submission Data Tabulation Model
- C. Medical Document for Regulatory Activities
- D. Individual Case Safety Report

정답: D

#### 설명:

The Individual Case Safety Report (ICSR) is the standard format used globally for the exchange of Serious Adverse Event (SAE) data between clinical data management systems (EDC) and safety management systems.

According to ICH E2B(R3) and Good Clinical Data Management Practices (GCDMP, Chapter: Safety Data Management and SAE Reconciliation), the ICSR provides the data structure and content standards for electronic transmission of safety data, including patient demographics, event details, outcomes, and product information. It ensures interoperability between systems by defining standardized message elements and controlled terminologies.

Other options are not applicable:

A . Medical Document for Regulatory Activities (MDRA) is not a recognized standard.

B . Biomedical Research Domain Model (BRIDG) provides conceptual modeling but not data exchange guidance.

D . SDTM is used for regulatory submission datasets, not real-time SAE exchange.

Thus, option C (Individual Case Safety Report) is correct, as it defines the internationally accepted electronic format for SAE data exchange between safety and clinical databases.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Safety Data Management and SAE Reconciliation, Section 4.3 - SAE Data Exchange and Standards

ICH E2B(R3): Electronic Transmission of Individual Case Safety Reports FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Postmarketing ICSRs (2014)

### 질문 # 88

The primary reason for system validation is to:

- A. Prove the system being tested works as intended.
- B. Allow a system to be used by its intended users.
- C. Meet regulatory requirements.
- D. Fulfill the validation plan.

정답: A

설명:

The primary purpose of system validation in clinical data management is to demonstrate and document that the computerized system performs as intended-accurately, reliably, and consistently-throughout its lifecycle.

According to the Good Clinical Data Management Practices (GCDMP, Chapter on System Validation) and FDA 21 CFR Part 11, validation ensures that all system functions (e.g., data entry, edit checks, audit trails, security) work as designed, providing data integrity, traceability, and regulatory compliance. The focus is on fitness for intended use, meaning the system reliably produces correct and reproducible results in the context of its operational environment.

While meeting regulatory requirements (option C) and fulfilling a validation plan (option B) are components of the process, they are not the ultimate purpose. The essential goal is ensuring that the system performs as intended, maintaining accuracy and data integrity for clinical trial operations.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and System Validation, Section 5.2 - Purpose and Scope of System Validation  
FDA 21 CFR Part 11 - Validation of Computerized Systems for Intended Use ICH E6(R2) GCP, Section 5.5.3 - Computerized System Validation and Data Integrity

### 질문 # 89

A group of researchers is planning an investigator-initiated study. Assuming that SOPs are not available, which is the best approach for documentation of data management in the planned study?

- A. Data management SOPs must be developed prior to initiation of study
- B. Data handling should be documented in a data management plan
- C. A Data Management Plan (DMP) template should be developed and a study DMP should be created
- D. Data management related activities should be briefly described in the study protocol

정답: C

설명:

In the context of an investigator-initiated trial (IIT) where Standard Operating Procedures (SOPs) are not available, the most appropriate and compliant approach is to develop a Data Management Plan (DMP) template and then create a study-specific DMP based on that template (Option C).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Management Planning and Study Start-up), the DMP is the central document that defines all processes, responsibilities, systems, and quality controls related to data collection, processing, validation, and database management throughout the clinical study. The DMP serves as a formal framework for ensuring data integrity, traceability, and regulatory compliance, especially in the absence of established institutional SOPs.

While SOPs provide organizational-level standards, the DMP provides study-specific operational detail. In an investigator-initiated setting, researchers often lack institutional data management infrastructure, so the DMP must substitute for SOP guidance by detailing:

Data entry and validation procedures

Query management and resolution processes

CRF design and data flow specifications

Database design, backup, and security

Responsibilities of study personnel (investigator, data manager, statistician) Quality control and audit trail practices Option A ("Data handling should be documented in a DMP") is correct in principle but incomplete-without a DMP template, there is no standardized format or consistency across studies.

Option B (developing full SOPs) is not practical for a single IIT; SOPs are organizational-level documents requiring longer development and approval cycles.

Option D (briefly describing data management in the protocol) is insufficient, as the protocol should reference data management activities but not serve as the operational manual for them.

Therefore, Option C provides the most comprehensive, regulatory-compliant, and practical solution-ensuring structured documentation of all data management activities while maintaining flexibility for investigator-led research.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data

Management Planning and Study Start-up, Section 5.2 - Data Management Plan (DMP) Development and Maintenance ICH E6

(R2) Good Clinical Practice, Section 5.1 - Quality Management and Documentation Requirements FDA Guidance for Industry:

Computerized Systems Used in Clinical Investigations, Section 4 - Data Management and Documentation Practices SCDM

GCDMP, Chapter: Project Management in Data Management - Study-Specific Documentation and Planning in Investigator-Initiated Trials

### 질문 # 90

What is the main reason 21 CFR Part 11 requires that EDC systems maintain an audit trail?

- A. To preserve data integrity
- B. To preserve source document verifications
- C. To preserve data availability
- D. To preserve the ability for modifications

정답: A

설명:

The primary purpose of maintaining an audit trail as required under 21 CFR Part 11 is to preserve data integrity. According to the U.S. FDA's regulation on electronic records and signatures, every change to electronic data must be traceable, including information about who made the change, when it was made, and what the change entailed.

The Good Clinical Data Management Practices (GCDMP) outlines that an audit trail provides a permanent, chronological record of all modifications to clinical data. This ensures transparency and allows the reconstruction of the course of data entry and modification. The regulation aims to prevent unauthorized or undocumented data manipulation, thereby maintaining the accuracy, reliability, and validity of electronic records.

The FDA 21 CFR Part 11, Section 11.10(e) explicitly mandates that systems must use secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. This ensures the data remains trustworthy and defensible in regulatory reviews or inspections.

Therefore, the main reason for requiring an audit trail is to preserve data integrity - ensuring that all data captured, modified, or transmitted is authentic, accurate, and complete throughout the study lifecycle.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Compliance and Data Integrity FDA 21 CFR

Part 11 - Electronic Records; Electronic Signatures, Section 11.10(e) ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Integrity and System Validation

### 질문 # 91

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CCDM유효한 덤프자료 : <https://www.passtip.net/CCDM-pass-exam.html>

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