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Tags: C-C4H430-94퍼펙트 최신버전 공부자료, C-C4H430-94퍼펙트 최신버전 문제, C-C4H430-94는 통과율덤프문제, C-C4H430-94는 통과율덤프샘플 다운, C-C4H430-94최신 인증시험덤프문제

참고: Fast2test에서 Google Drive로 공유하는 무료, 최신 CCDM 시험 문제집이 있습니다: <https://drive.google.com/open?id=12wjs9xGYIgzVjBB4y2gcH5q0qTdAK0EC>

만약 시험만 응시하고 싶으시다면 우리의 최신SCDM CCDM자료로 시험 패스하실 수 있습니다. Fast2test 의 학습가이드에는SCDM CCDM인증시험의 예상문제, 시험문제와 답 입으로 100% 시험을 패스할 수 있습니다.우리의 SCDM CCDM시험자료로 충분한 시험준비하시는 것이 좋을것 같습니다. 그리고 우리는 일년무료 업데이트를 제공합니다.

## SCDM CCDM 시험요강:

주제	소개
주제 1	<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 2	<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>

주제 3	<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 4	<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 5	<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>

>> CCDM퍼펙트 덤프공부문제 <<

## CCDM덤프자료, CCDM자격증공부

SCDM인증 CCDM시험은 빨리 패스해야 되는데 어디서부터 어떻게 시험준비를 시작해야 하는지 갈피를 잡을수 없는 분들은Fast2test가 도와드립니다. Fast2test의 SCDM인증 CCDM덤프만 공부하면 시험패스에 자신이 생겨 불안한 상태에서 벗어날수 있습니다.덤프는 시장에서 가장 최신버전이기에 최신 시험문제의 모든 시험범위와 시험유형을 커버하여SCDM인증 CCDM시험을 쉽게 패스하여 자격증을 취득하여 찬란한 미래에 더 가깝도록 도와드립니다.

### 최신 Clinical Data Management CCDM 무료샘플문제 (Q148-Q153):

#### 질문 # 148

Which of the following actions is particularly important in merging data from different trials?

- A. Enrollment of investigative sites with similar patient populations
- B. Use of a common software platform
- C. Use of a common adverse event dictionary
- D. Exclusion of studies that use a cross-over design

정답: C

#### 설명:

When merging data from different clinical trials, the use of a common adverse event (AE) dictionary (such as MedDRA or WHO Drug) is essential to ensure consistency and comparability across datasets.

According to the GCDMP (Chapter: Standards and Data Mapping) and CDISC SDTM Implementation Guide, data integration across studies requires standardized terminology for adverse events, medications, and clinical outcomes. Using the same AE dictionary ensures that similar terms are coded consistently, allowing accurate cross-study analysis, pooled summaries, and safety reporting.

A shared software platform (option A) is not necessary if data are mapped to standard formats (e.g., CDISC SDTM). Patient population similarity (option B) affects interpretation but not technical data merging. Study design differences (option C) may influence statistical analysis but not data integration mechanics.

Therefore, Option D - Use of a common adverse event dictionary - is the correct and most critical action for consistent multi-study data integration.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Standards and Data Mapping, Section 5.1 - Use of Standardized Coding Dictionaries CDISC SDTM Implementation Guide, Section 4.3 - Controlled Terminology and Cross-Study Integration ICH E3 and E2B - Clinical Data Standards and Safety Coding Requirements

#### 질문 # 149

Which of the following roles commonly requires data entry and update privileges in an EDC application used in a clinical study?

- A. EDC System Administrator
- B. Study Statistician

- C. Clinical Study Monitor
- **D. Site Study Coordinator**

**정답: D**

**설명:**

In an EDC system, Site Study Coordinators are typically responsible for data entry and updates, as they are the site-level personnel who record subject data from source documents into the electronic CRFs (eCRFs).

The Good Clinical Data Management Practices (GCDMP, Chapter: EDC Systems) outlines that data entry and modification privileges should only be granted to qualified site personnel who have completed EDC system training and are listed on the study delegation log. These users directly handle patient-level data entry and correction.

In contrast:

Clinical Study Monitors (B) review and verify data but do not enter or modify it.

EDC System Administrators (C) manage user access and configuration settings, not study data.

Study Statisticians (D) work with extracted, cleaned datasets but never have data modification privileges.

Thus, option A (Site Study Coordinator) correctly identifies the role with authorized data entry and update privileges.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.2 - User Roles and Access Permissions ICH E6(R2) GCP, Section 4.1 - Investigator Responsibilities for Data Accuracy FDA 21 CFR Part 11 - User Access and Accountability in Electronic Systems

**질문 # 150**

In development of CRF Completion Guidelines (CCGs), which is a minimum requirement?

- **A. CCGs must include a version control on the updated document**
- B. CCGs are designed from the perspective of the Study Biostatistician to ensure that the data collected can be analyzed
- C. CCGs must be signed before database closure to include all possible protocol changes affecting CRF completion
- D. CCGs are developed with representatives of Data Management, Biostatistics, and Marketing departments

**정답: A**

**설명:**

Case Report Form Completion Guidelines (CCGs) are essential study documents that instruct site staff on how to complete each field of the CRF correctly. A minimum requirement for CCGs, according to Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), is that they must include version control.

Option A describes an important design consideration but not a minimum compliance requirement. Option B is inaccurate, as CCGs must be approved and implemented before data collection begins, not after. Option D includes an irrelevant stakeholder (Marketing).

Therefore, option C-"CCGs must include a version control on the updated document"-is correct and compliant with CCDM and GCP standards.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 4.3 - Development and Maintenance of CRF Completion Guidelines ICH E6(R2) GCP, Section 8.2.1 - Essential Documents and Version Control Requirements

**질문 # 151**

The serious adverse event (SAE) database should be reconciled against the clinical trial database prior to which occasion?

- A. Expedited safety reporting
- B. Case report form data entry
- **C. Database closure or locking**
- D. Database quality audit

**정답: C**

**설명:**

SAE reconciliation must be completed before database lock or closure to ensure all safety data are consistent between the clinical database and the pharmacovigilance (safety) database.

According to the GCDMP (Chapter: Safety Data Handling and Reconciliation), SAE reconciliation involves verifying that all adverse events reported in the clinical trial database are also captured and accurately recorded in the safety system (and vice versa). This is

essential to confirm that no SAE is missing, misclassified, or inconsistently dated or coded between the two systems. Performing this reconciliation before database lock ensures that any discrepancies are corrected, and both databases reflect consistent, verified information for regulatory submission. Conducting this after closure (or only at audit time) would risk data inconsistencies in the final submission datasets.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: SAE Reconciliation, Section 6.1 - Timing and Procedures for Reconciliation ICH E2A/E2F - Clinical Safety Data Management: Definitions and Standards FDA Guidance for Industry: E2A - Clinical Safety Data Management: Processing Standards for Safety Reports

### 질문 # 152

What additional task does the site study coordinator role perform when utilizing an EDC application compared to paper CRF?

- A. Data curation
- B. Resolving queries
- C. Data entry
- D. Medical record abstraction

정답: C

설명:

In paper-based trials, site staff (e.g., study coordinators) record data manually on paper Case Report Forms (CRFs), which are later transcribed by data entry personnel into an electronic database.

However, in EDC-based studies, the site coordinator is directly responsible for entering data into the EDC system. This eliminates the need for centralized double data entry and shortens data cleaning timelines.

The GCDMP (Chapter: Electronic Data Capture Systems) states that EDC systems shift certain tasks, including data entry, initial query response, and source verification preparation, to the site level. Yet, data entry remains the most significant additional responsibility compared to paper-based studies.

Option A (Query resolution) is performed in both EDC and paper-based systems.

Option C (Data curation) is typically a Data Management function.

Option D (Medical record abstraction) is part of source documentation, not specific to EDC.

Thus, option B (Data entry) is correct - it is the additional site coordinator duty unique to EDC environments.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.3 - Site Responsibilities and Workflow Changes ICH E6(R2) GCP, Section 5.5.3 - Data Entry and Role Delegation in Computerized Systems FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.2 - Site-Level Data Entry Controls

### 질문 # 153

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많은 사이트에서도 무료SCDM CCDM덤프데모를 제공합니다. 우리도 마찬가지입니다. 여러분은 그러한SCDM CCDM데모들을 보시고 다시 우리의 덤프와 비교하시면, 우리의 덤프는 다른 사이트덤프와 차원이 다른 덤프임을 아사될 것 입니다. 우리 Fast2test사이트에서 제공되는SCDM인증CCDM시험덤프의 일부본인 데모 즉 문제와 답을 다운받으셔서 체험해보면 우리Fast2test에 믿음이 갈 것입니다. 왜냐면 우리 Fast2test에는 베테랑의 전문가들로 이루어진 연구팀이 있습니다, 그들은 지식과 풍부한 경험으로 여러 가지 여러분이SCDM인증CCDM시험을 패스할 수 있을 자료 등을 만들었습니다 여러분이SCDM인증CCDM시험에 많은 도움이SCDM CCDM될 것입니다. Fast2test가 제공하는CCDM테스트버전과 문제집은 모두SCDM CCDM인증시험에 대하여 충분한 연구 끝에 만든 것이기에 무조건 한번에SCDM CCDM시험을 패스하실 수 있습니다. 때문에SCDM CCDM덤프의 인기는 당연히 짱 입니다.

CCDM덤프자료 : <https://kr.fast2test.com/CCDM-premium-file.html>

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