



본 연구는 많은 형태의 GCDM/GCDM이 존재함을 증명하기 성공적으로 도입되는 아이디어이다. 본 연구의 GCDM

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 $\text{SSD}_1 + \text{SSD}_2$: 다른 이의 수에 따라 계층화되는 일대일 대안과 같은 수에 대한 SSD와 SSD

SCDM CCDM 시험요강:

주제	소개
주제 1	<ul style="list-style-type: none"> 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 2	<ul style="list-style-type: none"> 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 3	<ul style="list-style-type: none"> 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 4	<ul style="list-style-type: none"> 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.
주제 5	<ul style="list-style-type: none"> 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.

최신 Clinical Data Management CCDM 무료 샘플문제 (Q93-Q98):

질문 # 93

A Clinical Data Manager reads a protocol for a clinical trial to test the efficacy of an antiviral to counteract a new epidemic. The stated primary efficacy endpoint is 3-month survival. Which data element is needed for the primary efficacy endpoint?

- A. Birth date
- **B. Death date**
- C. Date of autopsy
- D. Cause of death

정답: B

설명:

When the primary efficacy endpoint in a clinical trial is 3-month survival, the key data element required is the death date. This is because the survival endpoint is determined by calculating whether the subject lived or died within a defined time frame from study enrollment or randomization.

According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the Clinical Data Manager (CDM) must identify and ensure the capture of all critical data elements necessary to evaluate the study endpoints. For time-to-event analyses (e.g., survival studies), accurate event dates (death date) are essential for endpoint derivation and statistical analysis.

Other data elements such as cause of death or date of autopsy (options B and C) may support secondary analyses or safety reviews but are not necessary to determine the survival endpoint itself. Similarly, birth date (option D) contributes to demographic data but is unrelated to the primary efficacy outcome.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.4 - Critical Data Identification for Endpoints ICH E9 - Statistical Principles for Clinical Trials, Section 2.2.3 - Time-to-Event Data Considerations FDA Guidance for Industry: Clinical Trial Endpoints for Drug Development

질문 # 94

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

- A. Use of a common software platform
- B. Exclusion of studies that use a cross-over design

- C. Use of a common adverse event dictionary
- D. Enrollment of investigative sites with similar patient populations

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 # 95

A relational database has tables for PATIENT_DEMOGRAPHY and VITAL_SIGNS data collected during a visit. The primary key for the VITAL_SIGNS table is a composite key that includes the unique patient identifier, visit number, and vital signs parameter name. The two tables are joined on the patient identifier. What will be the number of records in the result set?

- A. One record per patient
- B. One record per patient per visit per vital sign parameter
- C. One record per patient per visit
- D. One record per visit

정답: B

설명:

In a relational database structure, each record in a table is uniquely identified by a primary key. In this case, the VITAL_SIGNS table uses a composite primary key consisting of:

Patient Identifier,

Visit Number, and

Vital Signs Parameter Name.

This means each record represents a unique measurement of a specific parameter (e.g., blood pressure, pulse) for a patient at a specific visit.

When joining PATIENT_DEMOGRAPHY and VITAL_SIGNS tables on the patient identifier, the result set will include one record for every combination of patient, visit, and parameter - i.e., one record per patient per visit per vital sign parameter.

Therefore, option C correctly describes the expected number of records.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Primary and Foreign Key Relationships in Relational Models CDISC SDTM Implementation Guide, Section 5.3 - Observation-Level Data Structures ICH E6(R2) GCP, Section 5.5.3 - Data Organization and Integration Principles

질문 # 96

Every database lock should follow documented approval of which stakeholders?

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

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 # 97

Which is the most important reason for why a data manager would review data before a monitor reviews it?

- A. Data managers have access to programming tools to identify discrepancies.
- **B. Data can be viewed and discrepancies highlighted prior to a monitor's review.**
- C. The GCDMP recommends that data managers review data prior to a monitor's review.
- D. Data managers write the Data Management Plan that specifies the data cleaning workflow.

정답: B

설명:

The primary reason data managers review data before a monitor's review is to identify and flag discrepancies or inconsistencies so that site monitors can focus their efforts more efficiently during on-site or remote source data verification (SDV).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), proactive data review by data management staff ensures data completeness and accuracy by identifying missing, inconsistent, or out-of-range values. This pre-review helps streamline the monitoring process, reduces the volume of open queries, and enhances data quality. Option A is true but not the main reason for pre-monitor review. Option C highlights a capability rather than a rationale. Option D is partially correct, but the GCDMP emphasizes process purpose, not prescriptive order. Thus, option B correctly captures the practical and process-oriented reason for early data review-to ensure data are ready and accurate for the monitor's review phase.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Data Review Timing and Purpose ICH E6(R2) GCP, Section 5.18 - Monitoring and Data Verification Requirements

질문 # 98

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SCDM CCDM덤프의 무료샘플을 원하신다면 우의 PDF Version Demo 버튼을 클릭하고 메일주소를 입력하시면 바로 다운받아SCDM CCDM덤프의 일부분 문제를 체험해 보실수 있습니다. SCDM CCDM 덤프는 모든 시험문제유형을 포함하고 있어 적응율이 아주 높습니다. SCDM CCDM덤프로SCDM CCDM시험패스 GO GO GO !

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