

시험패스 가능한CCDM자격증공부자료덤프데모문제보기



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SCDM CCDM 시험요강:

주제	소개
주제 1	<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.
주제 2	<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 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"> 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.

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최신 Clinical Data Management CCDM 무료샘플문제 (Q59-Q64):

질문 # 59

The Scope of Work would answer which of the following information needs?

- A. To look up the date of the next clinical monitoring visit for a specific site
- B. To determine the number of data transfers budgeted for a project
- C. To find the name and contact information of a specific clinical data associate
- D. To look up which visit PK samples are taken

정답: B

설명:

The Scope of Work (SOW) is a project management document that defines what services are included in the work agreement between the sponsor and the CRO or vendor. It outlines deliverables, responsibilities, timelines, and budget allocations.

According to the GCDMP (Chapter: Project Management in Data Management), the SOW includes specifications such as:

The number and frequency of data transfers,

Database build and lock milestones,

Quality control deliverables, and

Resource allocation for data management tasks.

The SOW does not cover operational site-level details such as monitoring schedules (B), protocol sampling details (C), or personnel contact lists (D).

Therefore, option A (number of data transfers budgeted for a project) correctly identifies a use case directly addressed in the SOW. Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Project Management, Section 4.1 - Scope of Work and Resource Planning ICH E6(R2) GCP, Section 5.5 - Sponsor Oversight and Data Management Responsibilities PMI Project Management Framework - Scope Definition and Deliverable Specifications

질문 # 60

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. Medical Document for Regulatory Activities

- C. Submission Data Tabulation Model
- 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 # 61

Which metric will identify edit checks that may not be working properly?

- A. Count by site of the number of times any edit check fired
- B. Average number of times each edit check has fired
- C. Count by edit check of the number of times the check fired
- D. Average number of edit check identified discrepancies per form

정답: C

설명:

The best metric to identify malfunctioning or ineffective edit checks is the count by edit check of the number of times the check fired. This allows data managers to assess whether specific edit checks are performing as intended.

According to the GCDMP, Chapter: Data Validation and Cleaning, edit checks are programmed logic conditions that identify data inconsistencies or potential errors during data entry. A properly functioning edit check should trigger only when data falls outside acceptable or logical limits. If an edit check fires too frequently or not at all, it may indicate a logic error in the check's programming or configuration.

By analyzing counts by individual edit checks, data managers can:

Identify checks that never trigger (potentially inactive or incorrectly written), Detect overactive checks (poorly designed parameters causing excessive false positives), and Optimize system performance and review efficiency.

This metric supports continuous improvement in data validation logic and contributes to cleaner, higher-quality clinical databases.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.2 - Edit Check Design and Performance Metrics FDA Guidance: Computerized Systems Used in Clinical Investigations - Section on Validation of Electronic Data Systems

질문 # 62

Which information should an auditee expect prior to an audit?

- A. Standard operating procedures
- B. Audit plan or agenda
- C. Corrective action requests
- D. Auditor's credentials and certification number

정답: B

설명:

Prior to an audit, the auditee should expect to receive an audit plan or agenda, which outlines the scope, objectives, schedule, and logistics of the audit.

According to the GCDMP (Chapter: Quality Assurance and Audits), an audit plan ensures transparency, preparation, and efficient execution. It typically includes details such as:

The audit scope and objectives,

The audit team members,

Documents or processes to be reviewed, and

The audit schedule and timeframe.

This allows the auditee to prepare the necessary records, staff, and facilities. While the auditor's credentials (option A) may be shared informally, they are not a regulatory requirement. Corrective actions (option B) are outcomes of the audit, not pre-audit materials. Standard Operating Procedures (option C) may be requested during the audit but are not provided in advance.

Thus, Option D - Audit Plan or Agenda - is the correct and compliant answer.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Quality Assurance and Audits, Section 6.1 - Pre-Audit Planning and Communication ICH E6 (R2) Good Clinical Practice, Section 5.19.3 - Audit Procedures and Responsibilities FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section 8.1 - Audit Preparation and Planning

질문 # 63

The result set from the query below would be which of the following?

SELECT Pt_ID, MRN, SSN FROM patient

- A. Narrower than the patient table
- B. Longer than the patient table
- C. Wider than the patient table
- D. Shorter than the patient table

정답: A

설명:

In a SQL (Structured Query Language) database, the SELECT statement specifies which columns to display from a table. In this query, only three columns - Pt_ID, MRN, and SSN - are being selected from the patient table.

This means the resulting dataset will contain:

The same number of rows (records) as the original table (assuming no WHERE filter), and Fewer columns than the full table.

In database terminology:

"Wider" refers to more columns (fields).

"Narrower" refers to fewer columns (fields).

Since this query retrieves only 3 columns (out of potentially many in the original table), the result set is narrower than the patient table, making option D correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.1 - Relational Databases and Query Logic ICH E6(R2) GCP, Section 5.5.3 - Data Retrieval and Integrity Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Database Query Controls

질문 # 64

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