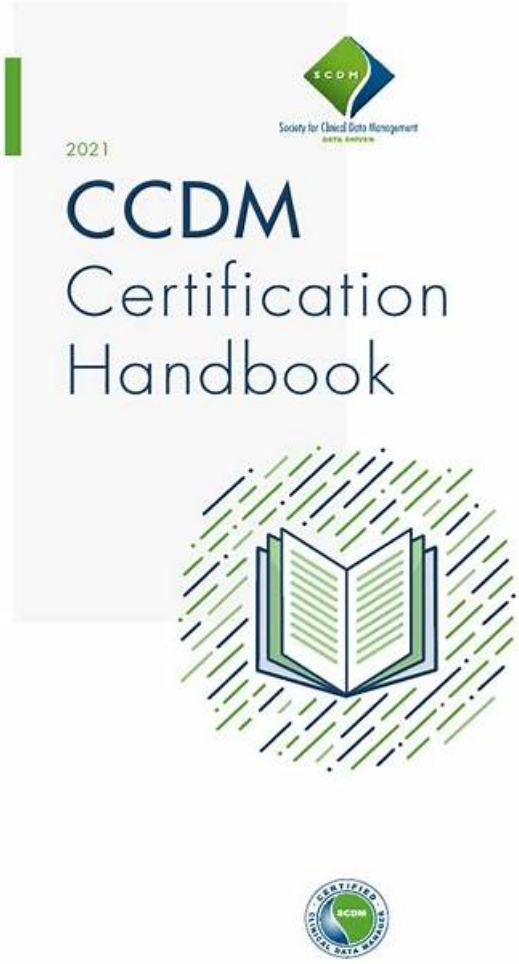
SCDM CCDM덤프최신버전 - CCDM최신기출자료



BONUS!!! Pass4Test CCDM 시험 문제집 전체 버전을 무료로 다운로드하세요: https://drive.google.com/open?id=1gtoumo7-7-e1RkkHyx6MoMvV5buglU-d

Pass4Test에서는 소프트웨어버전과 PDF버전 두가지버전으로 덤프를 제공해드립니다.PDF버전은 구매사이트에서 무료샘플을 다움받아 체험가능합니다. 소프트웨어버전은실력테스트용으로 PDF버전공부후 보조용으로 사용가능합니다. SCDM 인증CCDM덤프 무료샘플을 다운받아 체험해보세요.

SCDM CCDM 시험요강:

주제	소개
주제 1	• 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 2	• 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	• 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 4	• 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	• 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.

최신 Clinical Data Management CCDM 무료샘플문제 (Q47-Q52):

질문 # 47
Which attribute is NOT a characteristic of a standardized data collection element?

- A. A strictly enforced requirement for the positioning of each data element on a case report form
- B. A unique set of data storage metadata, including a variable name and data type
- C. An unambiguous definition for the data element
- D. A standard set of values used to respond to a data collection question

정답：A

설명:
A standardized data collection element has well-defined metadata, consistent naming conventions, and controlled terminology to ensure uniform data collection and interoperability across studies.
Key attributes, as per GCDMP and CDISC standards, include:
A clear definition of meaning (A)
A controlled set of response values (C)
Metadata specifications like variable names, formats, and data types (D) However, the physical positioning of a data element on a case report form (B) is a matter of form layout design, not a characteristic of data standardization. While consistent form structure aids usability, it is not part of data standardization or metadata management principles.
Hence, option B is correct - form positioning is not a standardized data element attribute.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Standards and Data Integration, Section 4.1 - Data Element Standardization CDISC CDASH Implementation Guide, Section 3.2 - Standardized Data Collection Elements and Metadata ICH E6(R2) GCP, Section 5.5.3 - Data Handling and Standardization

질문 # 48
Which method would best identify clinical chemistry lab data affected by a blood draw taken distal to a saline infusion?

- A. Abnormally low urine glucose values in a dataset
- B. Lab values from a blood draw with a very high sodium and very low other values
- C. Abnormally high sodium values in a dataset
- D. Lab values from a blood draw with a very low sodium and very high other values

정답：B

설명:
If a blood sample is drawn distal (downstream) from a saline infusion site, it may become contaminated with saline, leading to

abnormal laboratory results. Saline contains a high concentration of sodium chloride, which artificially elevates sodium while diluting other blood components.
Therefore, such samples would display:
Very high sodium levels, and
Abnormally low levels of other analytes (e.g., proteins, glucose, potassium).
This abnormal pattern (option B) is a classic indicator of saline contamination.
Per the GCDMP (Chapter: Data Validation and Cleaning), cross-variable consistency checks are critical for identifying biologically implausible patterns, such as this one, which indicate pre-analytical errors rather than true physiological changes.
Hence, option B accurately describes the data signature of a contaminated blood draw.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 6.2 - Logical and Consistency Checks for Laboratory Data ICH E6(R2) GCP, Section 5.1.1 - Data Quality and Biological Plausibility Checks FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Detecting Laboratory Anomalies

질문 # 49
What are the first logical specifications that need approval when building an efficient EDC database?

- A. Metric Reports
- B. Edit Check Logic
- C. eCRF Fields
- D. eCRF Guidelines

정답：C

설명：
In the EDC database build process, the first logical specifications that require approval are the electronic Case Report Form (eCRF) fields.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Database Design and Build), eCRF field specifications define what data elements are collected, their data types, permitted values, field lengths, and any associated metadata. Approval of these specifications forms the foundation for subsequent design components such as edit check programming, query management rules, and data validation logic.
Edit checks (B) are developed only after fields and structures are finalized.
Metric reports (C) and eCRF guidelines (D) are downstream documentation or tools, not logical specifications required at the build start.
Therefore, option A (eCRF fields) is correct, as their approval marks the first formal milestone in the EDC system development life cycle.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 4.2 - Logical Design and eCRF Field Specifications ICH E6(R2) GCP, Section 5.5.3 - System Design and Validation Documentation FDA 21 CFR Part 11 - System Validation and Documentation Controls

질문 # 50
According to the FDA Guidance for Industry, Providing Regulatory Submissions in Electronic Format (April 2006) and Good Clinical Data Management Practices (GCDMP, May 2007), which of the following is the most acceptable for a derived field?

- A. Providing the algorithm for calculating the average score on the CRF
- B. Providing CRF annotation "not entered in the database" next to the average score
- C. Providing CRF annotation AVE next to the average score
- D. Providing the algorithm for calculating the average score in the dataset definition file

정답：D

설명：
In clinical data management, a derived field refers to any variable that is not directly collected from the Case Report Form (CRF) but is instead calculated or inferred from one or more collected variables (for example, calculating an average blood pressure from multiple readings). Proper documentation of derived fields is essential for ensuring data traceability, transparency, and compliance with both FDA and SCDM guidelines.
According to the Good Clinical Data Management Practices (GCDMP, May 2007), all derivations and transformations applied to clinical data must be clearly defined and documented in metadata such as the dataset definition file (also referred to as data

specifications, variable definition tables, or Define.xml files). The derivation algorithm should be explicitly stated in this documentation to allow independent verification, regulatory review, and reproducibility of results.
The FDA Guidance for Industry (April 2006) on electronic submissions further emphasizes that derived fields must be supported by comprehensive metadata that defines the computational method used. This documentation enables the FDA or any regulatory body to audit and reproduce analytical results without ambiguity. Annotating or describing derivations directly on the CRF (as in options A, B, or D) is not sufficient, as CRFs represent data collection instruments-not analytical documentation.
Therefore, the correct and regulatory-compliant practice is to provide the derivation algorithm for a calculated field within the dataset definition file, aligning with both FDA and GCDMP expectations for data integrity and auditability.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Handling and Processing - Derived and Calculated Data Fields, Section 5.3.3 FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006, Section 3.2 on Dataset Documentation Requirements CDISC Define.xml Implementation Guide - Metadata and Algorithm Documentation for Derived Variables

질문 # 51
A study has an expected enrollment period of one year but has subject recruitment issues. Twelve new sites are added toward the end of the expected enrollment period to help boost enrollment. What is the most likely impact on data flow?

- A. Additional sites will likely have increased query rates since site training is occurring closer to study close.
- B. A bolus of CRFs at the end of the study will result in the need to increase data entry and cleaning rates to meet existing timelines.
- C. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- D. The database set-up will need to be changed to allow for additional sites as they are added to the study.

정답：B

설명:
Adding multiple new sites late in the enrollment period creates a concentrated influx of new data near the end of the study. These sites typically start enrolling patients later, resulting in a "bolus" of Case Report Forms (CRFs) that must be entered, validated, and cleaned within a shorter timeframe to meet database lock deadlines.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Data Flow), late site activation compresses the timeline for data management tasks, necessitating increased resources for data entry, query management, and cleaning. Data management teams must anticipate this surge and plan accordingly-either by increasing staffing or revising timelines to prevent bottlenecks and maintain quality.
While option D (increased query rates) can occur, it is a secondary effect. The most direct and consistent impact is the surge in data volume requiring expedited processing near study end.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management, Section 5.3 - Managing Changes in Site Activation and Data Flow ICH E6(R2) GCP, Section 5.1 - Quality Management and Oversight

질문 # 52
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