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SAP C_HANADEV_17 SAP Certified Development Associate - SAP HANA 2.0 SPS03 4

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Tags: **C_HANADEV_17최신 업데이트버전 덤프,C_HANADEV_17합격보장 가능 시험대비자료,C_HANADEV_17인기자격증,C_HANADEV_17퍼펙트 덤프 최신자료,C_HANADEV_17퍼펙트 덤프 최신 데모문제**

C_HANADEV_17최신업데이트버전덤프, C_HANADEV_17합격보장가능시험대비자료

그리고 Itcertkr CCDM 시험 문제집의 전체 버전을 클라우드 저장소에서 다운로드할 수 있습니다: https://drive.google.com/open?id=1YeaPZX0LdJwv5_nkrSJBODE9fPQzjHbn

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SCDM CCDM 시험요강:

주제	소개
주제 1	• 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	• 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 3	• 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 4	• 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 5	• 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 무료샘플문제 (Q43-Q48):

질문 # 43
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. 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.
- B. Additional sites will likely have increased query rates since site training is occurring closer to study close.
- C. The database set-up will need to be changed to allow for additional sites as they are added to the study.
- D. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.

정답： A

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 # 44
A protocol is updated mid-study to add an additional procedure about which data needs to be collected. Which of these statements applies?

- A. The DMP should be updated to reflect the changes to the protocol, but this update does not need to be communicated
- B. The DMP should be updated to reflect the changes to the protocol and stakeholders notified
- C. The DMP does not need to be updated as it represents the data at the beginning of the trial only

- D. The DMP does not need to be updated until the end of the trial and all updates are included in the DMP to indicate what happened in the trial

정답：B

설명：
When a protocol is amended mid-study, resulting in additional data collection requirements, the Data Management Plan (DMP) must be updated accordingly and all relevant stakeholders must be notified.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the DMP is a living document that defines all data management processes for a clinical study. It must accurately reflect the current data flow, CRF design, validation procedures, and reporting structure. Any protocol amendments affecting data capture, structure, or analysis require immediate DMP revision and distribution to ensure alignment across data management, clinical, and biostatistics teams.
Failure to update and communicate DMP changes can lead to misalignment in data handling and introduce compliance risks during audits or inspections. Therefore, Option B is correct: the DMP must be updated and the change communicated to all stakeholders (e.g., sponsor, CRO, clinical operations, biostatistics).
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Plan (DMP), Section 5.3 - Maintaining and Updating the DMP ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Documentation of Protocol Changes and Data Handling Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Data Management Documentation

질문 # 45
What are the first logical specifications that need approval when building an efficient EDC database?

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

정답：D

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 # 46
Which competency is necessary for EDC system use in a study using the medical record as the source?

- A. Training on how to log into Medical Records system
- B. Using ePRO devices
- C. Resolving discrepant data
- D. Screening study subjects

정답：A

설명：

In studies where the medical record serves as the source document, the Electronic Data Capture (EDC) system users (typically study coordinators or site personnel) must have appropriate training on how to access and log into the medical record system. This competency ensures that data abstracted from the electronic medical record (EMR) are complete, accurate, and verifiable in compliance with Good Clinical Practice (GCP) and Good Clinical Data Management Practices (GCDMP).
According to the GCDMP (Chapter: EDC Systems and Data Capture) and ICH E6(R2), all personnel involved in data entry and verification must be trained in both the EDC and the primary source systems (e.g., EMR). This ensures that the integrity of data flow-from source to EDC-is maintained, and that personnel understand system access controls, audit trails, and proper documentation of source verification.
While resolving discrepant data (C) and screening subjects (A) are part of study operations, the competency directly related to EDC system use in EMR-based studies is the ability to properly log into and navigate the medical records system to extract source data.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Electronic Data Capture (EDC), Section 5.1 - Source Data and System Access Requirements ICH E6(R2) Good Clinical Practice, Section 4.9 - Source Documents and Data Handling FDA Guidance: Use of Electronic Health Record Data in Clinical Investigations, Section 3 - Investigator Responsibilities

질문 # 47
A data manager takes the INTERSECTION data in two tables wanting only the 50 records common to both tables. What operation did the data manager perform?

- A. Inner join
- B. Full outer join
- C. Left outer join
- D. Right outer join

정답：A

설명：
The inner join operation retrieves only the records that exist in both tables, which is the intersection of two datasets.
In clinical data management, relational databases often store related data in multiple tables-for example, demographic data in one table and lab results in another. When a Data Manager needs to extract records that exist in both (e.g., subjects appearing in both demographics and labs), an inner join is used.
According to the GCDMP (Chapter: Database Design and Build), joins are fundamental relational operations ensuring data consistency and integrity across multiple data domains.
Inner join: Returns matching records from both tables (intersection).
Left/right outer joins: Return all records from one table and matching records from the other (preserving nonmatches).
Full outer join: Returns all records from both tables, whether matched or not.
Therefore, to select only the 50 records common to both tables, the correct operation is an inner join.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Build, Section 4.3 - Relational Database Concepts and Joins ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Processing and Validation

질문 # 48
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참고: Itcertkr에서 Google Drive로 공유하는 무료 2026 SCDM CCDM 시험 문제집이 있습니다: https://drive.google.com/open?id=1YeaPZX0LdJwv5_nkrSJBODE9fPQzjHbn