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>> CCDM熱門考古題 <<

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SCDM CCDM 考試大綱：

主題	簡介
主題 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.
主題 2	• 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.

主題 3	• 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.
主題 4	• 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.
主題 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.

最新的 Clinical Data Management CCDM 免費考試真題 (Q22-Q27):

問題 #22
Which of the following roles commonly requires data entry and update privileges in an EDC application used in a clinical study?

- A. Study Statistician
- B. EDC System Administrator
- C. Site Study Coordinator
- D. Clinical Study Monitor

答案：C

解題說明：
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

問題 #23
A site study coordinator attempts to make an update in a study database in an EDC system after lock. What occurs?

- A. The change is logged as occurring after lock
- B. The change is approved by the Data Manager before it is applied
- C. The site study coordinator is not able to make the change
- D. The old value is replaced in all locations by the new value

答案：C

解題說明：
Once a clinical database is locked, it becomes read-only - no further data modifications can be made by any users, including site personnel. This ensures that the data are finalized, consistent, and auditable for statistical analysis and regulatory submission.
According to the GCDMP (Chapter: Database Lock and Archiving), the lock process involves freezing the database to prevent accidental or unauthorized changes. After lock, access permissions are restricted, and all edit and update functions are disabled. If any corrections are required post-lock, the database must be unlocked under controlled procedures (with full audit trail

documentation).
Thus, option C - The site study coordinator is not able to make the change - correctly reflects standard EDC functionality and regulatory compliance.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.2 - Database Lock Procedures and Controls ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Audit Trail Requirements FDA 21 CFR Part 11 - Controls for Electronic Records and System Lock Functions

問題 #24
A study uses and collects pacemaker interrogation data for each patient weekly by selecting and downloading the data from the manufacturer's website. There are 200 patients in the study and it takes the Data Manager 30 minutes per file to download, import, and process the dat a. Assuming that the distribution of work is uniform over the six-month trial, how many Data Managers are needed for the activity data alone?

- A. One Data Manager per month
- B. Fifty percent of a Data Manager per month
- C. Two and a half Data Managers per month
- D. Two Data Managers per month

答案： B

解題說明：
Let's calculate the workload:
200 patients × 30 minutes = 6,000 minutes/week
6,000 minutes ÷ 60 = 100 hours/week
Over 6 months (~26 weeks): 100 × 26 = 2,600 hours total
Assuming a full-time Data Manager works approximately 160 hours/month, over 6 months (960 hours) per full-time equivalent (FTE):
2,600 ÷ 960 ≈ 2.7 FTEs total for the entire study period
To find the average per month, we divide evenly over 6 months:
2.7 ÷ 6 ≈ 0.45 FTE per month, or approximately 50% of a Data Manager per month.
Thus, the correct answer is B. Fifty percent of a Data Manager per month.
This estimate follows GCDMP best practices in resource planning, ensuring adequate data management capacity for ongoing external data handling activities.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management, Section 5.3 - Resource Estimation and Workload Planning ICH E6(R2) GCP, Section 5.1.1 - Quality Systems and Adequate Staffing

問題 #25
Which of the following tasks would be reasonable during a major upgrade of a clinical data management system?

- A. All of the case report forms should be pulled and compared to the archive.
- B. The data archive should be migrated to an offsite database server.
- C. The ability to access and read the clinical data archive should be tested.
- D. All of the data formats in the archive should be updated to new standards.

答案： C

解題說明：
During a major system upgrade, it is critical to verify that archived data remain accessible, readable, and intact following the implementation.
According to the GCDMP (Chapter: Database Lock and Archiving), regulatory requirements such as 21 CFR Part 11 and ICH E6(R2) mandate that archived data must remain retrievable in a human-readable format for the duration of retention (often years after study completion).
Therefore, as part of validation and verification testing, organizations must confirm that existing archives can still be accessed using the upgraded system or compatible tools.
Option A: Updating archive formats could alter original data integrity (noncompliant).
Option C: Migration offsite is an IT infrastructure task, not directly tied to the upgrade process.
Option D: Comparing CRFs to archives is unnecessary unless data corruption is suspected.

Hence, option B (testing archive accessibility) is the correct and compliant approach.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.4 - System Upgrades and Archive Validation ICH E6(R2) GCP, Section 5.5.3 - System Validation and Data Retention FDA 21 CFR Part 11 - Data Archiving, Retention, and Retrieval Requirements

問題 #26
During a database audit, it was determined that there were more errors than expected. Who is responsible for assessing the overall impact on the analysis of the data?

- A. Data Manager
- B. Investigator
- C. Quality Auditor
- D. Statistician

答案：D

解題說明：
The Statistician is responsible for assessing the overall impact of data errors on the analysis and study results.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control) and ICH E9 (Statistical Principles for Clinical Trials), while the Data Manager ensures data accuracy and completeness through cleaning and validation, the Statistician determines whether the observed data discrepancies are statistically significant or if they may affect the validity, power, or interpretability of the study's outcomes.
The Quality Auditor (C) identifies and reports issues but does not quantify analytical impact. The Investigator (D) is responsible for clinical oversight, not statistical assessment. Thus, after a database audit, the Statistician (B) performs a formal evaluation to determine whether the magnitude and nature of the errors could bias results or require reanalysis.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Data Audit and Impact Assessment ICH E9 - Statistical Principles for Clinical Trials, Section 3.2 - Data Quality and Analysis Impact Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Validation and Analysis Review

問題 #27
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