CCDM Fragenkatalog, CCDM Fragen&Antworten

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SCDM CCDM Prüfungsplan:

Thema	Einzelheiten
Thema 1	• 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.
Thema 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.
Thema 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.
Thema 4	• 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.
Thema 5	• 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.

>> CCDM Fragenkatalog <<

SCDM CCDM Fragen&Antworten & CCDM Zertifizierungsprüfung

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SCDM Certified Clinical Data Manager CCDM Prüfungsfragen mit Lösungen (Q141-Q146):

141. Frage
In a cross-functional team meeting, a monitor mentions performing source data verification (SDV) on daily diary data entered by patients on mobile devices. Which of the following is the best response?

- A. Diary data to be source data verified should be selected using a risk-based approach
- B. Diary data to be source data verified should be randomly selected
- C. All diary data should be source data verified
- D. The diary data should not be source data verified

Antwort: A

Begründung:
The best response is that diary data to be source data verified should be selected using a risk-based approach.
According to the GCDMP (Chapter: Data Quality Assurance and Control) and FDA Guidance on Risk-Based Monitoring (RBM), not all data require full SDV. Electronic patient-reported outcome (ePRO) or mobile diary data are typically direct electronic source data (eSource) captured at the time of entry, which already ensures authenticity and traceability.
A risk-based SDV approach focuses verification efforts on data critical to subject safety and primary efficacy endpoints, as defined in the study's Risk Assessment Plan or Monitoring Plan. Random or full verification of low-risk data (like diary compliance metrics) adds unnecessary effort and cost.
Thus, Option C aligns with current regulatory expectations and data management best practices.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Risk-Based Monitoring and SDV ICH E6 (R2) Good Clinical Practice, Section 5.18 - Risk-Based Quality Management FDA Guidance for Industry: Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring (2013)

142. Frage
During testing of an ePRO system, a test fails. Which information should be found in the validation documentation?

- A. Reconciliation datapoints
- B. Training requirements
- C. Expected and actual results
- D. Root cause analysis of the system errors

Antwort: C

Begründung:
When a system validation test fails during Electronic Patient-Reported Outcome (ePRO) system testing, the validation documentation must record the expected results (what should have occurred) and the actual results (what occurred).
According to the GCDMP (Chapter: Database Validation and Testing), proper system validation documentation ensures traceability, reproducibility, and compliance with FDA 21 CFR Part 11 and ICH E6 (R2). Each test case must include:
Test objective,
Preconditions,
Test steps,
Expected results,
Actual results, and
Pass/fail status.
If a test fails, this documentation provides the objective evidence necessary for deviation handling, issue resolution, and re-testing.

While a separate root cause analysis may be performed later (option D), the validation record itself must focus on verifying outcomes against predefined expectations.
Therefore, the correct answer is B - Expected and actual results.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Validation and Testing, Section 4.4 - Documentation of Test Results FDA 21 CFR Part 11 - Validation Requirements (Section 11.10(a)) ICH E6 (R2) GCP, Section 5.5.3 - Computer System Validation and Documentation

143. Frage
Which database table structure is most appropriate for vital signs data collected at every-other visit for each patient in a study?

- A. One record per visit
- B. One record per patient
- C. One record per patient per visit
- D. One record per patient per study

Antwort: C

Begründung:
In a relational clinical database, the most efficient and normalized structure for data collected repeatedly over time-such as vital signs-is one record per patient per visit.
Each patient will have multiple records, one for each visit when vital signs are assessed. This structure supports:
Time-based analysis (e.g., trends across visits),
Accurate data linkage with visit-level metadata, and
Efficient querying for longitudinal data.
According to the GCDMP (Chapter: Database Design and Build), the relational design principle dictates that data should be stored at the lowest unique level of observation. Since vital signs vary by both patient and visit, the combination of patient ID + visit ID forms a unique key for each record.
Option A (per visit) lacks patient identification, while options B and D aggregate data too broadly, losing temporal detail.
Thus, option C (One record per patient per visit) correctly represents the normalized design structure.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 4.2 - Normalization and Table Structure CDISC SDTM Implementation Guide, Section 5.3 - Visit-Level and Observation-Level Data Structures ICH E6(R2) GCP, Section 5.5.3 - Data Handling Principles

144. Frage
A study budgeted forty hours allocated over the three months following first protocol draft for Data Management Plan (DMP) creation. If there is a problem with this approach, what is it?

- A. There is no problem with the approach
- B. Forty hours is too little time to budget for DMP creation
- C. No time was allocated for maintenance of the DMP
- D. Forty hours is too much time to budget for DMP creation

Antwort: C

Begründung:
The main issue with this approach is that no time has been allocated for ongoing maintenance and updates of the Data Management Plan (DMP) throughout the study lifecycle.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the DMP is a living document - it must be continuously maintained and updated as study procedures evolve, particularly after protocol amendments, database modifications, or changes in data validation or reconciliation procedures.
Budgeting only for initial creation (forty hours) over three months ignores the substantial effort required for DMP version control, stakeholder communication, and mid-study updates. These updates are mandatory to maintain compliance with ICH E6 (R2) GCP Section 5.5.3, which requires that all procedural documentation accurately reflect current practices.
Thus, the problem is not the time allocated for creation but the lack of planning for ongoing maintenance.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Plan (DMP), Section 5.3 - DMP Maintenance and Version Control ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Documentation of Data Handling

Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Documentation Updates

145. Frage
Which of the following tasks would be reasonable during a major upgrade of a clinical data management system?

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

Antwort: B

Begründung:
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

146. Frage
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