CCDM Examsfragen, CCDM Deutsche

Die Examfragen zur SCDM CCDM Zertifizierungsprüfung von Fast2test ist von den IT-Experten verifiziert und überprüft. Die Fragen und Antworten zur SCDM CCDM Zertifizierungsprüfung sind die von der Praxis überprüfte Software und die Schulungsinstrumente. In Fast2test werden Sie die besten Zertifizierungsmaterialien finden, die originale Fragen und Antworten enthalten. Unsere Materialien bieten Ihnen die Chance, die echten Übungen zu machen. Endlich werden Sie Ihr Ziel, nämlich die SCDM CCDM Zertifizierungsprüfung zu bestehen, erreichen.

SCDM CCDM Prüfungsplan:

Thema	Einzelheiten
Thema 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.

Thema 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.
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	• 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 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.

CCDM PrüfungGuide, SCDM CCDM Zertifikat - Certified Clinical Data Manager

Haben Sie die Fragenkataloge von SCDM CCDM aus Fast2test, werden Sie zugleich den Schlüssel zum Erfolg und eine schönere Zukunft haben. Nachdem Sie die Fragenkataloge von SCDM CCDM aus Fast2test gekauft haben, werden Sie einjährige kostenlose Aktualisierung genießen. Wenn Ihre gekauften Produkte irgend ein Qualitätsproblem haben oder Sie die CCDM Prüfung nicht bestehen, erstatten wir alle Ihren bezahlten Summe zurück.

SCDM Certified Clinical Data Manager CCDM Prüfungsfragen mit Lösungen (Q85-Q90):

85. Frage
What should be done if the site continues to provide inconsistent data after several re-queries?

- A. Gently lead the site to the correct response
- B. Continue to re-query until the site changes the data
- C. Escalate the issue to the appropriate site contact personnel
- D. Do nothing, the data will remain inconsistent

Antwort: C

Begründung:
If a clinical site continues to provide inconsistent or illogical data after multiple queries, the correct course of action is to escalate the issue to the appropriate site contact personnel, typically the Clinical Research Associate (CRA) or Site Monitor.
According to the Good Clinical Data Management Practices (GCDMP), persistent data discrepancies often indicate a misunderstanding of the protocol, CRF instructions, or data entry procedures at the site level. Repeatedly re-querying the same data without escalation wastes time and risks introducing bias or error. By escalating through formal communication channels, the issue can be clarified through re-training, documentation review, or site monitoring visits.
The GCDMP emphasizes that escalation ensures data accuracy, site accountability, and protocol adherence, maintaining both data quality and regulatory compliance. Data managers must document the escalation process in the Data Management Plan (DMP) and ensure proper follow-up resolution is achieved.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 4.2 - Handling Persistent Data Discrepancies ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Communication
FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Issue Escalation

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

87. Frage
A Data Manager is designing a report to facilitate discussions with sites regarding late dat a. Which is the most important information to display on the report to encourage sites to provide data?

- A. List of outstanding forms
- B. Number of forms entered in the last week
- C. Expected versus actual forms entered
- D. Total number of forms entered to date

Antwort: A

Begründung:
In managing site data timeliness, the most actionable and effective tool is a report listing all outstanding (missing or incomplete) CRFs.
According to GCDMP (Chapter: Communication and Study Reporting), Data Managers must provide site-level performance reports highlighting:
Outstanding CRFs not yet entered,
Unresolved queries, and
Pending data corrections.
Such reports help sites prioritize and address data gaps efficiently.
Option A and D are historical metrics without actionable context.
Option B gives a general overview but lacks specific site-level actionability.
Hence, option C (List of outstanding forms) provides the clearest and most motivating feedback to sites for timely data entry and query resolution.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Communication and Study Reporting, Section 5.3 - Data Timeliness and Reporting Metrics ICH E6(R2) GCP, Section 5.1.1 - Sponsor Oversight and Data Communication Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Site-Level Data Timeliness Reporting

88. Frage
A Data Manager is asked to manage SOPs for a department. Given equal availability of the following systems, which of the following is the best choice for managing the organizational SOPs?

- A. Existing paper filing system
- B. Learning management system
- C. Document management system
- D. Customized Excel spreadsheet

Antwort: C

Begründung:
The best choice for managing Standard Operating Procedures (SOPs) in a compliant and auditable manner is a Document Management System (DMS).
According to the GCDMP (Chapter: Regulatory Requirements and Compliance) and ICH E6 (R2), SOPs must be version-controlled, securely stored, retrievable, and auditable. A validated DMS supports controlled access, document lifecycle management (draft, review, approval, and archival), and electronic audit trails, ensuring full compliance with FDA 21 CFR Part 11 and Good Documentation Practices (GDP).
While Learning Management Systems (C) track training, they are not intended for document control. Spreadsheets (B) and paper systems (D) cannot provide adequate version tracking, access security, or audit capability required for regulatory inspection readiness.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Requirements and Compliance, Section 5.2 - SOP Management and Document Control ICH E6 (R2) GCP, Section 5.5.3 - Document and Record Management FDA 21 CFR Part 11 - Electronic Records and Signatures, Section 11.10 - System Validation and Document Controls

89. Frage
A Data Manager is drafting a report for clinical operations staff for support in responding to questions about milestone-based site payments. Which is the most important information to display?

- A. Milestones met by month, by site
- B. Milestones met by month, by type
- C. Expected versus actual milestones met to date, by site
- D. Milestones included in the last payment by site, by patient

Antwort: C

Begründung:
When reporting milestone-based site payment information, the most critical information to include is expected versus actual milestones met to date, by site.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), effective reporting must support operational and financial decision-making by presenting performance indicators in a clear, actionable format. Site payments in clinical studies are typically tied to specific milestones such as subject enrollment, visit completion, or data cleaning achievements.
By comparing expected (planned) versus actual (achieved) milestones per site, the Data Manager provides clinical operations staff with an accurate view of site progress and payment eligibility. This allows for identification of delayed sites, forecasting of upcoming payments, and early intervention for underperforming centers.
While milestone summaries by month or type (options A and B) may be useful for trend analysis, they lack the operational detail required for financial tracking. Milestone data by patient (option D) is overly granular for site-level payment management.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Data Reporting for Site Performance and Payments ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication and Monitoring Reports FDA Guidance for Industry: Oversight of Clinical Investigations - Site Management and Reporting

90. Frage
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