

CCDM Testfagen - CCDM Vorbereitung



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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	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 3	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 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.
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 Vorbereitung - CCDM Testing Engine

Sorgen Sie noch darum, dass Sie keine autoritäre Lehrbücher über die SCDM CCDM Prüfung finden können? Leute aus aller Welt möchten die SCDM CCDM Zertifizierungsprüfung wählen. Pass4Test ist die einzigartige Webseite, die Ihnen hochwertige Schulungsunterlagen zur SCDM CCDM Zertifizierung bietet. Wenn Sie noch besorgt sind, können Sie einen Teil der kostenlosen Zertifizierungsantworten herunterladen, bevor Sie die CCDM Schulungsunterlagen von Pass4Test kaufen.

SCDM Certified Clinical Data Manager CCDM Prüfungsfragen mit Lösungen (Q31-Q36):

31. Frage

Electronic submission standards require that an individual subject's complete CRF should be provided as what type of file:

- **A. Portable Document Format (.pdf)**
- B. Microsoft Word (.docx)
- C. Statistical Analysis System (.sas)
- D. Rich Text Format (.rtf)

Antwort: A

Begründung:

Electronic submission standards, as established by FDA, CDISC, and ICH, require that an individual subject's complete Case Report Form (CRF) be submitted as a Portable Document Format (.pdf) file. The PDF format is universally recognized and accepted because it ensures that the structure, format, and visual fidelity of the CRF are preserved exactly as originally designed, regardless of software or hardware environment.

According to the FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format (2006) and CDISC SDTM standards, sponsors must include a subject-level CRF in PDF form for each participant in the submission dataset. This requirement ensures that reviewers can trace data points from analysis datasets back to their source entries in the CRF, fulfilling the principles of data traceability and transparency.

The Good Clinical Data Management Practices (GCDMP) also support this requirement, emphasizing that CRF archiving should maintain readability and regulatory accessibility. Formats like RTF, DOCX, or SAS datasets are not acceptable substitutes for regulatory CRF submission because they may alter formatting, structure, or introduce modifiable content, violating FDA data integrity principles.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Archiving and Submission FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006 CDISC SDTM Implementation Guide, Section 5.3 - CRF Representation and Traceability

32. Frage

The best example of a protocol compliance edit check is:

- A. An edit check that fires when a value is outside of the normal range for vital signs
- B. An edit check that fires when a field is left blank
- C. An edit check that fires when an invalid date is entered
- **D. An edit check that fires when a visit date is outside the specified window**

Antwort: D

Begründung:

A protocol compliance edit check is designed to ensure that the data collected adheres to the specific requirements defined in the study protocol, such as visit timing, procedure windows, and eligibility criteria.

The example in option A - an edit check that triggers when a visit date falls outside the protocol-specified window - directly verifies compliance with the study design. This type of check supports real-time monitoring of protocol adherence, a critical quality and regulatory requirement under GCDMP and ICH E6(R2).

Other options are examples of general data validation checks, not protocol compliance:

B: Ensures clinical plausibility (data range check).

C: Ensures completeness (missing data check).

D: Ensures format correctness (system validation check).

Thus, option A best represents a protocol compliance edit check, confirming that collected data conform to the visit schedule

defined in the protocol.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.4 - Protocol Compliance Edit Checks ICH E6(R2) GCP, Section 5.1.1 - Quality Management and Compliance Controls FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Edit Check Design and Validation

33. Frage

Which is a minimum prerequisite that should be in place before choosing an EDC system?

- A. Draft validation plan
- B. Completed installation qualification
- C. Updated governance documentation
- **D. Knowledge of functional requirements**

Antwort: D

Begründung:

Before selecting an Electronic Data Capture (EDC) system for a clinical trial, it is essential to have a clear understanding of the functional requirements. This serves as the minimum prerequisite to guide system selection, ensuring that the EDC solution aligns with the protocol needs, data workflow, security requirements, and regulatory compliance.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Computerized Systems and Compliance), functional requirements describe what the system must do—such as data entry capabilities, edit checks, query management, user roles, audit trails, and integration with external systems (e.g., labs, ePRO). This understanding allows sponsors and CROs to evaluate vendor systems effectively during the selection and qualification phase.

Other options:

B. Installation qualification and D. Validation plan occur after system selection.

C. Governance documentation supports operations but is not required before choosing the system.

Hence, option A is correct - the first and most essential prerequisite before EDC selection is a solid understanding of the functional requirements.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 4.2 - Requirements Gathering and System Selection FDA 21 CFR Part 11 - System Validation and Intended Use Requirements ICH E6(R2) GCP, Section 5.5.3 - Computerized System Selection and Qualification

34. Frage

An organization is using an international data exchange standard and a new version is released. Which of the following should be assessed first?

- A. Cost of migrating to the new version
- B. Content coverage of the new version
- C. Availability of other standards covering the same content
- **D. Existence of backwards compatibility**

Antwort: D

Begründung:

When an updated version of a data exchange standard (such as CDISC SDTM, ADaM, or ODM) is released, the first factor that should be assessed is backwards compatibility. This determines whether the new version can interoperate with or accept data from prior versions without significant reconfiguration or data loss.

According to the Good Clinical Data Management Practices (GCDMP) and CDISC Implementation Guides, assessing backwards compatibility ensures that historical or ongoing study data remain valid and usable within the updated environment. If the new version introduces structural or semantic changes (such as variable name modifications or controlled terminology updates), it could impact mapping, validation, or regulatory submissions.

Once backward compatibility is confirmed, secondary assessments such as content coverage, availability of overlapping standards, and migration cost can be considered. However, ensuring that the new version supports existing infrastructure and data continuity is the first critical step before adoption.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 4.2 - Data Standards Updates and Compatibility Considerations CDISC SDTM Implementation Guide, Section 1.5 - Backward Compatibility and Version Control ICH E6(R2)

35. Frage

Which of the following is a best practice for creating eCRFs for a study?

- **A. Develop eCRFs with cross-functional team members**
- B. Set up coded terms so they are available to the site user
- C. Develop eCRFs that closely follow paper CRF standards
- D. Set up features that automatically enter data into fields when bypassed

Antwort: A

Begründung:

The best practice for developing electronic Case Report Forms (eCRFs) is to involve cross-functional team members throughout the design process.

According to the GCDMP (Chapter: CRF Design and Data Collection), eCRFs should be collaboratively developed by data management, clinical operations, biostatistics, medical, and regulatory teams. Each function provides a unique perspective - data managers focus on data capture and validation; statisticians ensure alignment with analysis requirements; clinicians ensure medical relevance and protocol compliance.

Collaborative development ensures that the eCRFs are fit-for-purpose, capturing all required data accurately, minimizing redundancy, and supporting downstream data analysis.

Options A and B violate good data management practice because sites should not directly access coded terms (to prevent bias), and fields should never auto-populate without explicit source verification. Option D is outdated; while paper CRFs may inform structure, EDC-optimized eCRFs should leverage system functionality rather than mimic paper.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.2 -

Collaborative CRF Development ICH E6 (R2) GCP, Section 5.5.3 - Data Collection and System Validation FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 3.4 - CRF Design Considerations

36. Frage

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