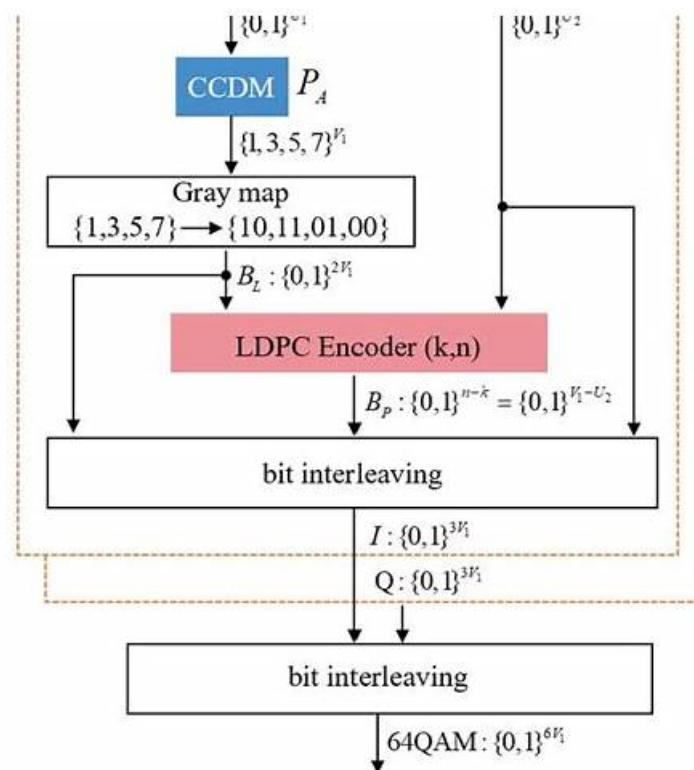


CCDM Zertifizierungsfragen & CCDM German



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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	• 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 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	• 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.

SCDM Certified Clinical Data Manager CCDM Prüfungsfragen mit Lösungen (Q150-Q155):

150. Frage

Which data are needed to monitor site variability in eligibility screening?

- A. Number of sites with low enrollment
- B. Number of sites with high enrollment
- **C. Number of subjects screened and number of subjects enrolled**
- D. Number of subjects enrolled

Antwort: C

Begründung:

To monitor site variability in eligibility screening, you must analyze the number of subjects screened versus the number of subjects enrolled at each site. This allows identification of sites that are over- or under-screening relative to their enrollment yield.

The GCDMP (Chapter: Data Quality Assurance and Metrics) emphasizes that screening-to-enrollment ratios are critical indicators of protocol compliance and data quality. Sites with unusually low conversion rates may have unclear understanding of inclusion/exclusion criteria, requiring targeted training or monitoring.

Other options (A, C, D) provide enrollment metrics but do not reveal screening efficiency or variability, which depend on both screening and enrollment data.

Thus, option B correctly identifies the data necessary for monitoring eligibility screening performance across sites.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Metrics, Section 5.4 - Site Performance Metrics ICH E6(R2) GCP, Section 5.18 - Monitoring and Site Oversight Requirements

151. Frage

Which type of edit check would be implemented to check the correctness of data present in a text box?

- A. Manual Check
- B. Back-end check
- **C. Front-end check**
- D. Programmed check

Antwort: C

Begründung:

A front-end check is a type of real-time validation performed at the point of data entry-typically within an Electronic Data Capture (EDC) system or data entry interface-designed to ensure that the data entered in a text box (or any input field) is valid, logically correct, and within expected parameters before the user can proceed or save the record.

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), edit checks are essential components of data validation that ensure data accuracy, consistency, and completeness. Front-end checks are implemented within the data collection interface and are triggered immediately when data are entered. They prevent invalid entries (such as letters in numeric fields, out-of-range values, or improper date formats) from being accepted by the system.

Examples of front-end checks include:

Ensuring a numeric field accepts only numbers (e.g., weight cannot include text characters).

Validating that a date is within an allowable range (e.g., not before the subject's date of birth).

Requiring mandatory fields to be completed before moving forward.

This differs from back-end checks or programmed checks, which are typically run later in batch processes to identify data inconsistencies after entry. Manual checks are human-performed reviews, often for context or data that cannot be validated automatically (e.g., narrative assessments).

Front-end edit checks are preferred wherever possible because they prevent errors at the source, reducing the number of downstream data queries and cleaning cycles. They contribute significantly to data quality assurance, regulatory compliance, and efficiency in data management operations.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.2 - Edit Checks and Real-Time Data Validation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Data Entry and Verification Controls ICH E6 (R2) Good Clinical Practice, Section 5.5 - Data Handling and Record Integrity CDISC Operational Data Model (ODM) Specification - Edit Check Implementation Standards

152. Frage

An external organization has been hired to manage SAE follow-up for a large study. Which of the following would be used as guidance for exchange of the SAE data between the EDC system and the vendor's safety management system?

- **A. Individual Case Safety Report**
- B. Medical Document for Regulatory Activities
- C. Biomedical Research Domain Model
- D. Submission Data Tabulation Model

Antwort: A

Begründung:

The Individual Case Safety Report (ICSR) is the standard format used globally for the exchange of Serious Adverse Event (SAE) data between clinical data management systems (EDC) and safety management systems.

According to ICH E2B(R3) and Good Clinical Data Management Practices (GCDMP, Chapter: Safety Data Management and SAE Reconciliation), the ICSR provides the data structure and content standards for electronic transmission of safety data, including patient demographics, event details, outcomes, and product information. It ensures interoperability between systems by defining standardized message elements and controlled terminologies.

Other options are not applicable:

A . Medical Document for Regulatory Activities (MDRA) is not a recognized standard.

B . Biomedical Research Domain Model (BRIDG) provides conceptual modeling but not data exchange guidance.

D . SDTM is used for regulatory submission datasets, not real-time SAE exchange.

Thus, option C (Individual Case Safety Report) is correct, as it defines the internationally accepted electronic format for SAE data exchange between safety and clinical databases.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Safety Data Management and SAE Reconciliation, Section 4.3 - SAE Data Exchange and Standards ICH E2B(R3): Electronic Transmission of Individual Case Safety Reports FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Postmarketing ICSRs (2014)

153. Frage

A relational database has tables for PATIENT_DEMOGRAPHY and VITAL_SIGNS data collected during a visit. The primary key for the VITAL_SIGNS table is a composite key that includes the unique patient identifier, visit number, and vital signs parameter name. The two tables are joined on the patient identifier. What will be the number of records in the result set?

- A. One record per visit
- **B. One record per patient per visit per vital sign parameter**
- C. One record per patient per visit
- D. One record per patient

Antwort: B

Begründung:

In a relational database structure, each record in a table is uniquely identified by a primary key. In this case, the VITAL_SIGNS table uses a composite primary key consisting of:

Patient Identifier,

Visit Number, and

Vital Signs Parameter Name.

This means each record represents a unique measurement of a specific parameter (e.g., blood pressure, pulse) for a patient at a specific visit.

When joining PATIENT_DEMOGRAPHY and VITAL_SIGNS tables on the patient identifier, the result set will include one record for every combination of patient, visit, and parameter - i.e., one record per patient per visit per vital sign parameter.

Therefore, option C correctly describes the expected number of records.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Primary and Foreign Key Relationships in Relational Models

CDISC SDTM Implementation Guide, Section 5.3 - Observation-Level Data Structures ICH E6(R2) GCP, Section 5.5.3 - Data

Organization and Integration Principles

154. Frage

On a dose escalation study, the Data Manager notices one site has a much higher number of queries than other sites and most are older than 30 days. The Data Safety Monitoring Board will meet in three weeks. What should the Data Manager providing CRO oversight do?

- A. Notify the CRO's Clinical Leader about the concerns
- **B. Consult the CRO's Lead Data Manager and the CRO's Project Leader**
- C. Ignore it for now and check back next week
- D. Call the site directly and ask the study coordinator about the concerns

Antwort: B

Begründung:

The correct action is to consult the CRO's Lead Data Manager and CRO's Project Leader (Option C) to ensure the issue is addressed through the appropriate oversight and escalation process.

According to the GCDMP (Chapter: Project Management and Communication), when a sponsor Data Manager identifies significant data management issues under CRO oversight - such as aging queries or site performance disparities - communication must follow the established governance and escalation pathway defined in the Scope of Work (SOW) and Data Management Plan (DMP).

Directly contacting the site (Option B) bypasses the CRO's chain of command and violates communication protocols. Notifying only the Clinical Leader (Option A) is insufficient, and ignoring the issue (Option D) jeopardizes the Data Safety Monitoring Board (DSMB) review timeline.

Therefore, Option C ensures a documented, collaborative approach to problem resolution within the contractual oversight structure.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 7.1 -

Oversight of CRO Data Management Activities ICH E6 (R2) GCP, Section 5.2 - Contract Research Organization Responsibilities

FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Roles and Communication Pathways

155. Frage

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