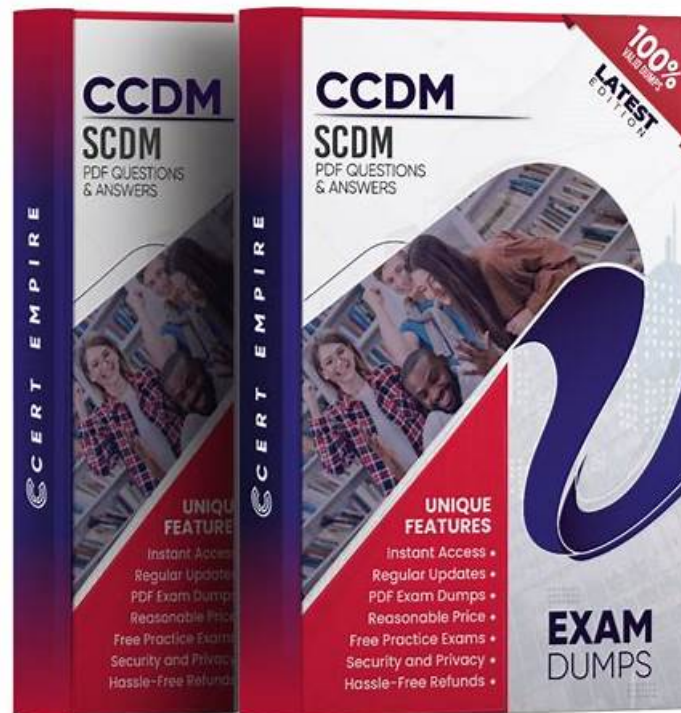# High-quality SCDM CCDM Latest Test Discount Technically Researched by SCDM First-Grade Trainers

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Quiz 2026 SCDM CCDM: Perfect Certified Clinical Data Manager Latest Test Discount

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SCDM Certified Clinical Data Manager Sample Questions (Q87-Q92):

NEW QUESTION # 87
Which information should an auditee expect prior to an audit?

- A. Auditor's credentials and certification number
- B. Standard operating procedures
- C. Corrective action requests
- D. Audit plan or agenda

Answer: D

Explanation:
Prior to an audit, the auditee should expect to receive an audit plan or agenda, which outlines the scope, objectives, schedule, and logistics of the audit.
According to the GCDMP (Chapter: Quality Assurance and Audits), an audit plan ensures transparency, preparation, and efficient execution. It typically includes details such as:
The audit scope and objectives,
The audit team members,
Documents or processes to be reviewed, and
The audit schedule and timeframe.
This allows the auditee to prepare the necessary records, staff, and facilities. While the auditor's credentials (option A) may be shared informally, they are not a regulatory requirement. Corrective actions (option B) are outcomes of the audit, not pre-audit materials. Standard Operating Procedures (option C) may be requested during the audit but are not provided in advance.
Thus, Option D - Audit Plan or Agenda - is the correct and compliant answer.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Quality Assurance and Audits, Section 6.1 - Pre-Audit Planning and Communication ICH E6 (R2) Good Clinical Practice, Section 5.19.3 - Audit Procedures and Responsibilities FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section 8.1 - Audit Preparation and Planning

NEW QUESTION # 88
Which attribute is NOT a characteristic of a standardized data collection element?

- A. A standard set of values used to respond to a data collection question
- B. A unique set of data storage metadata, including a variable name and data type
- C. An unambiguous definition for the data element
- D. A strictly enforced requirement for the positioning of each data element on a case report form

Answer: D

Explanation:
A standardized data collection element has well-defined metadata, consistent naming conventions, and controlled terminology to ensure uniform data collection and interoperability across studies.
Key attributes, as per GCDMP and CDISC standards, include:
A clear definition of meaning (A)
A controlled set of response values (C)
Metadata specifications like variable names, formats, and data types (D) However, the physical positioning of a data element on a case report form (B) is a matter of form layout design, not a characteristic of data standardization. While consistent form structure aids usability, it is not part of data standardization or metadata management principles.
Hence, option B is correct - form positioning is not a standardized data element attribute.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Standards and Data Integration, Section 4.1 - Data Element Standardization CDISC CDASH Implementation Guide, Section 3.2 - Standardized Data Collection Elements and Metadata ICH E6(R2) GCP, Section 5.5.3 - Data Handling and Standardization

NEW QUESTION # 89
ePRO data are collected for a study using study devices given to subjects. Which is the most appropriate quality control method for the data?

- A. Programmed edit checks to detect out of range values upon data entry
- B. Manual review of data by the site study coordinator at the next visit
- C. Data visualizations to look for site-to-site variation
- D. Programmed edit checks to detect out of range values after submission to the database

Answer: A

Explanation:
When electronic patient-reported outcomes (ePRO) devices are used, data are captured directly by subjects through validated devices and transmitted electronically to the study database. To ensure real-time data quality control, programmed edit checks should be implemented at the point of data entry - that is, as subjects input data into the device.
According to Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), front-end programmed edit checks are the optimal method to prevent entry of invalid or out-of-range values in ePRO systems. This helps maintain data accuracy at the source, minimizing downstream queries and data cleaning workload.
Options A and B involve post-submission or manual review, which is less efficient and not compliant with the principle of first-pass data validation. Option C (visualization) is a valuable secondary QC method for trends, but not for immediate data validation.
Therefore, option D is correct - programmed edit checks upon data entry ensure immediate validation and higher data integrity.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Automated Edit Checks and Front-End Validation ICH E6(R2) GCP, Section 5.5.3 - Computerized System Controls and Validation FDA Guidance for Industry: Electronic Source Data in Clinical Investigations (2013), Section 6 - Real-Time Data Quality Control

NEW QUESTION # 90

Which of the following scenarios requires a query to be sent to the central lab first when there is a discrepancy between the final lab data transfer and the CRF?

- A. The CRF has data for a visit but the central lab has missing data for the visit
- B. The central lab has data for a visit but the CRF has missing data for the visit
- C. Both the central lab and the CRF data have missing data for a visit
- D. Both the central lab and the CRF have data present for a visit

Answer: B

Explanation:
During data reconciliation between a central laboratory and CRF data, the source of truth is typically the central lab database, as it provides directly measured, vendor-generated results.
When the central lab has data but the CRF does not (option C), the Data Manager must first query the central lab to confirm that the result was transmitted correctly, since discrepancies may stem from data processing or timing issues. Once confirmed, a secondary query may be issued to the site to ensure CRF completion and alignment.
Conversely, if the CRF contains data but the central lab is missing results (option B), the issue is site-level, not vendor-level.
According to the GCDMP (Chapter: External Data Transfers and Reconciliation), priority for querying depends on the authoritative source - for lab data, the central lab is considered the source of record.
Therefore, option C is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: External Data Transfers and Reconciliation, Section 6.1 - Reconciliation of Central Lab and CRF Data ICH E6(R2) GCP, Section 5.5.3 - Source Data Verification and Vendor Reconciliation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Data Reconciliation and Traceability

NEW QUESTION # 91

In a study, data are key entered by one person after which a second person enters the data without knowledge of or seeing the values entered by the first. The second person is notified during entry if an entered value differs from first entry and the second person's decision is retained as the correct value. Which type of entry is being used?

- A. Single entry
- B. Blind verification
- C. Manual review
- D. Third-party compare

Answer: B

Explanation:
The described process is Blind Verification, also known as double data entry with blind verification. In this method, two independent operators enter the same data. The second operator is blinded to the first entry to avoid bias. When discrepancies arise, the system flags them for review, and the second entry (or an adjudicated value) is retained as the correct one.

According to GCDMP (Chapter: Data Entry and Data Tracking), blind double data entry is used primarily in paper-based studies to minimize transcription errors and ensure data accuracy.

Single entry (D): Only one operator enters data.

Manual review (B): Involves post-entry checking, not during entry.

Third-party compare (C): Used for reconciling external data sources, not CRF data.

Hence, option A (Blind verification) is the correct and CCDM-defined process.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Entry and Data Tracking, Section 5.1 - Double Data Entry and Verification Methods ICH E6(R2) GCP, Section 5.5.3 - Data Entry and Verification Controls FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.2 - Data Accuracy and Verification

NEW QUESTION # 92

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