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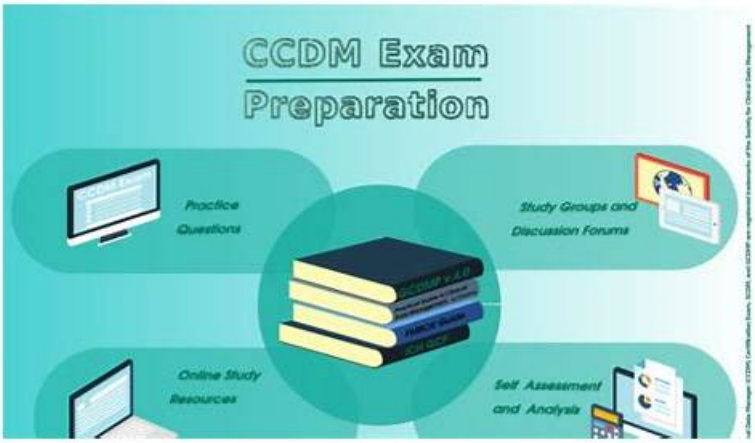

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Our Certified Clinical Data Manager exam question can make you stand out in the competition. Why is that? The answer is that you get the CCDM certificate. What certificate? Certificates are certifying that you have passed various qualifying examinations. Watch carefully you will find that more and more people are willing to invest time and energy on the CCDM Exam, because the exam is not achieved overnight, so many people are trying to find a suitable way. Fortunately, you have found our CCDM real exam materials, which is best for you.

SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 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.
Topic 2	• 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.
Topic 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.
Topic 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.
Topic 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q23-Q28):

NEW QUESTION # 23
Which attribute is NOT a characteristic of a standardized data collection element?

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

Answer: B

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 # 24
The result set from the query below would be which of the following?
SELECT Pt_ID, MRN, SSN FROM patient

- A. Wider than the patient table
- B. Longer than the patient table
- C. Shorter than the patient table
- D. Narrower than the patient table

Answer: D

Explanation:
In a SQL (Structured Query Language) database, the SELECT statement specifies which columns to display from a table. In this query, only three columns - Pt_ID, MRN, and SSN - are being selected from the patient table.
This means the resulting dataset will contain:
The same number of rows (records) as the original table (assuming no WHERE filter), and Fewer columns than the full table.
In database terminology:
"Wider" refers to more columns (fields).
"Narrower" refers to fewer columns (fields).
Since this query retrieves only 3 columns (out of potentially many in the original table), the result set is narrower than the patient table, making option D correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.1 - Relational Databases and Query Logic ICH E6(R2) GCP, Section 5.5.3 - Data Retrieval and Integrity Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Database Query Controls

NEW QUESTION # 25
Which list should be provided to support communication with sites regarding late data and queries?

- A. List of entered and clean data by site
- B. List of outstanding data and queries by site
- C. List of user account activity by site
- D. List of subjects screened and enrolled by site

Answer: B

Explanation:
Effective site communication in data management relies on transparent reporting of pending issues such as open queries, missing data, and overdue updates. According to the Good Clinical Data Management Practices (GCDMP, Chapter: Communication and Metrics), the list of outstanding data and queries by site provides a direct, actionable overview of what each site needs to address, supporting accountability and timely resolution.
This list typically includes subject identifiers, query types, dates generated, and status of resolution, allowing data managers to prioritize site follow-ups. Regular distribution of this report fosters efficient collaboration between the data management team, monitors, and site staff, ultimately improving database cleanliness and timeline adherence.
Options A and B reflect general study status but do not target data issue resolution. Option C pertains to user access oversight, not data progress. Hence, option D is the correct and most operationally relevant answer.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Communication and Metrics, Section 5.2 - Site Reporting and Query Management Metrics ICH E6(R2) GCP, Section 5.18 - Site Oversight and Communication Requirements

NEW QUESTION # 26
A protocol is updated mid-study to add an additional procedure about which data needs to be collected. Which of these statements applies?

- A. The DMP should be updated to reflect the changes to the protocol, but this update does not need to be communicated
- B. The DMP should be updated to reflect the changes to the protocol and stakeholders notified
- C. The DMP does not need to be updated as it represents the data at the beginning of the trial only
- D. The DMP does not need to be updated until the end of the trial and all updates are included in the DMP to indicate what happened in the trial

Answer: B

Explanation:
When a protocol is amended mid-study, resulting in additional data collection requirements, the Data Management Plan (DMP) must be updated accordingly and all relevant stakeholders must be notified.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the DMP is a living document that defines all data management processes for a clinical study. It must accurately reflect the current data flow, CRF design, validation procedures, and reporting structure. Any protocol amendments affecting data capture, structure, or analysis require immediate DMP revision and distribution to ensure alignment across data management, clinical, and biostatistics teams.
Failure to update and communicate DMP changes can lead to misalignment in data handling and introduce compliance risks during audits or inspections. Therefore, Option B is correct: the DMP must be updated and the change communicated to all stakeholders (e.g., sponsor, CRO, clinical operations, biostatistics).
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Plan (DMP), Section 5.3 - Maintaining and Updating the DMP ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Documentation of Protocol Changes and Data Handling Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Data Management Documentation

NEW QUESTION # 27
Which information should an auditee expect prior to an audit?

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

Answer: B

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 # 28
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