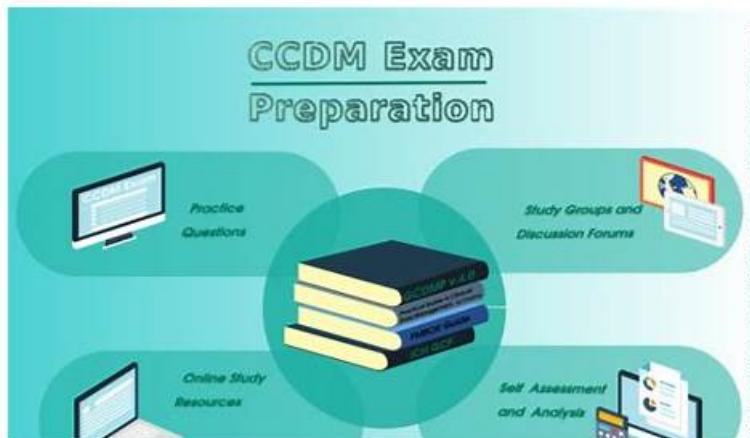


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SCDM CCDM certification exam is among those popular IT certifications. It is also the dream of ambitious IT professionals. This part of the candidates need to be fully prepared to allow them to get the highest score in the CCDM Exam, make their own configuration files compatible with market demand.

SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">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 2	<ul style="list-style-type: none">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 3	<ul style="list-style-type: none">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.
Topic 4	<ul style="list-style-type: none">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	<ul style="list-style-type: none">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.

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SCDM Certified Clinical Data Manager Sample Questions (Q38-Q43):

NEW QUESTION # 38

The Scope of Work would answer which of the following information needs?

- A. To determine the number of database migrations budgeted for a project
- B. To find the name and contact information of a specific clinical data associate
- C. To look up which visit PK samples are taken
- D. To look up the date of the next clinical monitoring visit for a specific site

Answer: A

Explanation:

The Scope of Work (SOW) is a contractual document that outlines the specific deliverables, responsibilities, timelines, and budgetary details for a given project between the sponsor and the contract research organization (CRO).

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), the SOW defines what work will be performed, how many resources are allocated, and the expected deliverables. This includes detailed information such as:

The number of database builds or migrations,

Timelines for deliverables (e.g., database lock),

Responsibility distribution between sponsor and CRO, and

Budget parameters for defined activities.

Therefore, if a Data Manager needs to determine how many database migrations are budgeted for a project, the SOW is the correct document to reference.

Information such as PK sample scheduling (option A), site monitoring dates (option B), or staff contact details (option D) would be found in operational plans or contact lists, not in the SOW.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Scope of Work Definition and Deliverables ICH E6 (R2) GCP, Section 5.5.3 - Documentation and Responsibilities for Data Management Tasks FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Agreements

NEW QUESTION # 39

Which information is required by most systems to specify data entry screens?

- A. Help text, review parameters, and answers
- B. Data type, prompt, and response format
- C. User role, access level, and permissions
- D. Page number and total number of pages

Answer: B

Explanation:

When designing or configuring data entry screens within an Electronic Data Capture (EDC) system, three critical components are required for each field:

Data Type - Defines the nature of the data (e.g., text, numeric, date).

Prompt - The label or question displayed to the user.

Response Format - Specifies how the user enters or selects data (e.g., free text, drop-down, checkbox).

According to the GCDMP (Chapter: EDC Systems and Database Design), these three attributes form the logical data structure required to build and validate data entry interfaces. They ensure consistency in how information is captured, displayed, and validated during data entry.

While user roles (A) and help text (D) are system-level configurations, not field-level specifications, page numbers (C) relate to printed CRFs rather than digital data screens.

Therefore, option B (Data type, prompt, and response format) correctly identifies the essential information needed to define data entry screens.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: EDC Systems and Database Design, Section 4.3 - Screen Design Specifications CDISC CDASH Implementation Guide, Section 3.2 - Data Field Attributes ICH E6(R2) GCP, Section 5.5.3 - Data Capture and Input Standards

NEW QUESTION # 40

It has been identified that ten adverse events were not reported in the trial prior to the database lock. What action should be taken to determine the next step?

- A. Evaluate the potential effect of the omission on the validity of the safety and efficacy analysis.
- B. Notify upper management immediately so the monitor can contact the site.
- C. Check the data from all sites again before relocking the database.
- D. Get the AE data entered immediately so the database can be locked again.

Answer: A

Explanation:

When adverse events (AEs) are discovered after a database lock, the appropriate first step is to evaluate the impact of the missing data on the integrity, safety analysis, and regulatory validity of the study results.

According to GCDMP (Chapter: Data Quality Assurance and Control), any post-lock data discovery requires a root cause assessment and impact analysis before deciding whether to unlock the database. The key question is whether the missing AEs:

Affect primary safety endpoints,

Introduce bias in safety reporting, or

Alter efficacy conclusions.

Based on the assessment, the Data Management and Biostatistics teams determine if unlocking and correction are justified. Simply entering data immediately (A) or repeating checks (D) without analysis may violate data control procedures.

Hence, option B is correct - the first step is to assess the impact on data validity and analysis.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 5.5 - Post-Lock Findings and Impact Assessment ICH E6(R2) GCP, Section 5.1.1 - Quality Management and Risk Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Post-Lock Data Management

NEW QUESTION # 41

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

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

Answer: B

Explanation:

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

NEW QUESTION # 42

An astute monitor discovers that a site is using nebulized albuterol rather than the inhaler provided in the study screening kit for the albuterol challenge. Which is the best response from the Data Manager?

- A. Query the site to enter a Protocol Violation
- B. Contact the Ethics Committee
- C. Update the CRF Completion Guidelines and notify all sites of the update
- D. No response is needed, the problem does not impact data

Answer: A

Explanation:

In this scenario, the site has deviated from the approved study protocol by using a different formulation (nebulized albuterol instead of inhaler). This is considered a protocol deviation or violation, depending on study definitions.

Per GCDMP (Chapter: Data Validation and Cleaning) and ICH E6(R2), Data Managers are responsible for ensuring that all protocol deviations affecting data integrity or subject safety are accurately captured and documented within the clinical database. The appropriate action is to issue a data query prompting the site to record the deviation in the designated section (e.g., "Protocol Deviations" CRF).

Option A: Incorrect - it affects data comparability.

Option B: Escalation to the Ethics Committee is handled by the sponsor, not the Data Manager.

Option C: Updating the CRF guidelines is premature; first, the deviation must be logged and assessed.

Therefore, option D (Query the site to enter a Protocol Violation) is the correct and compliant action.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 6.2 - Query Management and Protocol Deviations ICH E6(R2)

GCP, Section 4.5 - Compliance with Protocol FDA Guidance for Industry: Oversight of Clinical Investigations - Compliance and Protocol Deviation Reporting

NEW QUESTION # 43

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As the quick development of the world economy and intense competition in the international, the world labor market presents many new trends: company's demand for the excellent people is growing. As is known to us, the CCDM certification is one mainly mark of the excellent. If you want to improve your correct rates of exam, we believe the best method is inscribed according to the fault namely this in appearing weak sports, specific aim ground consolidates knowledge is nodded. Our CCDM Guide Torrent will help you establish the error sets. We believe that it must be very useful for you to take your exam, and it is necessary for you to use our CCDM test questions.

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