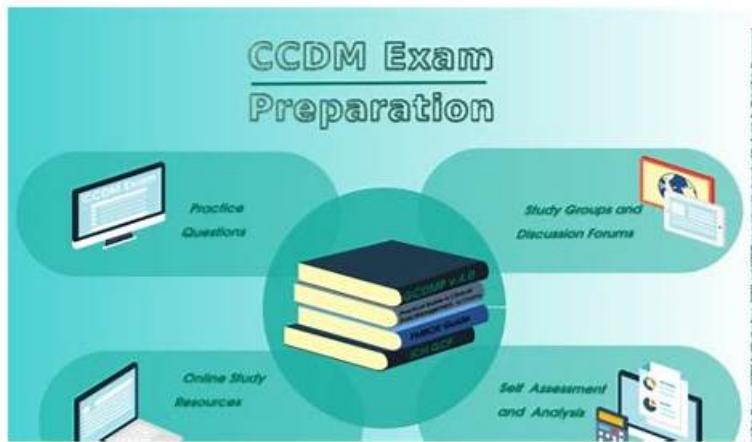


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SCDM CCDM Exam Syllabus Topics:

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">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 3	<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 4	<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 5	<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.

SCDM Certified Clinical Data Manager Sample Questions (Q15-Q20):

NEW QUESTION # 15

Which is the MOST appropriate flow for EDC set-up and implementation?

- A. Database created, Database tested, Sites trained, Protocol finalized, Database released
- B. CRF "wire-frames" created, CRFs reviewed, CRFs printed, CRFs distributed to sites
- C. Database created, Subjects enrolled, Database tested, Sites trained, Database released
- D. **Protocol finalized, Database created, Edit Checks created, Database tested, Sites trained**

Answer: D

Explanation:

The correct and compliant sequence for EDC system setup and implementation begins only after the study protocol is finalized, as all case report form (CRF) designs, database structures, and validation rules derive directly from the finalized protocol.

According to GCDMP (Chapter: EDC Systems Implementation), the proper order is:

Protocol finalized - defines endpoints and data requirements.

Database created - built according to the protocol and CRFs.

Edit checks created - programmed to validate data entry accuracy.

Database tested (UAT) - ensures functionality, integrity, and compliance.

Sites trained and system released - only then can data entry begin.

Option B follows this logical and regulatory-compliant sequence. Other options (A, C, D) are either paper-based workflows or violate GCP-compliant timelines (e.g., enrolling subjects before database validation).

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.2 - System Setup and Implementation Flow ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation and User Training Before Use FDA 21 CFR Part 11 - Validation and System Release Requirements

NEW QUESTION # 16

Which is the best way to see site variability in eligibility screening?

- A. Summarize screening rate by site
- B. Graph enrollment by site
- C. **Plot eligibility rate by site**
- D. List eligibility waivers by site

Answer: C

Explanation:

To identify site variability in eligibility screening, the most effective approach is to plot eligibility rate by site. This allows visual detection of differences in how well each site screens subjects according to protocol-defined inclusion and exclusion criteria.

The GCDMP (Chapter: Data Quality Assurance and Metrics) emphasizes the importance of graphical analysis for identifying anomalies and site-level performance variability. By plotting the eligibility rate by site, data managers and clinical operations teams can quickly identify outliers-sites that screen too many or too few eligible subjects-indicating potential training issues, misunderstanding of inclusion/exclusion criteria, or even possible protocol deviations.

While summarizing screening rate (B) provides useful numeric data, it lacks visual comparability. Listing waivers (A) or enrollment

counts (C) provide limited insights into eligibility consistency.

Therefore, option D-Plot eligibility rate by site-is the best analytic and visualization practice to assess site variability in screening outcomes.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.1 - Use of Metrics and Graphical Review for Site Performance ICH E6(R2) GCP, Section 5.18.4 - Identification of Systematic or Site-Specific Issues

NEW QUESTION # 17

A Data Manager is asked to manage SOPs for a department. Given equal availability of the following systems, which of the following is the best choice for managing the organizational SOPs?

- A. Customized Excel spreadsheet
- B. Learning management system
- **C. Document management system**
- D. Existing paper filing system

Answer: C

Explanation:

The best choice for managing Standard Operating Procedures (SOPs) in a compliant and auditable manner is a Document Management System (DMS).

According to the GCDMP (Chapter: Regulatory Requirements and Compliance) and ICH E6 (R2), SOPs must be version-controlled, securely stored, retrievable, and auditable. A validated DMS supports controlled access, document lifecycle management (draft, review, approval, and archival), and electronic audit trails, ensuring full compliance with FDA 21 CFR Part 11 and Good Documentation Practices (GDP).

While Learning Management Systems (C) track training, they are not intended for document control. Spreadsheets (B) and paper systems (D) cannot provide adequate version tracking, access security, or audit capability required for regulatory inspection readiness.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Requirements and Compliance, Section 5.2 - SOP Management and Document Control ICH E6 (R2) GCP, Section 5.5.3 - Document and Record Management FDA 21 CFR Part 11 - Electronic Records and Signatures, Section 11.10 - System Validation and Document Controls

NEW QUESTION # 18

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

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

Answer: A

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 # 19

Which of the following data verification checks would most likely be included in a manual or visual data review step?

- A. Checking an entered value against a valid list of values
- B. Checking a value against a reference range
- C. Checking mandatory fields for missing values
- D. Checking adverse event treatments against concomitant medications

Answer: D

Explanation:

Manual or visual data review is used to identify complex clinical relationships and contextual inconsistencies that cannot be detected by automated edit checks.

According to the GCDMP (Chapter: Data Validation and Cleaning), automated edit checks are ideal for structured validations, such as missing fields (option C), reference ranges (option D), or predefined value lists (option A). However, certain clinical cross-checks-such as verifying adverse event treatments against concomitant medication records-require clinical judgment and contextual understanding.

For example, if an adverse event of "severe headache" was reported but no analgesic appears in the concomitant medication log, the data may warrant manual review and query generation. These context-based checks are best performed by trained data reviewers or medical data managers during manual data review cycles.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.3 - Manual Review and Clinical Data Consistency Checks ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Clinical Data Review Responsibilities FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Verification Principles

NEW QUESTION # 20

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