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Certified Clinical Data Manager (CCDM) Practice Exam

Question 1: What does Clinical Data Management primarily involve?

- A. Developing clinical protocols
- B. Ensuring accurate and timely collection, validation, and reporting of trial data
- C. Marketing clinical research findings
- D. Overseeing patient recruitment processes

Answer: B

Explanation: Clinical Data Management focuses on collecting, validating, and reporting trial data accurately and on time, which is essential for reliable study outcomes.

Question 2: Which stakeholder is primarily responsible for overseeing regulatory compliance of clinical trial data?

- A. Clinical Data Manager
- B. Sponsor
- C. Regulatory Bodies
- D. Site Investigator

Answer: C

Explanation: Regulatory bodies, such as the FDA, are charged with ensuring that clinical trial data meets regulatory standards.

Question 3: Which document outlines the procedures for data collection and management in clinical trials?

- A. Informed Consent Form
- B. Data Management Plan
- C. Clinical Study Report
- D. Investigator Brochure

Answer: B

Explanation: The Data Management Plan (DMP) details the procedures for data collection, validation, cleaning, and reporting throughout the trial.

Question 4: What is a key responsibility of a Clinical Data Manager?

- A. Designing marketing strategies
- B. Managing data validation and query resolution
- C. Recruiting study participants
- D. Developing new drugs

Answer: B

Explanation: Clinical Data Managers are responsible for data validation, ensuring data integrity, and managing queries to resolve discrepancies.

Question 5: Which guideline is commonly followed to ensure data quality in clinical trials?

- A. ICH-GCP
- B. ISO 9001
- C. Six Sigma

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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 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"> • 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"> • 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 5	<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.

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SCDM Certified Clinical Data Manager Sample Questions (Q35-Q40):

NEW QUESTION # 35

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

Answer: D

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 # 36

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

Answer: A

Explanation:

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

NEW QUESTION # 37

Which metric reveals the timeliness of the site-work dimension of site performance?

- A. Time from final protocol to first patient enrolled
- B. Median and range of time from query generation to resolution
- C. Time from Last Patient Last Visit to database lock
- D. Time from site contract execution to first patient enrolled

Answer: B

Explanation:

The site-work dimension of site performance evaluates how efficiently sites manage and resolve data-related tasks - particularly query resolution, data entry, and correction timelines. Among the given metrics, the median and range of time from query generation to resolution (D) directly measures the site's responsiveness and data management efficiency.

According to the GCDMP (Chapter on Metrics and Performance Measurement), this indicator helps identify sites that delay query resolution, which can impact overall study timelines and data quality. Tracking this metric allows the data management team to proactively provide additional training or communication to underperforming sites.

Other options measure different aspects of project progress:

A reflects overall database closure speed.

B and C relate to study startup and enrollment readiness, not ongoing data work.

Thus, option D accurately represents a site performance timeliness metric, aligning with CCDM principles for operational performance measurement.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Metrics and Performance Management, Section 5.4 - Site

Query Resolution Metrics ICH E6(R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Performance Oversight

NEW QUESTION # 38

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 user account activity by site
- C. List of subjects screened and enrolled by site
- D. List of entered and clean data 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 # 39

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

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

Answer: B

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 # 40

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