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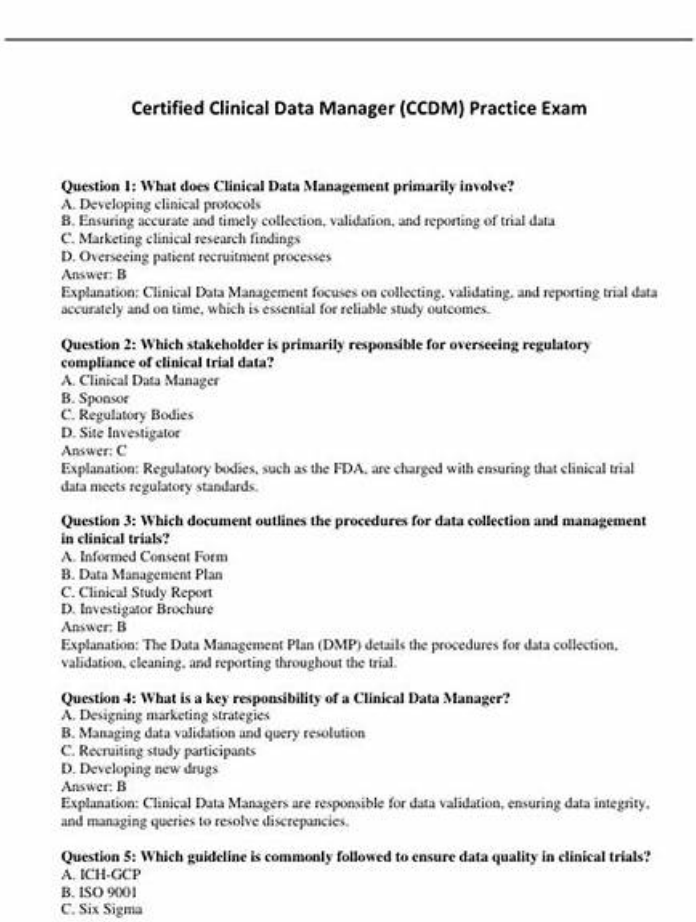

Certified Clinical Data Manager (CCDM) Practice Exam

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 考試大綱：

主題	簡介
主題 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.

主題 2	• 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.
主題 3	• 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.
主題 4	• 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.
主題 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.

最新的 Clinical Data Management CCDM 免費考試真題 (Q117-Q122):

問題 #117
What action should a data manager take if an investigator retires in the middle of an EDC trial and the replacement does not agree to use EDC for the remainder of the trial?

- A. Discuss the use of the site's data with the project statistician.
- B. Explore other options for the site with the study team.
- C. Notify the project manager and request that the site be closed.
- D. Talk with the clinical research associate to identify alternative sites.

答案：B

解題說明：
When an investigator retires mid-study and the replacement refuses to use the Electronic Data Capture (EDC) system, the data manager must not take unilateral action but rather collaborate with the study team to explore acceptable solutions.
Per the GCDMP (Chapter: Project Management in Data Management), any deviation from the established data capture method - particularly a change that affects regulatory compliance, data consistency, or site operations - requires a cross-functional assessment. The study team, which includes clinical operations, project management, regulatory affairs, and data management, should evaluate feasible alternatives such as:
Allowing paper CRF entry followed by centralized data transcription,
Retraining site staff on EDC use, or
Temporarily suspending data entry until compliance can be restored.
Immediate site closure (option A) or unilateral decisions by data management (options C and D) violate escalation and communication protocols. Collaborative decision-making ensures continuity, compliance, and data integrity, in line with ICH E6 (R2) GCP and FDA 21 CFR Part 11.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 5.2 - Handling Site and Investigator Changes ICH E6 (R2) Good Clinical Practice, Section 4.1 - Investigator Responsibilities FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on EDC Operations and Site Management

問題 #118

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

答案：C

解題說明：
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

問題 #119
Which is the most important reason for why a data manager would review data before a monitor reviews it?

- A. Data can be viewed and discrepancies highlighted prior to a monitor's review.
- B. The GCDMP recommends that data managers review data prior to a monitor's review.
- C. Data managers have access to programming tools to identify discrepancies.
- D. Data managers write the Data Management Plan that specifies the data cleaning workflow.

答案：A

解題說明：
The primary reason data managers review data before a monitor's review is to identify and flag discrepancies or inconsistencies so that site monitors can focus their efforts more efficiently during on-site or remote source data verification (SDV).
According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), proactive data review by data management staff ensures data completeness and accuracy by identifying missing, inconsistent, or out-of-range values. This pre-review helps streamline the monitoring process, reduces the volume of open queries, and enhances data quality.
Option A is true but not the main reason for pre-monitor review. Option C highlights a capability rather than a rationale. Option D is partially correct, but the GCDMP emphasizes process purpose, not prescriptive order. Thus, option B correctly captures the practical and process-oriented reason for early data review-to ensure data are ready and accurate for the monitor's review phase.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Data Review Timing and Purpose ICH E6(R2) GCP, Section 5.18 - Monitoring and Data Verification Requirements

問題 #120
A Clinical Data Manager is drafting data element definitions for a new study. One of the definitions provided is:
"Baby's crown to heel length measured lying on back, measured physical quantity, precision of 0.1." Which of the following is missing from the definition?

- A. Discrete values for a drop-down list
- B. Data type of the data element
- C. Unit or dimensionality of measure
- D. Enumeration

答案：C

解題說明：
A complete data element definition in clinical data management should include:
Name and clear description of the data element,
Data type (e.g., numeric, text, date),
Precision or scale (if numeric), and
Unit or dimensionality of measure (e.g., centimeters, inches).
In this example, while the data type ("measured physical quantity") and precision (0.1) are defined, the unit of measurement (e.g., centimeters or inches) is missing. This omission leads to ambiguity and could cause serious discrepancies when comparing or analyzing measurements.
The GCDMP (Chapter: Database Design and Build) emphasizes that units and dimensionality must be explicitly defined and consistently applied in all CRFs, metadata dictionaries, and data transformations.
Thus, option D (Unit or dimensionality of measure) is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Metadata and Data Element Definitions CDISC CDASH Implementation Guide, Section 3.3 - Data Element Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Data Accuracy and Standardized Definitions

問題 #121
Which of the following ensures that the trials are conducted and the data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)?

- A. Statistical Analysis Plan (SAP)
- B. Standard Operating Procedures (SOP)
- C. Data Management Plan (DMP)
- D. CRFs

答案：B

解題說明：
Standard Operating Procedures (SOPs) are formal, controlled documents that define standardized processes to ensure clinical trials are conducted in compliance with Good Clinical Practice (GCP), the study protocol, and regulatory requirements (such as ICH and FDA).
According to Good Clinical Data Management Practices (GCDMP) and ICH E6(R2) GCP, SOPs are fundamental to quality management systems. They describe how tasks are performed, ensuring consistency, accountability, and traceability across all studies and team members. Proper adherence to SOPs guarantees that data are accurately generated, documented, and reported in compliance with ethical and regulatory standards.
Other options serve different purposes:
SAP (B) defines statistical methodology, not compliance control.
DMP (C) focuses on study-specific data handling, not organizational compliance.
CRFs (D) are tools for data collection but do not enforce compliance by themselves.
Therefore, option A (SOP) is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Quality Management and Compliance, Section 5.1 - Role of SOPs in Regulatory Compliance ICH E6(R2) GCP, Section 2.13 and 5.1.1 - Quality Management Systems and SOP Requirements FDA 21 CFR Part 312.50 - Sponsor Responsibilities and Compliance Systems

問題 #122
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