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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 Certified Clinical Data Manager Sample Questions (Q65-Q70):

NEW QUESTION # 65

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

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

Answer: D

Explanation:

The Scope of Work (SOW) is a project management document that defines what services are included in the work agreement between the sponsor and the CRO or vendor. It outlines deliverables, responsibilities, timelines, and budget allocations.

According to the GCDMP (Chapter: Project Management in Data Management), the SOW includes specifications such as:

The number and frequency of data transfers,

Database build and lock milestones,

Quality control deliverables, and

Resource allocation for data management tasks.

The SOW does not cover operational site-level details such as monitoring schedules (B), protocol sampling details (C), or personnel contact lists (D).

Therefore, option A (number of data transfers budgeted for a project) correctly identifies a use case directly addressed in the SOW.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Project Management, Section 4.1 - Scope of Work and Resource Planning ICH E6(R2) GCP, Section 5.5 - Sponsor Oversight and Data Management Responsibilities PMI Project Management Framework - Scope Definition and Deliverable Specifications

NEW QUESTION # 66

Based on the project Gantt chart as of 01 Nov 2019, an interim analysis is scheduled to occur early Q2 of 2020. All of the following are valid for initially assessing the status of data cleanliness EXCEPT:

- **A. Identifying the number of discrepancies resolved to date**
- B. Identifying missing pages where visits have been completed to date
- C. Determining CRF data entry status of received pages
- D. Identifying all outstanding discrepancies to date and aging

Answer: A

Explanation:

When initially assessing data cleanliness in preparation for an interim analysis, the focus should be on outstanding issues that could affect data completeness and reliability.

According to the GCDMP (Chapter: Data Quality Assurance and Control), key indicators of readiness include:

The CRF data entry status of received pages (option A) to confirm completeness.

Identification of missing pages or visits (option B) to verify subject-level completeness.

A listing of outstanding discrepancies and their aging (option D) to assess unresolved data issues.

Counting the number of discrepancies resolved to date (option C), however, does not reflect data quality or current data readiness-it indicates past actions rather than current unresolved risks. Therefore, it is not a valid measure for assessing interim data cleanliness.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.1 - Data Readiness Assessments for Analysis ICH E6 (R2) GCP, Section 5.18.4 - Ongoing Data Quality Review FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section 7 - Data Quality Indicators

NEW QUESTION # 67

Which of the following scenarios requires a query to be sent to the central lab first when there is a discrepancy between the final lab data transfer and the CRF?

- A. The CRF has data for a visit but the central lab has missing data for the visit
- B. Both the central lab and the CRF have data present for a visit
- **C. The central lab has data for a visit but the CRF has missing data for the visit**
- D. Both the central lab and the CRF data have missing data for a visit

Answer: C

Explanation:

During data reconciliation between a central laboratory and CRF data, the source of truth is typically the central lab database, as it provides directly measured, vendor-generated results.

When the central lab has data but the CRF does not (option C), the Data Manager must first query the central lab to confirm that the result was transmitted correctly, since discrepancies may stem from data processing or timing issues. Once confirmed, a secondary query may be issued to the site to ensure CRF completion and alignment.

Conversely, if the CRF contains data but the central lab is missing results (option B), the issue is site-level, not vendor-level.

According to the GCDMP (Chapter: External Data Transfers and Reconciliation), priority for querying depends on the authoritative source - for lab data, the central lab is considered the source of record.

Therefore, option C is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers and Reconciliation, Section 6.1 - Reconciliation of Central Lab and CRF Data

ICH E6(R2) GCP, Section 5.5.3 - Source Data Verification and Vendor Reconciliation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Data Reconciliation and Traceability

NEW QUESTION # 68

A Data Manager receives an audit finding of missing or undocumented training for two database developers according to the organization's training SOP and matrix. Which is the best response to the audit finding?

- A. Remove the training items from the training matrix
- **B. Identify the root cause and improve the process to prevent it**
- C. Send the two developers to the required training
- D. Reprimand the person responsible for maintaining training documentation

Answer: B

Explanation:

When an audit identifies missing or undocumented training, the most appropriate and compliant response is to identify the root cause of the issue and implement corrective and preventive actions (CAPA) to ensure that similar findings do not recur.

According to Good Clinical Data Management Practices (GCDMP, Chapter: Quality Management and Auditing), effective quality systems require root cause analysis (RCA) for all audit findings. The process involves:

Investigating why the documentation gap occurred (e.g., poor tracking, outdated SOP, or lack of oversight).

Correcting the immediate issue (e.g., ensuring the developers complete or document training).

Updating processes, training systems, or oversight mechanisms to prevent recurrence.

While sending the two developers to training (D) addresses the symptom, it does not resolve the systemic issue identified by the audit. Options B and C are non-compliant and do not address quality system improvement.

Therefore, option A (Identify the root cause and improve the process) is the best and CCDM-compliant response.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Quality Management and Auditing, Section 6.2 - Corrective and Preventive Actions (CAPA) ICH

E6(R2) GCP, Section 5.1.1 - Quality Management and Continuous Process Improvement FDA 21 CFR Part 820.100 - Corrective and Preventive Action (CAPA) Requirements

NEW QUESTION # 69

In a physical therapy study, range of motion is assessed by a physical therapist at each site using a study-provided goniometer. Which is the most appropriate quality control method for the range of motion measurement?

- A. Reviewing data listings for illogical changes in range of motion between visits
- B. Programmed edit checks to detect out-of-range values upon data entry
- **C. Independent assessment by a second physical therapist during the visit**
- D. Comparison to the measurement from the previous visit

Answer: C

Explanation:

In this scenario, the variable of interest-range of motion (ROM)-is a clinically measured, observer-dependent variable. The accuracy and reliability of such data depend primarily on the precision and consistency of the measurement technique, not merely on data entry validation. Therefore, the most appropriate quality control (QC) method is independent verification of the measurement by a second qualified assessor during the visit (Option D).

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Quality Assurance and Control), quality control procedures must be tailored to the nature of the data. For clinically assessed variables, especially those involving human judgment (e.g., physical measurements, imaging assessments, or subjective scoring), real-time verification by an independent qualified assessor ensures that data are valid and reproducible at the point of collection. This approach directly addresses measurement bias, observer variability, and instrument misuse, which are primary sources of data error in clinical outcome assessments.

Other options, while valuable, address only data consistency or plausibility after collection:

Option A (comparison to previous visit) and Option C (reviewing data listings) are retrospective data reviews, suitable for identifying trends but not preventing measurement error.

Option B (programmed edit checks) detects only extreme or impossible values, not measurement inaccuracies due to technique or observer inconsistency.

The GCDMP and ICH E6 (R2) Good Clinical Practice guidelines emphasize that data quality assurance should begin at the source, through standardized procedures, instrument calibration, and dual assessments for observer-dependent measures. Having an independent second assessor ensures inter-rater reliability and provides direct confirmation that the recorded value reflects an accurate and valid measurement.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.4 - Measurement Quality and Verification ICH E6 (R2) Good Clinical Practice, Section 2.13 - Quality Systems and Data Integrity FDA Guidance for Industry: Patient-Reported Outcome Measures and Clinical Outcome Assessment Data, Section 5.3 - Quality Control of Clinician-Assessed Data SCDM GCDMP Chapter: Source Data Verification and Quality Oversight Procedures

NEW QUESTION # 70

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