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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 (Q144-Q149):

NEW QUESTION # 144

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

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

Answer: C

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 # 145

The serious adverse event (SAE) database should be reconciled against the clinical trial database prior to which occasion?

- A. Case report form data entry
- **B. Database closure or locking**
- C. Database quality audit
- D. Expedited safety reporting

Answer: B

Explanation:

SAE reconciliation must be completed before database lock or closure to ensure all safety data are consistent between the clinical database and the pharmacovigilance (safety) database.

According to the GCDMP (Chapter: Safety Data Handling and Reconciliation), SAE reconciliation involves verifying that all adverse events reported in the clinical trial database are also captured and accurately recorded in the safety system (and vice versa). This is essential to confirm that no SAE is missing, misclassified, or inconsistently dated or coded between the two systems.

Performing this reconciliation before database lock ensures that any discrepancies are corrected, and both databases reflect consistent, verified information for regulatory submission. Conducting this after closure (or only at audit time) would risk data inconsistencies in the final submission datasets.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: SAE Reconciliation, Section 6.1 - Timing and Procedures for Reconciliation ICH E2A/E2F - Clinical Safety Data Management: Definitions and Standards FDA Guidance for Industry: E2A - Clinical Safety Data Management: Processing Standards for Safety Reports

NEW QUESTION # 146

Which is a minimum prerequisite that should be in place before choosing an EDC system?

- A. Knowledge of functional requirements
- B. Draft validation plan
- C. Updated governance documentation
- D. Completed installation qualification

Answer: A

Explanation:

Before selecting an Electronic Data Capture (EDC) system for a clinical trial, it is essential to have a clear understanding of the functional requirements. This serves as the minimum prerequisite to guide system selection, ensuring that the EDC solution aligns with the protocol needs, data workflow, security requirements, and regulatory compliance.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Computerized Systems and Compliance), functional requirements describe what the system must do—such as data entry capabilities, edit checks, query management, user roles, audit trails, and integration with external systems (e.g., labs, ePRO). This understanding allows sponsors and CROs to evaluate vendor systems effectively during the selection and qualification phase.

Other options:

B . Installation qualification and D. Validation plan occur after system selection.

C . Governance documentation supports operations but is not required before choosing the system

Hence, option A is correct - the first and most essential prerequisite before EDC selection is a solid understanding of the functional requirements.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 4.2 - Requirements Gathering and System Selection

FDA 21 CFR Part 11 - System Validation and Intended Use Requirements ICH E6(R2) GCP, Section 5.5.3 - Computerized System Selection and Qualification

NEW QUESTION # 147

Which document contains the details of when, to whom, and in what manner the vendor data will be sent?

- A. Data Transfer Agreement
- B. Project Plan
- C. Data Management Plan
- D. Communication Plan

Answer: A

Explanation:

A Data Transfer Agreement (DTA) defines the operational and technical details for transferring data between a sponsor and an external vendor (e.g., central lab, ECG vendor). It is a formalized, controlled document specifying what data will be sent, when transfers will occur, the transfer method, file structure, encryption or security protocols, and the recipients of the data.

The DTA is developed jointly by the sponsor and vendor before production data transfers begin. According to the GCDMP, Chapter on External Data Transfers, this agreement ensures both parties share a clear understanding of timing, responsibility, and data content to minimize errors and ensure regulatory compliance.

The Data Management Plan (DMP) outlines general data handling processes but does not capture the technical specifics of vendor data transfer logistics. The Project Plan (A) and Communication Plan (B) are broader operational tools and not specific to data transfer protocols.

Hence, option C (Data Transfer Agreement) is the correct answer, as it precisely governs the procedural and technical framework of vendor data exchange.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers, Section 4.1 - Data Transfer Agreements and Specifications ICH E6(R2) Good Clinical Practice, Section 5.5 - Trial Management, Data Handling, and Record Keeping

NEW QUESTION # 148

In the transfer of obligations for a double-blind, multi-center trial, a sponsor has maintained the task of creating the randomization schedule. Who at the sponsor company should create the randomization schedule?

- A. The sponsor's project statistical programmer
- B. A sponsor's biostatistician not on the project
- C. The CRO biostatistician

- D. The sponsor's project biostatistician

Answer: B

Explanation:

In a double-blind clinical trial, the randomization schedule must be generated by an independent biostatistician not directly involved in study operations or data management to preserve study blinding and integrity.

According to ICH E9 and the GCDMP (Chapter: Regulatory Requirements and Compliance), randomization generation and blinding must be handled in a way that prevents bias or unintentional unblinding of study personnel. The sponsor's biostatistician not assigned to the project (Option C) is the appropriate person because they have the necessary statistical expertise but remain operationally independent from study execution.

A project biostatistician (Option D) or programmer (Option A) directly involved in data analysis could inadvertently compromise blinding. The CRO biostatistician (Option B) should not perform this function if the sponsor retains randomization responsibility.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Requirements and Compliance, Section 6.4 - Randomization and Blinding ICH E9 - Statistical Principles for Clinical Trials, Section 5.4 - Randomization Procedures and Blinding FDA Guidance for Industry: Adaptive Design Clinical Trials for Drugs and Biologics, Section 4.3 - Maintaining Blinding Integrity

NEW QUESTION # 149

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