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SCDM Certified Clinical Data Manager Sample Questions (Q96-Q101):

NEW QUESTION # 96

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

Answer: D

Explanation:

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

NEW QUESTION # 97

Which type of edit check would be implemented to check the correctness of data present in a text box?

- A. Manual Check
- B. Programmed check
- C. Back-end check
- **D. Front-end check**

Answer: D

Explanation:

A front-end check is a type of real-time validation performed at the point of data entry-typically within an Electronic Data Capture (EDC) system or data entry interface-designed to ensure that the data entered in a text box (or any input field) is valid, logically correct, and within expected parameters before the user can proceed or save the record.

According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), edit checks are essential components of data validation that ensure data accuracy, consistency, and completeness. Front-end checks are implemented within the data collection interface and are triggered immediately when data are entered. They prevent invalid entries (such as letters in numeric fields, out-of-range values, or improper date formats) from being accepted by the system.

Examples of front-end checks include:

Ensuring a numeric field accepts only numbers (e.g., weight cannot include text characters).

Validating that a date is within an allowable range (e.g., not before the subject's date of birth).

Requiring mandatory fields to be completed before moving forward.

This differs from back-end checks or programmed checks, which are typically run later in batch processes to identify data

inconsistencies after entry. Manual checks are human-performed reviews, often for context or data that cannot be validated automatically (e.g., narrative assessments).

Front-end edit checks are preferred wherever possible because they prevent errors at the source, reducing the number of downstream data queries and cleaning cycles. They contribute significantly to data quality assurance, regulatory compliance, and efficiency in data management operations.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.2 - Edit Checks and Real-Time Data Validation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Data Entry and Verification Controls ICH E6 (R2) Good Clinical Practice, Section 5.5 - Data Handling and Record Integrity CDISC Operational Data Model (ODM) Specification - Edit Check Implementation Standards

NEW QUESTION # 98

Which of the following roles commonly requires data entry and update privileges in an EDC application used in a clinical study?

- A. Clinical Study Monitor
- **B. Site Study Coordinator**
- C. EDC System Administrator
- D. Study Statistician

Answer: B

Explanation:

In an EDC system, Site Study Coordinators are typically responsible for data entry and updates, as they are the site-level personnel who record subject data from source documents into the electronic CRFs (eCRFs).

The Good Clinical Data Management Practices (GCDMP, Chapter: EDC Systems) outlines that data entry and modification privileges should only be granted to qualified site personnel who have completed EDC system training and are listed on the study delegation log. These users directly handle patient-level data entry and correction.

In contrast:

Clinical Study Monitors (B) review and verify data but do not enter or modify it.

EDC System Administrators (C) manage user access and configuration settings, not study data.

Study Statisticians (D) work with extracted, cleaned datasets but never have data modification privileges.

Thus, option A (Site Study Coordinator) correctly identifies the role with authorized data entry and update privileges.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.2 - User Roles and Access Permissions ICH E6(R2) GCP, Section 4.1 - Investigator Responsibilities for Data Accuracy FDA 21 CFR Part 11 - User Access and Accountability in Electronic Systems

NEW QUESTION # 99

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

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

Answer: A

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 -

NEW QUESTION # 100

Which of the following SOPs are required for management of an EDC system?

- A. Maintenance of coding dictionaries
- B. Measurement of data quality
- C. Change control
- D. Management of vendors

Answer: C

Explanation:

The most essential Standard Operating Procedure (SOP) for management of an Electronic Data Capture (EDC) system is Change Control.

Per GCDMP (Chapter: Computerized Systems and Compliance) and FDA 21 CFR Part 11, any changes made to an EDC system- whether to software configuration, study database design, or system functionality- must follow a documented, validated, and auditable change control process. This ensures that:

Modifications are properly authorized, tested, and approved before implementation.

System validation remains intact.

Data integrity, traceability, and regulatory compliance are maintained.

While vendor management (A) and coding maintenance (C) have supporting SOPs, change control (D) is mandatory for any system handling regulated clinical data. Measurement of data quality (B) is important but not specifically tied to system management procedures.

Thus, option D (Change control) is the correct answer.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 5.3 - Change Control and System Maintenance FDA 21 CFR Part 11 - Electronic Records and Electronic Signatures, Section 11.10(a-k) ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation and Change Documentation

NEW QUESTION # 101

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