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SCDM Certified Clinical Data Manager Sample Questions (Q136-Q141):

NEW QUESTION # 136

Which mode of data entry is most commonly used in EDC systems?

- A. Third party compare
- **B. Single entry**
- C. Double entry
- D. Blind verification

Answer: B

Explanation:

The most common mode of data entry in Electronic Data Capture (EDC) systems is single data entry.

According to the GCDMP (Chapter: Electronic Data Capture Systems), EDC systems have built-in edit checks, validation rules, and audit trails that ensure data accuracy and integrity at the point of entry. These real-time validation capabilities make double data entry (a legacy practice from paper studies) unnecessary.

EDC systems automatically verify data as they are entered by site staff, generating queries for inconsistencies or out-of-range values immediately. Blind verification (option B) and third-party comparisons (option D) are not standard data entry modes but may be used for specialized reconciliation or external data imports.

Thus, single data entry (Option C) is the industry standard approach, ensuring both efficiency and compliance with FDA 21 CFR Part 11 and ICH E6 (R2) data integrity requirements.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 5.4 - Data Entry and Verification Processes ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Computerized Systems and Data Validation FDA 21 CFR Part 11 - Electronic Records and Electronic Signatures: Validation and Data Entry Requirements

NEW QUESTION # 137

A study budgeted forty hours allocated over the three months following first protocol draft for Data Management Plan (DMP) creation. If there is a problem with this approach, what is it?

- A. Forty hours is too much time to budget for DMP creation
- B. There is no problem with the approach
- C. No time was allocated for maintenance of the DMP
- D. Forty hours is too little time to budget for DMP creation

Answer: C

Explanation:

The main issue with this approach is that no time has been allocated for ongoing maintenance and updates of the Data Management Plan (DMP) throughout the study lifecycle.

According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the DMP is a living document - it must be continuously maintained and updated as study procedures evolve, particularly after protocol amendments, database modifications, or changes in data validation or reconciliation procedures.

Budgeting only for initial creation (forty hours) over three months ignores the substantial effort required for DMP version control, stakeholder communication, and mid-study updates. These updates are mandatory to maintain compliance with ICH E6 (R2) GCP Section 5.5.3, which requires that all procedural documentation accurately reflect current practices.

Thus, the problem is not the time allocated for creation but the lack of planning for ongoing maintenance.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Plan (DMP), Section 5.3 - DMP Maintenance and Version Control ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Documentation of Data Handling Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Documentation Updates

NEW QUESTION # 138

When reviewing local lab data from a paper study, a Data Manager notices there are lab values not entered. What should the Data Manager request data-entry personnel do?

- A. Flag the module for review
- B. Issue a query
- C. Call the patient to verify the information
- D. Nothing

Answer: B

Explanation:

When laboratory data are missing from a paper-based clinical study, the Data Manager should direct data-entry personnel to issue a query to the investigative site for clarification or correction.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), every missing, inconsistent, or out-of-range data point must be reviewed and, if necessary, resolved through the formal query management process. This ensures that all discrepancies between the source documents and database entries are properly documented, traceable, and auditable.

Data-entry staff are not authorized to infer or fill in missing information. They must escalate such discrepancies to the site via query, preserving data integrity and regulatory compliance with ICH E6 (R2) and FDA 21 CFR Part 11. Calling the patient directly (option B) would violate confidentiality and site communication protocol, while simply flagging or ignoring the issue (options A and D) would not meet GCDMP query resolution standards.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.2 - Query Management and Resolution ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication of Data Discrepancies FDA 21 CFR Part 11 - Electronic Records; Query Audit Trails Requirements

NEW QUESTION # 139

The primary reason for system validation is to:

- A. Fulfill the validation plan.
- **B. Prove the system being tested works as intended.**
- C. Allow a system to be used by its intended users.
- D. Meet regulatory requirements.

Answer: B

Explanation:

The primary purpose of system validation in clinical data management is to demonstrate and document that the computerized system performs as intended-accurately, reliably, and consistently-throughout its lifecycle.

According to the Good Clinical Data Management Practices (GCDMP, Chapter on System Validation) and FDA 21 CFR Part 11, validation ensures that all system functions (e.g., data entry, edit checks, audit trails, security) work as designed, providing data integrity, traceability, and regulatory compliance. The focus is on fitness for intended use, meaning the system reliably produces correct and reproducible results in the context of its operational environment.

While meeting regulatory requirements (option C) and fulfilling a validation plan (option B) are components of the process, they are not the ultimate purpose. The essential goal is ensuring that the system performs as intended, maintaining accuracy and data integrity for clinical trial operations.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and System Validation, Section 5.2 - Purpose and Scope of System Validation
 FDA 21 CFR Part 11 - Validation of Computerized Systems for Intended Use ICH E6(R2) GCP, Section 5.5.3 - Computerized System Validation and Data Integrity

NEW QUESTION # 140

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

- A. To look up the date of the next clinical monitoring visit for a specific site
- B. To find the name and contact information of a specific clinical data associate
- C. To look up which visit PK samples are taken
- **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 # 141

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