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SCDM Certified Clinical Data Manager Sample Questions (Q139-Q144):

NEW QUESTION # 139

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

Answer: B

Explanation:

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

NEW QUESTION # 140

If database auditing is used for data quality control during a study, which is the optimal timing of the audits?

- **A. Periodically throughout the study**
- B. After the first few cases have been entered
- C. Immediately following database lock
- D. A week or two before database lock

Answer: A

Explanation:

Database audits are conducted to ensure ongoing data accuracy, completeness, and compliance throughout the lifecycle of a clinical trial. According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control), quality audits are most effective when performed periodically during study conduct, rather than waiting until study completion.

Performing audits periodically allows early detection of data entry errors, protocol deviations, and system inconsistencies, thereby reducing the risk of large-scale data issues before database lock. This proactive approach aligns with risk-based quality management principles outlined in ICH E6(R2) and ensures corrective actions are implemented in real time.

Options A and B represent reactive quality control, which occurs too late to prevent data issues. Option C (after first few cases) provides initial validation but does not ensure continuous oversight.

Therefore, option D - "Periodically throughout the study" - represents the optimal and compliant timing for quality audits of the database.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 5.3 - Ongoing Quality Control and Auditing ICH E6(R2)
GCP, Section 5.1.1 - Quality Management System and Risk-Based Monitoring FDA Guidance for Industry: Computerized Systems
Used in Clinical Investigations, Section 6.5 - Data Review and Auditing Practices

NEW QUESTION # 141

What is the main reason 21 CFR Part 11 requires that EDC systems maintain an audit trail?

- A. To preserve data integrity
- B. To preserve data availability
- C. To preserve source document verifications
- D. To preserve the ability for modifications

Answer: A

Explanation:

The primary purpose of maintaining an audit trail as required under 21 CFR Part 11 is to preserve data integrity. According to the U.S. FDA's regulation on electronic records and signatures, every change to electronic data must be traceable, including information about who made the change, when it was made, and what the change entailed.

The Good Clinical Data Management Practices (GCDMP) outlines that an audit trail provides a permanent, chronological record of all modifications to clinical data. This ensures transparency and allows the reconstruction of the course of data entry and modification. The regulation aims to prevent unauthorized or undocumented data manipulation, thereby maintaining the accuracy, reliability, and validity of electronic records.

The FDA 21 CFR Part 11, Section 11.10(e) explicitly mandates that systems must use secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. This ensures the data remains trustworthy and defensible in regulatory reviews or inspections.

Therefore, the main reason for requiring an audit trail is to preserve data integrity - ensuring that all data captured, modified, or transmitted is authentic, accurate, and complete throughout the study lifecycle.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Compliance and Data Integrity FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures, Section 11.10(e) ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Integrity and System Validation

NEW QUESTION # 142

Electronic submission standards require that an individual subject's complete CRF should be provided as what type of file:

- A. Statistical Analysis System (.sas)
- B. Microsoft Word (.docx)
- C. Portable Document Format (.pdf)
- D. Rich Text Format (.rtf)

Answer: C

Explanation:

Electronic submission standards, as established by FDA, CDISC, and ICH, require that an individual subject's complete Case Report Form (CRF) be submitted as a Portable Document Format (.pdf) file. The PDF format is universally recognized and accepted because it ensures that the structure, format, and visual fidelity of the CRF are preserved exactly as originally designed, regardless of software or hardware environment.

According to the FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format (2006) and CDISC SDTM standards, sponsors must include a subject-level CRF in PDF form for each participant in the submission dataset. This requirement ensures that reviewers can trace data points from analysis datasets back to their source entries in the CRF, fulfilling the principles of data traceability and transparency.

The Good Clinical Data Management Practices (GCDMP) also support this requirement, emphasizing that CRF archiving should maintain readability and regulatory accessibility. Formats like RTF, DOCX, or SAS datasets are not acceptable substitutes for regulatory CRF submission because they may alter formatting, structure, or introduce modifiable content, violating FDA data integrity principles.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Archiving and Submission FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006 CDISC SDTM Implementation Guide, Section 5.3 -

NEW QUESTION # 143

A Data Manager is importing data from an external facility. Which is commonly checked first?

- A. Incoming files have the expected number of records
- B. Data in incoming files are consistent with existing data in the study database
- C. Data in the incoming files are internally consistent
- **D. Incoming files are conformant to the data transfer specifications**

Answer: D

Explanation:

When importing external data (e.g., laboratory or imaging results) into a clinical database, the first step in data import quality control is to verify that incoming files conform to the pre-specified data transfer specifications (DTS).

According to the GCDMP (Chapter: External Data Transfers and Integration), the Data Transfer Specification defines file structure, variable names, data types, delimiters, record counts, and validation rules. The initial import check confirms that the received file matches the technical and structural requirements before content or record consistency is evaluated.

Subsequent checks-such as record counts (A), data consistency with existing database (C), and internal logical consistency (D)-are performed only after the file structure is validated and confirmed to match the specifications. Failure to perform this first check may cause import errors or corrupted data loads.

Thus, the first and most critical verification step is ensuring file conformity to the agreed data transfer specifications, making option B correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers, Section 4.2 - Data Transfer File Validation and Import Checks ICH E6(R2)

GCP, Section 5.5.3 - Validation of Computerized Systems and Data Imports

NEW QUESTION # 144

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