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SCDM CCDM Exam Syllabus Topics:

| Topic | Details |
|---------|--|
| Topic 1 | <ul style="list-style-type: none">• Data Processing Tasks: This section measures skills of Clinical Systems Analysts and focuses on handling, transforming, integrating, reconciling, coding, querying, updating, and archiving study data while maintaining quality, consistency, and proper privileges over the data lifecycle. |
| Topic 2 | <ul style="list-style-type: none">• Testing Tasks: This section measures the skills of Data Managers and involves creating test plans, generating test data, executing validation and user acceptance testing, and documenting results to ensure systems and processes perform reliably and according to specifications. |
| Topic 3 | <ul style="list-style-type: none">• Coordination and Project Management Tasks: This domain evaluates the skills of a Clinical Systems Analyst in coordinating data management workload, vendor selection, scheduling, cross-team communication, project timeline management, risk handling, metric tracking, and preparing for audits. |
| Topic 4 | <ul style="list-style-type: none">• Design Tasks: This section of the CCDM Exam measures skills of Data Managers and covers how to design and document data collection instruments, develop workflows and data flows, specify data elements, CRF forms, edit checks, reports, database structure, and define standards and procedures for traceability and auditability. |
| Topic 5 | <ul style="list-style-type: none">• Review Tasks: This section measures the skills of Data Managers and involves reviewing protocols, CRFs, data tables, listings, figures, and clinical study reports (CSRs) for consistency, accuracy, and alignment with data handling definitions and regulatory requirements. |

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SCDM Certified Clinical Data Manager Sample Questions (Q56-Q61):

NEW QUESTION # 56

Which is the best reason why front-end checks are usually kept minimal, when compared to back-end checks, in a paper-based clinical study?

- A. There is no need to alert the site personnel immediately about a data issue, as the study has happened already
- **B. Data entry staff should be able to enter a value into the database just as it appears in the paper CRF**
- C. Data review can be performed at a later time due to the paper-based studies being smaller in size
- D. There are approvals required to raise a Data Clarification Form which could take time

Answer: B

Explanation:

In paper-based clinical studies, front-end data checks (those performed during data entry) are intentionally kept minimal to ensure that data are entered exactly as recorded on the paper CRF. This principle ensures data integrity by maintaining fidelity between source and electronic records before any cleaning or edit validation occurs.

The GCDMP (Chapter: Data Validation and Cleaning) explains that data entry operators should input values as written, even if they appear incorrect or inconsistent, because the purpose of front-end checks is not to interpret but to capture data faithfully. The back-end edit checks-performed later by data managers-are designed to identify inconsistencies, out-of-range values, or logical errors that require clarification through queries.

This approach separates data capture from data cleaning, minimizing bias and preserving original investigator input. Hence, option A accurately states the rationale for keeping front-end checks minimal in paper-based studies.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 4.2 - Data Entry, Edit Checks, and Query Process ICH E6(R2) GCP, Section 5.5.3 - Data Handling and System Controls FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - Data Entry and Verification Processes

NEW QUESTION # 57

A Data Manager is asked to manage SOPs for a department. Given equal availability of the following systems, which of the following is the best choice for managing the organizational SOPs?

- **A. Document management system**
- B. Existing paper filing system
- C. Learning management system
- D. Customized Excel spreadsheet

Answer: A

Explanation:

The best choice for managing Standard Operating Procedures (SOPs) in a compliant and auditable manner is a Document Management System (DMS).

According to the GCDMP (Chapter: Regulatory Requirements and Compliance) and ICH E6 (R2), SOPs must be version-controlled, securely stored, retrievable, and auditable. A validated DMS supports controlled access, document lifecycle management (draft, review, approval, and archival), and electronic audit trails, ensuring full compliance with FDA 21 CFR Part 11 and Good Documentation Practices (GDP).

While Learning Management Systems (C) track training, they are not intended for document control. Spreadsheets (B) and paper systems (D) cannot provide adequate version tracking, access security, or audit capability required for regulatory inspection readiness.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Requirements and Compliance, Section 5.2 - SOP Management and Document Control ICH E6 (R2) GCP, Section 5.5.3 - Document and Record Management FDA 21 CFR Part 11 - Electronic Records and Signatures, Section 11.10 - System Validation and Document Controls

NEW QUESTION # 58

ePRO data are collected for a study using study devices given to subjects. Which is the most appropriate quality control method for the data?

- A. Programmed edit checks to detect out of range values after submission to the database
- B. Data visualizations to look for site-to-site variation
- C. Programmed edit checks to detect out of range values upon data entry
- D. Manual review of data by the site study coordinator at the next visit

Answer: C

Explanation:

When electronic patient-reported outcomes (ePRO) devices are used, data are captured directly by subjects through validated devices and transmitted electronically to the study database. To ensure real-time data quality control, programmed edit checks should be implemented at the point of data entry - that is, as subjects input data into the device.

According to Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), front-end programmed edit checks are the optimal method to prevent entry of invalid or out-of-range values in ePRO systems. This helps maintain data accuracy at the source, minimizing downstream queries and data cleaning workload.

Options A and B involve post-submission or manual review, which is less efficient and not compliant with the principle of first-pass data validation. Option C (visualization) is a valuable secondary QC method for trends, but not for immediate data validation.

Therefore, option D is correct - programmed edit checks upon data entry ensure immediate validation and higher data integrity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Automated Edit Checks and Front-End Validation ICH E6(R2) GCP, Section 5.5.3 - Computerized System Controls and Validation FDA Guidance for Industry: Electronic Source Data in Clinical Investigations (2013), Section 6 - Real-Time Data Quality Control

NEW QUESTION # 59

A site study coordinator attempts to make an update in a study database in an EDC system after lock. What occurs?

- A. The site study coordinator is not able to make the change
- B. The change is logged as occurring after lock
- C. The change is approved by the Data Manager before it is applied
- D. The old value is replaced in all locations by the new value

Answer: A

Explanation:

Once a clinical database is locked, it becomes read-only - no further data modifications can be made by any users, including site personnel. This ensures that the data are finalized, consistent, and auditable for statistical analysis and regulatory submission.

According to the GCDMP (Chapter: Database Lock and Archiving), the lock process involves freezing the database to prevent accidental or unauthorized changes. After lock, access permissions are restricted, and all edit and update functions are disabled. If any corrections are required post-lock, the database must be unlocked under controlled procedures (with full audit trail documentation).

Thus, option C - The site study coordinator is not able to make the change - correctly reflects standard EDC functionality and regulatory compliance.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.2 - Database Lock Procedures and Controls ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Audit Trail Requirements FDA 21 CFR Part 11 - Controls for Electronic Records and System Lock Functions

NEW QUESTION # 60

An external organization has been hired to manage SAE follow-up for a large study. Which of the following would be used as guidance for exchange of the SAE data between the EDC system and the vendor's safety management system?

- A. Medical Document for Regulatory Activities
- B. Biomedical Research Domain Model
- C. Individual Case Safety Report

- Answer: C**

ICH E2B(R3): Electronic Transmission of Individual Case Safety Reports FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Postmarketing ICSRs (2014)

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