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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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 3	• 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 4	• 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.
Topic 5	• 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.

SCDM Certified Clinical Data Manager Sample Questions (Q145-Q150):

NEW QUESTION # 145
A Data Manager is establishing a timeline for database lock for a 100-person study where the data have been maintained almost all clean throughout the study. All data from external labs have been received and reconciled. Which is the best estimate of the amount of time needed to lock the database after Last Patient Last Visit?

- A. A few hours
- B. A few weeks
- C. A few months
- D. A few days

Answer: D

Explanation:
For a well-maintained 100-subject study with ongoing data cleaning and completed reconciliations, the database lock process typically takes a few days after the Last Patient Last Visit (LPLV).
According to the GCDMP (Chapter: Database Lock and Archiving), the duration of the lock process depends on the level of data cleanliness at LPLV. If the study team has conducted continuous data cleaning, query resolution, and external data reconciliation throughout the trial, then the final lock steps (e.g., final data review, documentation, and approvals) can be completed in 2-5 days. However, if significant cleaning or reconciliation remains outstanding, lock may take several weeks. Since the question states that data are "maintained almost all clean," Option B - a few days - is the appropriate estimate.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Lock and Archiving, Section 6.2 - Database Lock Preparation and Timelines ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Quality and Lock Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Lock and Archiving Procedures

NEW QUESTION # 146
What should be done if the site continues to provide inconsistent data after several re-queries?

- A. Escalate the issue to the appropriate site contact personnel
- B. Continue to re-query until the site changes the data
- C. Do nothing, the data will remain inconsistent
- D. Gently lead the site to the correct response

Answer: A

Explanation:
If a clinical site continues to provide inconsistent or illogical data after multiple queries, the correct course of action is to escalate the issue to the appropriate site contact personnel, typically the Clinical Research Associate (CRA) or Site Monitor.
According to the Good Clinical Data Management Practices (GCDMP), persistent data discrepancies often indicate a misunderstanding of the protocol, CRF instructions, or data entry procedures at the site level. Repeatedly re-querying the same data without escalation wastes time and risks introducing bias or error. By escalating through formal communication channels, the issue can be clarified through re-training, documentation review, or site monitoring visits.
The GCDMP emphasizes that escalation ensures data accuracy, site accountability, and protocol adherence, maintaining both data quality and regulatory compliance. Data managers must document the escalation process in the Data Management Plan (DMP) and ensure proper follow-up resolution is achieved.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 4.2 - Handling Persistent Data Discrepancies ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Communication
FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Issue Escalation

NEW QUESTION # 147
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 the incoming files are internally consistent
- C. Incoming files are conformant to the data transfer specifications
- D. Data in incoming files are consistent with existing data in the study database

Answer: C

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 # 148
A Data Manager is designing a report to facilitate discussions with sites regarding late dat a. Which is the most important information to display on the report to encourage sites to provide data?

- A. Number of forms entered in the last week
- B. Total number of forms entered to date
- C. List of outstanding forms
- D. Expected versus actual forms entered

Answer: C

Explanation:

In managing site data timeliness, the most actionable and effective tool is a report listing all outstanding (missing or incomplete) CRFs.
According to GCDMP (Chapter: Communication and Study Reporting), Data Managers must provide site-level performance reports highlighting:
Outstanding CRFs not yet entered,
Unresolved queries, and
Pending data corrections.
Such reports help sites prioritize and address data gaps efficiently.
Option A and D are historical metrics without actionable context.
Option B gives a general overview but lacks specific site-level actionability.
Hence, option C (List of outstanding forms) provides the clearest and most motivating feedback to sites for timely data entry and query resolution.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Communication and Study Reporting, Section 5.3 - Data Timeliness and Reporting Metrics ICH E6(R2) GCP, Section 5.1.1 - Sponsor Oversight and Data Communication Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Site-Level Data Timeliness Reporting

NEW QUESTION # 149
Which statement is true regarding User Acceptance Testing (UAT) in an EDC application?

- A. System tools in EDC do not remove the need for UAT
- B. Data should not be collected in a production environment until UAT is completed
- C. Every rule should be tested with at least one "pass" and one "fail" scenario
- D. The extent of UAT (i.e., the number of test cases and rules) cannot be risk-based

Answer: B

Explanation:
In Electronic Data Capture (EDC) system validation, User Acceptance Testing (UAT) is a mandatory phase that must be completed before data collection begins in the production environment.
According to the GCDMP (Chapter: Database Design, Validation, and Testing) and FDA 21 CFR Part 11, UAT ensures that the EDC system meets all protocol-specific, functional, and regulatory requirements before it is deployed for live use. The goal is to verify that the system performs exactly as intended by simulating real-world user interactions with test data in a validated test environment.
Data collection prior to UAT completion would violate validation requirements and risk noncompliance with ICH E6 (R2) GCP Section 5.5.3, which mandates that all computerized systems be validated and tested before use.
While options A and C describe correct components of testing strategy, the key regulatory requirement is that UAT must be completed and approved before live data entry begins. Option D is incorrect - risk-based UAT is an accepted modern validation approach under both FDA and GAMP5 principles.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Validation, Section 5.3 - User Acceptance Testing FDA 21 CFR Part 11 - Validation of Electronic Systems (Section 11.10(a)) ICH E6 (R2) GCP, Section 5.5.3 - Validation Before Use in Production Environment

NEW QUESTION # 150
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