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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	• 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 3	• 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 4	• 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 5	• 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q122-Q127):

NEW QUESTION # 122
Query rules were tested with test data for each logic condition within each rule. Which of the following types of testing was conducted?

- A. White box testing
- B. T box testing
- C. User box testing
- D. Black box testing

Answer: D

Explanation:
Testing query rules with test data inputs to confirm expected outputs without examining the underlying program logic is an example of black box testing.
According to the GCDMP (Chapter: Data Validation and System Testing), black box testing is a functional testing approach used to verify that the system performs correctly from the end-user's perspective. In this method, testers input various conditions and observe outputs to ensure the system behaves as intended - for instance, that edit checks trigger correctly when data fall outside predefined limits.
In contrast, white box testing involves examining internal logic, code, and algorithm structures. Because data managers typically validate edit checks through data-driven test cases rather than code inspection, black box testing is the appropriate and industry-standard method. This ensures compliance with validation documentation standards as outlined in FDA 21 CFR Part 11, Section 11.10(a) and ICH E6 (R2) system validation expectations.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Validation and Testing, Section 4.1 - Testing Approaches (Black Box and White Box) FDA 21 CFR Part 11 - System Validation Requirements ICH E6 (R2) GCP, Section 5.5.3 - Computerized Systems Validation

NEW QUESTION # 123
Which competency is necessary for EDC system use in a study using the medical record as the source?

- A. Using ePRO devices

- B. Resolving discrepant data
- C. Training on how to log into Medical Records system
- D. Screening study subjects

Answer: C

Explanation:
In studies where the medical record serves as the source document, the Electronic Data Capture (EDC) system users (typically study coordinators or site personnel) must have appropriate training on how to access and log into the medical record system. This competency ensures that data abstracted from the electronic medical record (EMR) are complete, accurate, and verifiable in compliance with Good Clinical Practice (GCP) and Good Clinical Data Management Practices (GCDMP).
According to the GCDMP (Chapter: EDC Systems and Data Capture) and ICH E6(R2), all personnel involved in data entry and verification must be trained in both the EDC and the primary source systems (e.g., EMR). This ensures that the integrity of data flow-from source to EDC-is maintained, and that personnel understand system access controls, audit trails, and proper documentation of source verification.
While resolving discrepant data (C) and screening subjects (A) are part of study operations, the competency directly related to EDC system use in EMR-based studies is the ability to properly log into and navigate the medical records system to extract source data.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Electronic Data Capture (EDC), Section 5.1 - Source Data and System Access Requirements ICH E6(R2) Good Clinical Practice, Section 4.9 - Source Documents and Data Handling FDA Guidance: Use of Electronic Health Record Data in Clinical Investigations, Section 3 - Investigator Responsibilities

NEW QUESTION # 124
A Data Manager is designing a CRF for a study for which the efficacy data are not covered by the current SDTM domains. Which search should the Data Manager do?

- A. Use controlled terminology covering the needed concepts
- B. Search for relevant data element standards
- C. Work with the study team to define new data elements
- D. Advise the study team not to collect the data

Answer: B

Explanation:
When existing SDTM (Study Data Tabulation Model) domains do not cover specific efficacy data, the best practice is to first search for relevant data element standards that may be available through CDISC CDASH (Clinical Data Acquisition Standards Harmonization) or other recognized industry standards.
Per GCDMP (Chapter: Standards and Data Integration), Data Managers must ensure that new CRF elements are consistent with standardized definitions, controlled terminology, and data models to support interoperability, future analysis, and regulatory submission.
If no existing standards exist, only then should the Data Manager collaborate with the study team to define new elements - but standard searches always come first.
Thus, option C is correct - search for relevant data element standards ensures alignment with CDISC best practices and regulatory expectations.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.1 - Use of CDISC Standards in CRF Design CDISC CDASH Implementation Guide, Section 4.1 - Standardization of Data Collection Fields FDA Study Data Technical Conformance Guide (SDTCG), Section 2.4 - Use of Standard and Custom Domains

NEW QUESTION # 125
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. Notify the project manager and request that the site be closed.
- B. Explore other options for the site with the study team.
- C. Discuss the use of the site's data with the project statistician.
- D. Talk with the clinical research associate to identify alternative sites.

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 # 126
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. List of outstanding forms
- B. Total number of forms entered to date
- C. Expected versus actual forms entered
- D. Number of forms entered in the last week

Answer: A

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 # 127
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