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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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	• 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	• 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 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 (Q90-Q95):

NEW QUESTION # 90
What does RACI stand for?

- A. Responsibility, Accountability, Consultation, Information
- B. Responsible, Accountable, Contribute, Input
- C. Responsible, Accountable, Consulted, Informed
- D. Recommend, Approve, Calibrate, Innovate

Answer: C

Explanation:
RACI is a project management and governance framework used to define roles and responsibilities within a project. Each letter represents a distinct role type:
Responsible (R): The person(s) who perform the work or execute the task.
Accountable (A): The individual ultimately answerable for the task's completion and success (only one per activity).
Consulted (C): Subject matter experts who provide input or guidance before decisions are made.
Informed (I): Individuals kept up to date on progress or outcomes but not directly involved in execution.
The RACI model ensures clarity in ownership and accountability, preventing duplication of effort or responsibility confusion. It is a key component of the GCDMP (Chapter: Project Management in Data Management) for ensuring clear delegation and communication within clinical data management teams.
Hence, option D is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management in Data Management, Section 5.1 - Roles, Responsibilities, and RACI Matrices
Project Management Institute (PMI) Framework - Responsibility Assignment Matrices (RACI) ICH E6(R2) GCP, Section 5.1.1 - Defined Roles and Quality Oversight Responsibilities

NEW QUESTION # 91
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. Data entry staff should be able to enter a value into the database just as it appears in the paper CRF
- B. There are approvals required to raise a Data Clarification Form which could take time
- C. Data review can be performed at a later time due to the paper-based studies being smaller in size
- D. There is no need to alert the site personnel immediately about a data issue, as the study has happened already

Answer: A

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 # 92
A Data Manager receives an audit finding of three different instances of simultaneous log-ins to the EDC system by the same site user. This was observed at three different sites. Which of the following is the best long-term response to the audit finding?

- A. Acquiring technical controls from the same or a different system vendor that prevent simultaneous log-ins from the same

user

- B. Refresher training for the offending users, re-communication of the binding nature of e-signatures to all users, routine monitoring for simultaneous log-ins from the same user
- C. Requesting that the sites fire the offending users for a HIPAA violation and increasing the monitoring for the offending sites
- D. Removing all access to the system until the situation is resolved

Answer: B

Explanation:
The best long-term corrective and preventive action (CAPA) in this situation is a combination of user re-training, communication, and routine monitoring - as described in Option B.
According to the GCDMP (Chapter: Electronic Data Capture Systems) and FDA 21 CFR Part 11, user credentials and electronic signatures in clinical systems are legally binding and must be used only by the assigned individual. Simultaneous log-ins under the same credentials often indicate credential sharing, a compliance violation that must be addressed through user education, reinforced security policies, and ongoing system oversight.
While technical controls (option A) may be considered, behavioral and procedural reinforcement are the first lines of defense.
Options C and D are excessive and not aligned with proportional CAPA practices.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 7.1 - User Access, Authentication, and Training FDA 21 CFR Part 11 - Electronic Records and Electronic Signatures, Sections 11.10(i) and 11.200(a) ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Access Control and Audit Trail Requirements

NEW QUESTION # 93
The Medical Dictionary for Regulatory Activities (MedDRA) structure is in which of the following hierarchical orders, from most specific to least specific?

- A. LLT, PT, HLT, HLGT, SOC
- B. LLT, HLGT, PT, HLT, SOC
- C. LLT, PT, HLGT, HLT, SOC
- D. LLT, HLGT, HLT, PT, SOC

Answer: A

Explanation:
The MedDRA (Medical Dictionary for Regulatory Activities) is a standardized medical terminology used for coding and analyzing adverse event (AE) and medical history data in clinical trials. Its hierarchical structure supports aggregation, analysis, and reporting across varying levels of medical specificity.
From most specific to least specific, the hierarchy is as follows:
Lowest Level Term (LLT): The most granular term, often reflecting the verbatim text reported by the investigator.
Preferred Term (PT): The standardized medical concept representing one or more LLTs describing the same condition.
High Level Term (HLT): A grouping of related PTs describing similar medical conditions.
High Level Group Term (HLGT): A broader grouping of related HLTs.
System Organ Class (SOC): The highest level of classification, grouping HLGTs by body system or etiology (e.g., cardiac disorders, infections).
Thus, the correct order - from most specific to least specific - is:
LLT → PT → HLT → HLGT → SOC, which corresponds to option D.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Medical Coding and Dictionaries, Section 5.2 - MedDRA Hierarchical Structure ICH M1 MedDRA Terminology Guide, Version 26.0 - Hierarchy Overview ICH E2B(R3) Guidelines - Clinical Safety Data Management

NEW QUESTION # 94
In an EDC study, user training and access must be monitored and addressed when all the following situations occur EXCEPT:

- A. Site staff moves off of the study.
- B. Site staff is new to the study.
- C. A software upgrade is made that does not impact site staff or study team members.
- D. Study team members are reassigned to a different role within the study.

Answer: C

Explanation:
In Electronic Data Capture (EDC) studies, proper user training and access management are essential for maintaining data integrity, security, and regulatory compliance. According to the Good Clinical Data Management Practices (GCDMP) and FDA 21 CFR Part 11, EDC systems must ensure that only qualified and trained personnel can access study data, and that all access rights reflect current study responsibilities.
User training and access must therefore be reviewed and updated whenever:
Site staff leave the study (access revocation is required),
New site staff are added (training and credentialing are required), and Study team members change roles (access levels must be modified accordingly).
However, if a software upgrade occurs that does not impact the functional roles, user permissions, or data handling processes, retraining or reauthorization is not required. This is because such updates do not alter compliance-critical workflows or user interactions.
Therefore, the exception is C - when a software upgrade does not affect users.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 7.1 - User Access and Training Controls FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures, Section 11.10(i) & (k) ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - System Security and User Training

NEW QUESTION # 95
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