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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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	• 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	• 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	• 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q21-Q26):

NEW QUESTION # 21
According to ICH E6, developing a Monitoring Plan is the responsibility of whom?

- A. Sponsor
- B. Monitor
- C. CRO
- D. Data Manager

Answer: A

Explanation:
According to ICH E6(R2) Good Clinical Practice (GCP), Section 5.18.1, the Sponsor is ultimately responsible for developing and implementing the Monitoring Plan.
The Monitoring Plan defines:
The extent and nature of monitoring (e.g., on-site, remote, risk-based).
The responsibilities of monitors.
The communication and escalation procedures for data quality and protocol compliance.
While the CRO (B) or Monitor (D) may perform monitoring activities under delegation, the Sponsor retains legal accountability for ensuring a compliant and effective plan is developed and maintained. The Data Manager (C) may contribute by outlining data review workflows, but is not responsible for authoring or owning the plan.
Therefore, option A (Sponsor) is the correct answer.
Reference (CCDM-Verified Sources):
ICH E6(R2) GCP, Section 5.18.1 - Purpose and Responsibilities for Monitoring SCDM GCDMP, Chapter: Regulatory Compliance and Oversight, Section 5.3 - Sponsor Responsibilities in Monitoring and Quality Assurance FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor Responsibilities (2013)

NEW QUESTION # 22
In development of CRF Completion Guidelines (CCGs), which is a minimum requirement?

- A. CCGs must be signed before database closure to include all possible protocol changes affecting CRF completion
- B. CCGs are designed from the perspective of the Study Biostatistician to ensure that the data collected can be analyzed
- C. CCGs are developed with representatives of Data Management, Biostatistics, and Marketing departments
- D. CCGs must include a version control on the updated document

Answer: D

Explanation:
Case Report Form Completion Guidelines (CCGs) are essential study documents that instruct site staff on how to complete each field of the CRF correctly. A minimum requirement for CCGs, according to Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), is that they must include version control.
Option A describes an important design consideration but not a minimum compliance requirement. Option B is inaccurate, as CCGs must be approved and implemented before data collection begins, not after. Option D includes an irrelevant stakeholder (Marketing).
Therefore, option C-"CCGs must include a version control on the updated document"-is correct and compliant with CCDM and GCP standards.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 4.3 - Development and Maintenance of CRF Completion Guidelines ICH E6(R2) GCP, Section 8.2.1 - Essential Documents and Version Control Requirements

NEW QUESTION # 23
Before the EDC system used for the trial is upgraded, what should be the data manager's first task?

- A. Update the user manual
- B. Notify the sites of the upgrade
- C. Redesign the eCRF
- D. Assess the impact on the data

Answer: D

Explanation:
Before implementing an EDC system upgrade, the first task of the Data Manager is to assess the impact on the data.
According to the GCDMP (Chapter: Electronic Data Capture Systems) and FDA 21 CFR Part 11, any system upgrade must undergo impact assessment to determine how the change might affect data integrity, functionality, validation, and ongoing study operations. This assessment ensures that no data are lost, corrupted, or rendered inconsistent during or after the upgrade.
The Data Manager should evaluate:
Potential effects on existing data, edit checks, and reports,
System functionality impacting current workflows, and
Any revalidation requirements.
Only after the impact is understood should the Data Manager proceed to communicate with sites (option A), update documentation (option B), or modify CRFs if required (option D).
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 7.3 - System Upgrades and Change Control FDA 21 CFR Part 11 - Change Control and Validation Requirements ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Change Impact on Data Integrity and System Validation

NEW QUESTION # 24
What action should be taken regarding the clinical database when MedDRA releases a new version of its dictionary?

- A. Identify an alternative dictionary.
- B. Continue using the existing version to code.
- C. Evaluate the extent and impact of the changes.
- D. Upgrade the version immediately and recode.

Answer: C

Explanation:
When a new version of MedDRA (Medical Dictionary for Regulatory Activities) is released, the correct action is to evaluate the extent and impact of the changes before implementation.
According to the GCDMP (Chapter: Medical Coding and Dictionaries), MedDRA updates are published twice yearly (March and September). Each release may introduce new terms, modify hierarchies, or retire old ones. Prior to adopting a new version, the Data Manager and Medical Coder must:
Assess the number and type of term changes,
Determine the potential effect on ongoing coding consistency, and

Decide whether migration to the new version is warranted mid-study or deferred until database lock.

Immediate recoding (option C) without evaluation may cause inconsistencies and require additional validation. Continuing with the existing version (option B) may be acceptable short-term but must be justified. Using an alternative dictionary (option D) is noncompliant, as MedDRA is the regulatory standard for safety reporting.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Medical Coding and Dictionaries, Section 6.3 - Version Control and Impact Assessment MedDRA Term Selection: Points to Consider (MSSO, Latest Version), Section 3 - Versioning and Maintenance ICH E2B(R3) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

NEW QUESTION # 25

Which of the following factors can be tested through a second test transfer?

- A. File format
- B. Transfer frequency
- C. Transfer method
- D. Change management

Answer: A

Explanation:

In the context of database design and external data management, a test data transfer (or trial data load) is performed to ensure the proper configuration, structure, and integrity of data imported from an external vendor or system. The second test transfer is specifically useful to confirm that data structures and formats are consistently aligned between the sending and receiving systems after initial adjustments have been made from the first test.

According to the Good Clinical Data Management Practices (GCDMP), the file format - including variables, data types, field lengths, delimiters, and encoding - must be validated during test transfers to confirm compatibility and ensure accurate loading into the target database. Once the initial test identifies and corrects errors (e.g., mismatched variable names or data types), the second transfer verifies that the corrections have been implemented correctly and that the file structure functions as intended.

Testing change management (A) involves procedural controls, not data transfers. The transfer method (C) and transfer frequency (D) are validated during initial process setup, not during subsequent test transfers.

Therefore, option B (File format) is correct, as the second test transfer verifies the technical integrity of the file structure before live production transfers begin.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers and Data Integration, Section 5.2 - Test Transfers and File Validation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Data Import and Validation Controls

NEW QUESTION # 26

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