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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	• 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	• 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 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	• 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q82-Q87):

NEW QUESTION # 82

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

- A. Notify the sites of the upgrade
- B. Update the user manual
- 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 # 83

In a cross-functional team meeting, a monitor mentions performing source data verification (SDV) on daily diary data entered by patients on mobile devices. Which of the following is the best response?

- A. The diary data should not be source data verified
- B. Diary data to be source data verified should be selected using a risk-based approach
- C. Diary data to be source data verified should be randomly selected
- D. All diary data should be source data verified

Answer: B

Explanation:

The best response is that diary data to be source data verified should be selected using a risk-based approach.
According to the GCDMP (Chapter: Data Quality Assurance and Control) and FDA Guidance on Risk-Based Monitoring (RBM), not all data require full SDV. Electronic patient-reported outcome (ePRO) or mobile diary data are typically direct electronic source data (eSource) captured at the time of entry, which already ensures authenticity and traceability.
A risk-based SDV approach focuses verification efforts on data critical to subject safety and primary efficacy endpoints, as defined in the study's Risk Assessment Plan or Monitoring Plan. Random or full verification of low-risk data (like diary compliance metrics) adds unnecessary effort and cost.
Thus, Option C aligns with current regulatory expectations and data management best practices.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Risk-Based Monitoring and SDV ICH E6 (R2) Good Clinical Practice, Section 5.18 - Risk-Based Quality Management FDA Guidance for Industry: Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring (2013)

NEW QUESTION # 84

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 weeks
- B. A few hours
- 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 # 85

A Clinical Data Manager reads a protocol for a clinical trial to test the efficacy and safety of a new blood thinner for prevention of secondary cardiac events. The stated endpoint is all-cause mortality at 1 year. Which data element would be required for the efficacy endpoint?

- A. Drug level
- B. Cause of death
- C. Date of death
- D. Coagulation time

Answer: C

Explanation:
The efficacy endpoint of all-cause mortality at one year directly depends on the date of death for each subject, making Option D - Date of death the required data element.
According to the GCDMP (Chapter: Clinical Trial Protocols and Data Planning) and ICH E3/E9 Guidelines, the primary efficacy analysis must be based on time-to-event data, particularly when the endpoint involves mortality or survival. The date of death allows accurate calculation of time from randomization to event, essential for survival analysis (e.g., Kaplan-Meier curves).
While cause of death (C) may be collected for safety or secondary analyses, all-cause mortality specifically includes any death regardless of cause. Drug levels (A) and coagulation times (B) may serve as pharmacodynamic or exploratory endpoints but do not directly measure mortality.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Protocol Review, Section 5.4 - Defining Data Required for Endpoints ICH E9 - Statistical Principles for Clinical Trials, Section 2.3 - Time-to-Event Endpoints FDA Guidance for Industry: Clinical Trial Endpoints for Drug Development and Approval

NEW QUESTION # 86

A group of researchers is planning an investigator-initiated study. Assuming that SOPs are not available, which is the best approach for documentation of data management in the planned study?

- A. Data management SOPs must be developed prior to initiation of study
- B. Data handling should be documented in a data management plan
- C. A Data Management Plan (DMP) template should be developed and a study DMP should be created
- D. Data management related activities should be briefly described in the study protocol

Answer: C

Explanation:
In the context of an investigator-initiated trial (IIT) where Standard Operating Procedures (SOPs) are not available, the most appropriate and compliant approach is to develop a Data Management Plan (DMP) template and then create a study-specific DMP based on that template (Option C).
According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Management Planning and Study Start-

up), the DMP is the central document that defines all processes, responsibilities, systems, and quality controls related to data collection, processing, validation, and database management throughout the clinical study. The DMP serves as a formal framework for ensuring data integrity, traceability, and regulatory compliance, especially in the absence of established institutional SOPs.

While SOPs provide organizational-level standards, the DMP provides study-specific operational detail. In an investigator-initiated setting, researchers often lack institutional data management infrastructure, so the DMP must substitute for SOP guidance by detailing:

Data entry and validation procedures

Query management and resolution processes

CRF design and data flow specifications

Database design, backup, and security

Responsibilities of study personnel (investigator, data manager, statistician) Quality control and audit trail practices Option A ("Data handling should be documented in a DMP") is correct in principle but incomplete-without a DMP template, there is no standardized format or consistency across studies.

Option B (developing full SOPs) is not practical for a single IIT; SOPs are organizational-level documents requiring longer development and approval cycles.

Option D (briefly describing data management in the protocol) is insufficient, as the protocol should reference data management activities but not serve as the operational manual for them.

Therefore, Option C provides the most comprehensive, regulatory-compliant, and practical solution-ensuring structured documentation of all data management activities while maintaining flexibility for investigator-led research.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 5.2 - Data Management Plan (DMP) Development and Maintenance ICH E6 (R2) Good Clinical Practice, Section 5.1 - Quality Management and Documentation Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 4 - Data Management and Documentation Practices SCDM GCDMP, Chapter: Project Management in Data Management - Study-Specific Documentation and Planning in Investigator-Initiated Trials

NEW QUESTION # 87

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