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SCDM CCDM Exam Syllabus Topics:

| Topic | Details |
|---------|--|
| Topic 1 | <ul style="list-style-type: none">• 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 | <ul style="list-style-type: none">• 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 (Q144-Q149):

NEW QUESTION # 144

Which of the following SOPs are required for management of an EDC system?

- A. Measurement of data quality
- B. Maintenance of coding dictionaries
- C. Management of vendors
- D. Change control

Answer: D

Explanation:

The most essential Standard Operating Procedure (SOP) for management of an Electronic Data Capture (EDC) system is Change Control.

Per GCDMP (Chapter: Computerized Systems and Compliance) and FDA 21 CFR Part 11, any changes made to an EDC system-whether to software configuration, study database design, or system functionality-must follow a documented, validated, and auditable change control process. This ensures that:

Modifications are properly authorized, tested, and approved before implementation.

System validation remains intact.

Data integrity, traceability, and regulatory compliance are maintained.

While vendor management (A) and coding maintenance (C) have supporting SOPs, change control (D) is mandatory for any system handling regulated clinical data. Measurement of data quality (B) is important but not specifically tied to system management procedures.

Thus, option D (Change control) is the correct answer.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 5.3 - Change Control and System Maintenance FDA 21 CFR Part 11 - Electronic Records and Electronic Signatures, Section 11.10(a-k) ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation and Change Documentation

NEW QUESTION # 145

Every database lock should follow documented approval of which stakeholders?

- A. Clinical/Scientific Representative, Biostatistician

- B. Clinical/Scientific Representative, Data Manager, Biostatistician
- C. Clinical/Scientific Representative, Biostatistician, Programmer
- D. Clinical/Scientific Representative, Data Manager

Answer: B

Explanation:

According to the Good Clinical Data Management Practices (GCDMP), the database lock (DBL) process signifies the formal closure of the clinical trial database, ensuring that no further changes can be made to the data before statistical analysis. This process must be documented, controlled, and approved by key study stakeholders to ensure data accuracy, completeness, and readiness for analysis.

The GCDMP specifies that database lock should occur only after all data cleaning, discrepancy resolution, and reconciliation activities are complete. The lock authorization typically requires the approval of the Clinical/Scientific Representative (to confirm clinical completeness), the Data Manager (to confirm data integrity and query closure), and the Biostatistician (to confirm readiness for statistical analysis).

This tri-party approval ensures that the database reflects final, verified data consistent with the clinical protocol, and that the statistical analysis dataset derived from the database is accurate and auditable. The approval process is documented via a Database Lock Authorization Form or Sign-off Log, which becomes part of the permanent trial master file (TMF).

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Lock and Archiving, Section 7.1 - Lock Procedures and Approvals ICH E6 (R2) GCP, Section 5.5.3 - Data Handling and Record Keeping FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Database Closure

NEW QUESTION # 146

Which of the following is the best reason for a statistician to review the case report form prior to using it in a study?

- A. To ensure the header fields will provide a unique key for each subject
- B. To ensure the data from the CRF can be analyzed for safety and efficacy
- C. To ensure the layout will make a logical, useful programming guide
- D. To ensure the variable names conform to statistical programming standards

Answer: B

Explanation:

The primary reason a statistician reviews the Case Report Form (CRF) is to ensure that the data being collected will support the planned statistical analyses for both safety and efficacy endpoints.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), CRF design should always align with the statistical analysis plan (SAP) to ensure that all necessary data elements are collected accurately and in analyzable formats. The statistician verifies that the CRF captures:

All endpoints specified in the protocol

Proper derivation or calculation fields

Timing of assessments

Consistency across visits and forms

Options B, C, and D address secondary or technical design considerations but not the primary analytical purpose. The review ensures that the CRF provides a complete and analyzable dataset for meeting study objectives, regulatory submissions, and statistical integrity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 4.4 - Role of Statistics in CRF Design ICH E9 - Statistical Principles for Clinical Trials, Section 5.2 - Data Collection and Analysis Alignment FDA Guidance for Industry: E6(R2) GCP, Section 5.1 - Quality Management and Design Input from Stakeholders

NEW QUESTION # 147

A Data Manager is drafting a report for clinical operations staff for support in responding to questions about milestone-based site payments. Which is the most important information to display?

- A. Milestones included in the last payment by site, by patient
- B. Milestones met by month, by type
- C. Milestones met by month, by site
- D. Expected versus actual milestones met to date, by site

Answer: D

Explanation:

When reporting milestone-based site payment information, the most critical information to include is expected versus actual milestones met to date, by site.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), effective reporting must support operational and financial decision-making by presenting performance indicators in a clear, actionable format. Site payments in clinical studies are typically tied to specific milestones such as subject enrollment, visit completion, or data cleaning achievements.

By comparing expected (planned) versus actual (achieved) milestones per site, the Data Manager provides clinical operations staff with an accurate view of site progress and payment eligibility. This allows for identification of delayed sites, forecasting of upcoming payments, and early intervention for underperforming centers.

While milestone summaries by month or type (options A and B) may be useful for trend analysis, they lack the operational detail required for financial tracking. Milestone data by patient (option D) is overly granular for site-level payment management.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Data Reporting for Site Performance and Payments ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication and Monitoring Reports FDA Guidance for Industry: Oversight of Clinical Investigations - Site Management and Reporting

NEW QUESTION # 148

Which is the best way to identify sites with high subject attrition?

- A. Proportion of late visits by site
- B. Proportion of patients for which two visit periods have passed without data by site
- C. Number of late visits per site
- D. Number of patients for which two visit periods have passed without data

Answer: B

Explanation:

The best method to identify sites with high subject attrition is to calculate the proportion of patients for which two visit periods have passed without data, by site.

According to the GCDMP (Chapter: Data Quality Assurance and Control), subject attrition is an important performance indicator for data completeness and site compliance. Evaluating missing or delayed data across multiple consecutive visit periods allows for early detection of potential dropouts or site-level operational issues.

By assessing this proportion at the site level, the Data Manager can distinguish between random missing data and systematic site underperformance. Counting or proportioning late visits (options B and C) identifies scheduling delays, not attrition. Looking at missing data without site context (option D) fails to identify site-specific patterns, limiting corrective action.

This metric aligns with risk-based monitoring (RBM) practices recommended by ICH E6 (R2) and FDA RBM Guidance, which promote proactive identification of sites at risk of data loss.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 5.4 - Site Performance Metrics ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Performance Evaluation FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section 6 - Site Performance Metrics

NEW QUESTION # 149

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