CCDM Exam Registration & SCDM Best CCDM Vce: Certified Clinical Data Manager Latest Released


CCDM Exam Application

Section 1

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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	• 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 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 (Q116-Q121):

NEW QUESTION # 116
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. All diary data should be source data verified
- B. Diary data to be source data verified should be selected using a risk-based approach
- C. The diary data should not be source data verified
- D. Diary data to be source data verified should be randomly selected

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 # 117
Which information is most useful in working with sites to catch up a backlog of unresolved queries at sites?

- A. Table of outstanding queries counts by site
- B. Graph of expected versus actual enrollment
- C. Graph and summary table of clean cases by site
- D. List of late queries by site and summary table

Answer: D

Explanation:
The most effective information for addressing a backlog of unresolved queries at investigative sites is a list of late queries by site combined with a summary table.
According to the GCDMP (Chapter: Communication and Issue Escalation), timely and structured feedback to sites is critical for efficient query resolution. A detailed list of late or overdue queries, accompanied by summary statistics (e.g., counts, durations, status), enables data managers and monitors to prioritize follow-up actions, target problem areas, and provide focused support or retraining to underperforming sites.
While query count summaries (option B) are helpful for overview metrics, they lack the specific information (query ID, date, field, status) required for targeted follow-up. Graphs of enrollment or clean cases (options A and C) are unrelated to discrepancy resolution performance.
Thus, the combination of detailed lists and summarized performance metrics offers both granularity and a high-level overview - the optimal tool for query management communication.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 5.1 - Site Query Management Reports ICH E6 (R2) GCP, Section 5.18.4 - Communication Between Monitors and Sites FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Query Metrics and Site Performance Review

NEW QUESTION # 118
ACME Intervention Co. is testing a new carotid artery stent in patients with coronary artery disease, in hopes of proving superiority over the current standard of care. After a subject signs consent, the surgeon enrolls the patient and retrieves information on which stent to use, but the surgeon does not share this information with the subject. Yesterday, the surgeon was instructed to use the control stent. Today, the surgeon has completed two surgeries: the first one the surgeon was instructed to use the control stent; the second one the surgeon was instructed to use the test stent. In what type of trial is the surgeon participating?

- A. Open label
- B. Single-blind
- C. Cross-over
- D. Double-blind

Answer: B

Explanation:
This scenario describes a single-blind trial, in which only one party-typically the subject-is unaware of the treatment assignment, while the investigator or surgeon knows which intervention is being administered.
In this case, the surgeon receives instructions on which stent (test or control) to use, meaning they are aware of treatment allocation. However, the subject is blinded to which device is being implanted. This setup minimizes subject bias while maintaining procedural safety since the surgeon must know which product to use.
Double-blind (A): Neither subject nor investigator knows the treatment.
Open-label (B): Both subject and investigator know the treatment.
Cross-over (D): Each subject receives both treatments in different periods.
Thus, the correct answer is C. Single-blind, as only the participant remains blinded in this surgical device trial design.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Clinical Trial Phases and Protocols, Section 3.2 - Study Blinding and Randomization Concepts ICH E6(R2) GCP, Section 1.10 - Definition of Blinding/Masking FDA Guidance for Industry: Design Considerations for Pivotal Clinical Investigations for Medical Devices, Section 5.3 - Blinding in Device Studies

NEW QUESTION # 119
Which document describes what study subjects expect with respect to data disclosure during and after a study?

- A. Study data sharing plan
- B. Informed consent form
- C. ICH essential documents
- D. Study protocol

Answer: B

Explanation:

The Informed Consent Form (ICF) is the document that explicitly describes what study subjects can expect regarding data disclosure, privacy, and confidentiality during and after participation in a clinical trial. According to ICH E6 (R2) Good Clinical Practice and FDA Human Subject Protection Regulations (21 CFR Parts 50 and 56), participants must be fully informed about how their personal and clinical data will be collected, used, stored, and shared - both during the study and in any subsequent data-sharing or publication activities.
The GCDMP reiterates that clinical data managers must ensure that all data handling practices align with the privacy commitments made in the ICF. This includes compliance with data protection regulations such as HIPAA (in the U.S.) and GDPR (in the EU).
The ICF defines the permissible scope of data use, ensuring ethical management and subject protection.
Documents like the protocol or data sharing plan may outline procedures and responsibilities but do not directly inform participants of their rights and data use expectations. Only the ICF is designed for that ethical communication purpose.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Ethics, Privacy, and Data Security ICH E6 (R2) Good Clinical Practice, Sections 4.8.10 & 4.8.12 FDA 21 CFR Part 50 - Protection of Human Subjects, Informed Consent Requirements

NEW QUESTION # 120
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 related activities should be briefly described in the study protocol
- B. A Data Management Plan (DMP) template should be developed and a study DMP should be created
- C. Data handling should be documented in a data management plan
- D. Data management SOPs must be developed prior to initiation of study

Answer: B

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 # 121

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