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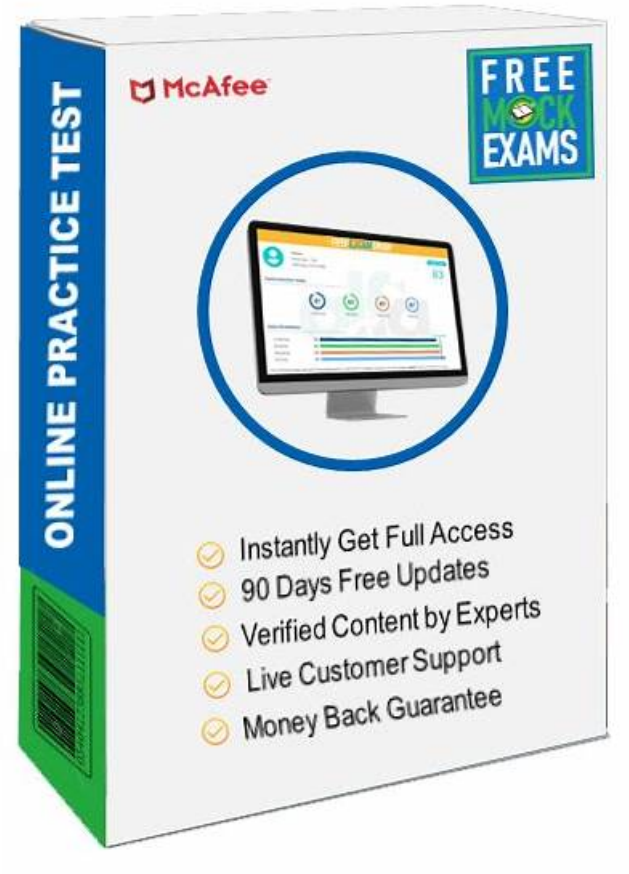

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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 3	• 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 4	• 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 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 (Q43-Q48):

NEW QUESTION # 43
If a data manager generated no additional manual queries on data in an EDC system and the data were deemed clean, why could the data appear to be not clean during the next review?

- A. The medical monitor can override safety information entered in the system.
- B. The data manager may have accidentally changed the data.
- C. The CRA can change the data during a quality review of source to database.
- D. The study coordinator can change the data due to re-review of the source.

Answer: D

Explanation:
In an Electronic Data Capture (EDC) system, even after a data manager completes all manual queries and marks data as "clean," the data may later appear unclean if the site (study coordinator) makes subsequent updates in the system after re-reviewing the source documents.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Electronic Data Capture Systems), site users maintain the authority to modify data entries as long as the system remains open for data entry. The EDC system audit trail captures such changes, which can automatically invalidate prior data reviews, triggering new discrepancies or changing system edit-check statuses.
This situation commonly occurs when the site identifies corrections in the source (e.g., wrong date or lab result) and updates the EDC form accordingly. These post-cleaning changes require additional review cycles to ensure the database reflects accurate and verified information before final lock.
Options B, C, and D are incorrect - CRAs and medical monitors cannot directly change EDC data; they can only raise queries or request updates.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 6.3 - Post-Cleaning Data Changes and Audit Trails ICH E6 (R2) GCP, Section 5.5.3 - Data Integrity and Change Control FDA 21 CFR Part 11 - Electronic Records: Change Documentation Requirements

NEW QUESTION # 44
A Data Manager is asked to manage SOPs for a department. Given equal availability of the following systems, which of the following is the best choice for managing the organizational SOPs?

- A. Document management system
- B. Learning management system
- C. Existing paper filing system
- D. Customized Excel spreadsheet

Answer: A

Explanation:
The best choice for managing Standard Operating Procedures (SOPs) in a compliant and auditable manner is a Document Management System (DMS).
According to the GCDMP (Chapter: Regulatory Requirements and Compliance) and ICH E6 (R2), SOPs must be version-controlled, securely stored, retrievable, and auditable. A validated DMS supports controlled access, document lifecycle management (draft, review, approval, and archival), and electronic audit trails, ensuring full compliance with FDA 21 CFR Part 11 and Good Documentation Practices (GDP).
While Learning Management Systems (C) track training, they are not intended for document control. Spreadsheets (B) and paper systems (D) cannot provide adequate version tracking, access security, or audit capability required for regulatory inspection readiness.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Requirements and Compliance, Section 5.2 - SOP Management and Document Control ICH E6 (R2) GCP, Section 5.5.3 - Document and Record Management FDA 21 CFR Part 11 - Electronic Records and Signatures, Section 11.10 - System Validation and Document Controls

NEW QUESTION # 45
QA is conducting an audit on a study for ophthalmology which is ready for lock. Inconsistencies are found between the database and the source. Of the identified fields containing potential data errors, which fields are considered critical for this particular study?

- A. Concomitant Medications
- B. Subject Identifier
- C. Weight
- D. Medical History

Answer: A

Explanation:
In an ophthalmology clinical study, data criticality is determined by how directly a data element affects safety evaluation, efficacy assessment, and regulatory decision-making. According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), critical data fields are those that:
Have a direct impact on the primary and secondary endpoints, or
Are essential for safety interpretation and adverse event causality assessment.
Among the listed options, Concomitant Medications (Option B) are considered critical data for ophthalmology studies. This is because many ocular treatments and investigational products can interact with systemic or topical medications, potentially affecting ocular response, intraocular pressure, corneal healing, or visual function outcomes. Any inconsistency in concomitant medication data could directly influence safety conclusions or efficacy interpretations.
Other options, while important, are less critical for this study type:
Subject Identifier (A) is essential for data traceability and audit purposes but is not directly related to safety or efficacy outcomes.
Weight (C) may be relevant in dose-dependent drug trials but is rarely a pivotal variable in ophthalmology, where local administration (eye drops, intraocular injections) is common.
Medical History (D) provides contextual background but does not have the same immediate impact on endpoint analysis as current concomitant treatments that can confound the therapeutic effect or cause ocular adverse events.
Per GCDMP and ICH E6 (R2) GCP guidelines, data validation plans must define critical data fields during study setup, reflecting therapeutic area-specific priorities. For ophthalmology, concomitant medications, ocular assessments (visual acuity, intraocular pressure, retinal thickness, etc.), and adverse events are typically designated as critical fields requiring heightened validation, source verification, and reconciliation accuracy before database lock.
Thus, when QA identifies discrepancies between the CRF and source, the Concomitant Medications field (Option B) is the most critical to address immediately to ensure clinical and regulatory data integrity.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.4 - Critical Data Fields and Data Validation Prioritization ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Source Data Verification FDA Guidance for Industry: Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring, Section 5.3 - Identification of Critical Data and Processes SCDM GCDMP Chapter: Data Quality

Assurance and Control - Therapeutic Area-Specific Data Criticality Examples (Ophthalmology Studies)

NEW QUESTION # 46
Which of the following actions is particularly important in merging data from different trials?

- A. Use of a common adverse event dictionary
- B. Use of a common software platform
- C. Exclusion of studies that use a cross-over design
- D. Enrollment of investigative sites with similar patient populations

Answer: A

Explanation:
When merging data from different clinical trials, the use of a common adverse event (AE) dictionary (such as MedDRA or WHO Drug) is essential to ensure consistency and comparability across datasets.
According to the GCDMP (Chapter: Standards and Data Mapping) and CDISC SDTM Implementation Guide, data integration across studies requires standardized terminology for adverse events, medications, and clinical outcomes. Using the same AE dictionary ensures that similar terms are coded consistently, allowing accurate cross-study analysis, pooled summaries, and safety reporting.
A shared software platform (option A) is not necessary if data are mapped to standard formats (e.g., CDISC SDTM). Patient population similarity (option B) affects interpretation but not technical data merging. Study design differences (option C) may influence statistical analysis but not data integration mechanics.
Therefore, Option D - Use of a common adverse event dictionary - is the correct and most critical action for consistent multi-study data integration.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Standards and Data Mapping, Section 5.1 - Use of Standardized Coding Dictionaries CDISC SDTM Implementation Guide, Section 4.3 - Controlled Terminology and Cross-Study Integration ICH E3 and E2B - Clinical Data Standards and Safety Coding Requirements

NEW QUESTION # 47
Which of the following scenarios requires a query to be sent to the central lab first when there is a discrepancy between the final lab data transfer and the CRF?

- A. Both the central lab and the CRF have data present for a visit
- B. The central lab has data for a visit but the CRF has missing data for the visit
- C. The CRF has data for a visit but the central lab has missing data for the visit
- D. Both the central lab and the CRF data have missing data for a visit

Answer: B

Explanation:
During data reconciliation between a central laboratory and CRF data, the source of truth is typically the central lab database, as it provides directly measured, vendor-generated results.
When the central lab has data but the CRF does not (option C), the Data Manager must first query the central lab to confirm that the result was transmitted correctly, since discrepancies may stem from data processing or timing issues. Once confirmed, a secondary query may be issued to the site to ensure CRF completion and alignment.
Conversely, if the CRF contains data but the central lab is missing results (option B), the issue is site-level, not vendor-level.
According to the GCDMP (Chapter: External Data Transfers and Reconciliation), priority for querying depends on the authoritative source - for lab data, the central lab is considered the source of record.
Therefore, option C is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: External Data Transfers and Reconciliation, Section 6.1 - Reconciliation of Central Lab and CRF Data ICH E6(R2) GCP, Section 5.5.3 - Source Data Verification and Vendor Reconciliation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Data Reconciliation and Traceability

NEW QUESTION # 48
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