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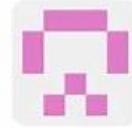
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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 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	• 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 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	• 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 (Q114-Q119):

NEW QUESTION # 114
A CRF was approved by the Sponsor and development of a clinical database has been started according to the data management plan. What is the next responsibility of the Data Manager?

- A. Prepare system requirements specification
- B. Prepare a communications plan
- C. Prepare a data validation plan for the clinical database
- D. Plan the timelines to ensure a clinical database is ready before the first screening

Answer: C

Explanation:
Once the Case Report Form (CRF) has been finalized and database development has begun, the next primary responsibility of the Data Manager is to prepare a Data Validation Plan (DVP) for the clinical database.
According to the GCDMP (Chapter: Database Design and Build), the DVP documents all planned validation procedures - including edit checks, cross-form validations, discrepancy management workflows, and system testing requirements. This ensures that data entry, processing, and cleaning are consistent with protocol requirements and that the database will produce reliable, auditable data for analysis.
While system requirement specifications (option B) are prepared before database development begins, and timeline planning (option C) occurs during the study startup phase, the DVP is the critical next step post-CRF approval to define and validate system logic before user acceptance testing (UAT).
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Build, Section 6.4 - Data Validation Plan (DVP) Development ICH E6 (R2) GCP, Section 5.5.3 - Validation of Computerized Systems FDA 21 CFR Part 11 - System Validation Requirements for Electronic Records

NEW QUESTION # 115
Which information should an auditee expect prior to an audit?

- A. Standard operating procedures
- B. Audit plan or agenda
- C. Auditor's credentials and certification number
- D. Corrective action requests

Answer: B

Explanation:
Prior to an audit, the auditee should expect to receive an audit plan or agenda, which outlines the scope, objectives, schedule, and logistics of the audit.
According to the GCDMP (Chapter: Quality Assurance and Audits), an audit plan ensures transparency, preparation, and efficient execution. It typically includes details such as:
The audit scope and objectives,
The audit team members,
Documents or processes to be reviewed, and
The audit schedule and timeframe.
This allows the auditee to prepare the necessary records, staff, and facilities. While the auditor's credentials (option A) may be shared informally, they are not a regulatory requirement. Corrective actions (option B) are outcomes of the audit, not pre-audit materials. Standard Operating Procedures (option C) may be requested during the audit but are not provided in advance.
Thus, Option D - Audit Plan or Agenda - is the correct and compliant answer.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Quality Assurance and Audits, Section 6.1 - Pre-Audit Planning and Communication ICH E6 (R2) Good Clinical Practice, Section 5.19.3 - Audit Procedures and Responsibilities FDA

NEW QUESTION # 116
A Data Manager is designing a CRF for a study for which the efficacy data are not covered by the current SDTM domains. Which of the following should the Data Manager consult first?

- A. Forms used by other sponsors in the same therapeutic area
- B. SNOMED terms used in the therapeutic area
- C. Data elements used in clinical registries in the therapeutic area
- D. A CDISC therapeutic-area implementation guide

Answer: D

Explanation:
When efficacy data are not covered by existing CDISC SDTM domains, the first resource the Data Manager should consult is the CDISC Therapeutic Area Implementation Guide (TAIG) for that therapeutic field.
According to the GCDMP (Chapter: Standards and Data Mapping), CDISC's Therapeutic Area User Guides (TAUGs) and Implementation Guides provide standardized data structures, variable definitions, controlled terminology, and implementation examples for specific diseases or therapeutic areas. These guides ensure consistency across studies, promote interoperability, and align data collection with regulatory submission expectations.
Consulting other sponsors' forms or external registries (options A and C) can be informative but do not provide authoritative CDISC-compliant standards. SNOMED terms (option B) address medical terminology, not structural data domain definitions.
Therefore, Option D is correct-CDISC TA Implementation Guides are the recognized primary reference when extending or designing SDTM-compliant CRFs.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Standards and Data Mapping, Section 4.2 - Use of CDISC Standards CDISC Therapeutic Area User Guides (TAUGs) - Implementation Guidance for Domain Extension FDA Data Standards Catalog - CDISC Therapeutic Area Standards

NEW QUESTION # 117
With the implementation of EDC, which company Standard Operating Procedure (SOP) would require updates for new procedures of handling data?

- A. Data Review and Validation
- B. Handling External Data
- C. Coding Medical and Clinical Terms
- D. Data Backup, Recovery, and Contingency Plans

Answer: A

Explanation:
When a company transitions from paper-based data capture to Electronic Data Capture (EDC) systems, one of the most critical areas requiring procedural updates is the Data Review and Validation SOP. The introduction of EDC systems fundamentally changes how data is collected, reviewed, validated, and queried.
According to the Good Clinical Data Management Practices (GCDMP), the implementation of EDC introduces real-time data entry and review, automated edit checks, and electronic query management. These functionalities necessitate revised procedures to define how data validation, discrepancy management, and monitoring are conducted electronically. The SOP must specify roles, responsibilities, system access controls, and processes for electronic source verification (eSource), ensuring compliance with 21 CFR Part 11 and ICH E6 (R2) requirements.
Other SOPs such as Handling External Data or Data Backup may require minor updates, but the Data Review and Validation SOP undergoes the most extensive change because EDC technology shifts validation responsibilities from post-data entry review to real-time oversight within the system.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 6.3 - SOP Adaptation for EDC Implementation FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Handling and Validation

NEW QUESTION # 118

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

Answer: C

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 # 119

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