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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	• 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 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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Valid CCDM Test Topics - CCDM Practice Exam Online

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SCDM Certified Clinical Data Manager Sample Questions (Q103-Q108):

NEW QUESTION # 103
A protocol is updated mid-study to add an additional procedure about which data needs to be collected. Which of these statements applies?

- A. The DMP should be updated to reflect the changes to the protocol, but this update does not need to be communicated
- B. The DMP does not need to be updated until the end of the trial and all updates are included in the DMP to indicate what happened in the trial
- C. The DMP should be updated to reflect the changes to the protocol and stakeholders notified
- D. The DMP does not need to be updated as it represents the data at the beginning of the trial only

Answer: C

Explanation:
When a protocol is amended mid-study, resulting in additional data collection requirements, the Data Management Plan (DMP) must be updated accordingly and all relevant stakeholders must be notified.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the DMP is a living document that defines all data management processes for a clinical study. It must accurately reflect the current data flow, CRF design, validation procedures, and reporting structure. Any protocol amendments affecting data capture, structure, or analysis require immediate DMP revision and distribution to ensure alignment across data management, clinical, and biostatistics teams.
Failure to update and communicate DMP changes can lead to misalignment in data handling and introduce compliance risks during audits or inspections. Therefore, Option B is correct: the DMP must be updated and the change communicated to all stakeholders (e.g., sponsor, CRO, clinical operations, biostatistics).
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Plan (DMP), Section 5.3 - Maintaining and Updating the DMP ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Documentation of Protocol Changes and Data Handling Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Data Management Documentation

NEW QUESTION # 104
A Data Manager is importing data from an external facility. Which is commonly checked first?

- A. Incoming files have the expected number of records
- B. Data in incoming files are consistent with existing data in the study database
- C. Incoming files are conformant to the data transfer specifications
- D. Data in the incoming files are internally consistent

Answer: C

Explanation:
When importing external data (e.g., laboratory or imaging results) into a clinical database, the first step in data import quality control is to verify that incoming files conform to the pre-specified data transfer specifications (DTS).
According to the GCDMP (Chapter: External Data Transfers and Integration), the Data Transfer Specification defines file structure, variable names, data types, delimiters, record counts, and validation rules. The initial import check confirms that the received file matches the technical and structural requirements before content or record consistency is evaluated.
Subsequent checks-such as record counts (A), data consistency with existing database (C), and internal logical consistency (D)-are performed only after the file structure is validated and confirmed to match the specifications. Failure to perform this first check may cause import errors or corrupted data loads.
Thus, the first and most critical verification step is ensuring file conformity to the agreed data transfer specifications, making option B correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: External Data Transfers, Section 4.2 - Data Transfer File Validation and Import Checks ICH E6(R2) GCP, Section 5.5.3 - Validation of Computerized Systems and Data Imports

NEW QUESTION # 105
An organization is using an international data exchange standard and a new version is released. Which of the following should be assessed first?

- A. Existence of backwards compatibility
- B. Availability of other standards covering the same content

- C. Cost of migrating to the new version
- D. Content coverage of the new version

Answer: A

Explanation:
When an updated version of a data exchange standard (such as CDISC SDTM, ADaM, or ODM) is released, the first factor that should be assessed is backwards compatibility. This determines whether the new version can interoperate with or accept data from prior versions without significant reconfiguration or data loss.
According to the Good Clinical Data Management Practices (GCDMP) and CDISC Implementation Guides, assessing backwards compatibility ensures that historical or ongoing study data remain valid and usable within the updated environment. If the new version introduces structural or semantic changes (such as variable name modifications or controlled terminology updates), it could impact mapping, validation, or regulatory submissions.
Once backward compatibility is confirmed, secondary assessments such as content coverage, availability of overlapping standards, and migration cost can be considered. However, ensuring that the new version supports existing infrastructure and data continuity is the first critical step before adoption.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Standards and Data Integration, Section 4.2 - Data Standards Updates and Compatibility Considerations CDISC SDTM Implementation Guide, Section 1.5 - Backward Compatibility and Version Control ICH E6(R2) GCP, Section 5.5 - Data Handling and Standardization

NEW QUESTION # 106
According to ICH E6, developing a Monitoring Plan is the responsibility of whom?

- A. CRO
- B. Data Manager
- C. Sponsor
- D. Monitor

Answer: C

Explanation:
According to ICH E6(R2) Good Clinical Practice (GCP), Section 5.18.1, the Sponsor is ultimately responsible for developing and implementing the Monitoring Plan.
The Monitoring Plan defines:
The extent and nature of monitoring (e.g., on-site, remote, risk-based).
The responsibilities of monitors.
The communication and escalation procedures for data quality and protocol compliance.
While the CRO (B) or Monitor (D) may perform monitoring activities under delegation, the Sponsor retains legal accountability for ensuring a compliant and effective plan is developed and maintained. The Data Manager (C) may contribute by outlining data review workflows, but is not responsible for authoring or owning the plan.
Therefore, option A (Sponsor) is the correct answer.
Reference (CCDM-Verified Sources):
ICH E6(R2) GCP, Section 5.18.1 - Purpose and Responsibilities for Monitoring SCDM GCDMP, Chapter: Regulatory Compliance and Oversight, Section 5.3 - Sponsor Responsibilities in Monitoring and Quality Assurance FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor Responsibilities (2013)

NEW QUESTION # 107
The Scope of Work would answer which of the following information needs?

- A. To look up which visit PK samples are taken
- B. To look up the date of the next clinical monitoring visit for a specific site
- C. To find the name and contact information of a specific clinical data associate
- D. To determine the number of data transfers budgeted for a project

Answer: D

Explanation:
The Scope of Work (SOW) is a project management document that defines what services are included in the work agreement

between the sponsor and the CRO or vendor. It outlines deliverables, responsibilities, timelines, and budget allocations.
According to the GCDMP (Chapter: Project Management in Data Management), the SOW includes specifications such as:
The number and frequency of data transfers,
Database build and lock milestones,
Quality control deliverables, and
Resource allocation for data management tasks.
The SOW does not cover operational site-level details such as monitoring schedules (B), protocol sampling details (C), or personnel contact lists (D).
Therefore, option A (number of data transfers budgeted for a project) correctly identifies a use case directly addressed in the SOW.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management, Section 4.1 - Scope of Work and Resource Planning ICH E6(R2) GCP, Section 5.5 - Sponsor Oversight and Data Management Responsibilities PMI Project Management Framework - Scope Definition and Deliverable Specifications

NEW QUESTION # 108
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