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## SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none"> <li>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.</li> </ul>
Topic 2	<ul style="list-style-type: none"> <li>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.</li> </ul>
Topic 3	<ul style="list-style-type: none"> <li>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.</li> </ul>
Topic 4	<ul style="list-style-type: none"> <li>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.</li> </ul>
Topic 5	<ul style="list-style-type: none"> <li>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.</li> </ul>

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### SCDM Certified Clinical Data Manager Sample Questions (Q106-Q111):

#### NEW QUESTION # 106

A sponsor may transfer responsibility for any or all of their obligations to a contract research organization. Which of the following statements is true?

- A. A description of each of the obligations being assumed by the contract research organization is required.
- B. A general statement that all obligations have been transferred is acceptable.
- C. Any written description is not transferred to the contract research organization.
- D. A description of each of the obligations being transferred to the contract research organization is not required.

**Answer: A**

Explanation:

Under ICH E6 (R2) Good Clinical Practice and 21 CFR Part 312.52, when a sponsor delegates or transfers obligations for a clinical trial to a Contract Research Organization (CRO), there must be a written description of each specific obligation being assumed by the CRO.

According to the Good Clinical Data Management Practices (GCDMP), while sponsors may outsource responsibilities such as data management, monitoring, or biostatistics, ultimate accountability remains with the sponsor. The documentation of the transfer of responsibilities ensures regulatory transparency and compliance.

This written agreement, often referred to as a Transfer of Obligations (TOO) document, defines exactly which duties the CRO is responsible for (e.g., CRF design, data cleaning, database lock), as well as any retained sponsor oversight. A general statement that "all obligations are transferred" (option D) is insufficient per regulatory expectations, as sponsors must retain traceability of responsibility.

Therefore, Option B is correct - a detailed written description of transferred obligations is required.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Compliance and Oversight, Section 5.2 - Sponsor and CRO Responsibilities ICH E6 (R2) Good Clinical Practice, Section 5.2.1 - Transfer of Trial-Related Duties and Functions FDA 21 CFR 312.52 - Transfer of Obligations to a Contract Research Organization

#### NEW QUESTION # 107

Query rules were tested with test data for each logic condition within each rule. Which of the following types of testing was conducted?

- A. T box testing
- B. Black box testing
- C. User box testing
- D. White box testing

**Answer: B**

Explanation:

Testing query rules with test data inputs to confirm expected outputs without examining the underlying program logic is an example of black box testing.

According to the GCDMP (Chapter: Data Validation and System Testing), black box testing is a functional testing approach used to verify that the system performs correctly from the end-user's perspective. In this method, testers input various conditions and observe outputs to ensure the system behaves as intended - for instance, that edit checks trigger correctly when data fall outside predefined limits.

In contrast, white box testing involves examining internal logic, code, and algorithm structures. Because data managers typically validate edit checks through data-driven test cases rather than code inspection, black box testing is the appropriate and industry-standard method. This ensures compliance with validation documentation standards as outlined in FDA 21 CFR Part 11, Section 11.10(a) and ICH E6 (R2) system validation expectations.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Validation and Testing, Section 4.1 - Testing Approaches (Black Box and White Box) FDA 21 CFR Part 11 - System Validation Requirements ICH E6 (R2) GCP, Section 5.5.3 - Computerized Systems Validation

### NEW QUESTION # 108

What additional task does the site study coordinator role perform when utilizing an EDC application compared to paper CRF?

- A. Data entry
- B. Data curation
- C. Resolving queries
- D. Medical record abstraction

**Answer: A**

Explanation:

In paper-based trials, site staff (e.g., study coordinators) record data manually on paper Case Report Forms (CRFs), which are later transcribed by data entry personnel into an electronic database.

However, in EDC-based studies, the site coordinator is directly responsible for entering data into the EDC system. This eliminates the need for centralized double data entry and shortens data cleaning timelines.

The GCDMP (Chapter: Electronic Data Capture Systems) states that EDC systems shift certain tasks, including data entry, initial query response, and source verification preparation, to the site level. Yet, data entry remains the most significant additional responsibility compared to paper-based studies.

Option A (Query resolution) is performed in both EDC and paper-based systems.

Option C (Data curation) is typically a Data Management function.

Option D (Medical record abstraction) is part of source documentation, not specific to EDC.

Thus, option B (Data entry) is correct - it is the additional site coordinator duty unique to EDC environments.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.3 - Site Responsibilities and Workflow Changes ICH E6(R2) GCP, Section 5.5.3 - Data Entry and Role Delegation in Computerized Systems FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.2 - Site-Level Data Entry Controls

### NEW QUESTION # 109

Electronic submission standards require that an individual subject's complete CRF should be provided as what type of file:

- A. Statistical Analysis System (.sas)
- B. Rich Text Format (.rtf)
- C. Microsoft Word (.docx)
- D. Portable Document Format (.pdf)

**Answer: D**

Explanation:

Electronic submission standards, as established by FDA, CDISC, and ICH, require that an individual subject's complete Case Report Form (CRF) be submitted as a Portable Document Format (.pdf) file. The PDF format is universally recognized and accepted because it ensures that the structure, format, and visual fidelity of the CRF are preserved exactly as originally designed, regardless of software or hardware environment.

According to the FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format (2006) and CDISC SDTM standards, sponsors must include a subject-level CRF in PDF form for each participant in the submission dataset. This requirement ensures that reviewers can trace data points from analysis datasets back to their source entries in the CRF, fulfilling the principles of data traceability and transparency.

The Good Clinical Data Management Practices (GCDMP) also support this requirement, emphasizing that CRF archiving should maintain readability and regulatory accessibility. Formats like RTF, DOCX, or SAS datasets are not acceptable substitutes for regulatory CRF submission because they may alter formatting, structure, or introduce modifiable content, violating FDA data integrity principles.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Archiving and Submission FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006 CDISC SDTM Implementation Guide, Section 5.3 - CRF Representation and Traceability

### NEW QUESTION # 110

A study team member wants to let sites enroll patients before the system is ready. Which are important considerations?

- A. If the study were audited, enrolling subjects prior to having the EDC system ready would become an audit finding
- B. Starting the study prior to the EDC system being ready will delay processing of milestone-based site payments
- C. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study
- D. There is no way to identify, report and track adverse events and serious adverse events without the EDC system in place

**Answer: C**

Explanation:

Enrolling subjects before the Electronic Data Capture (EDC) system is ready poses major data integrity and compliance risks. The primary issue is that data cannot be accurately captured, validated, or monitored without the system in place.

Per the GCDMP (Chapter: Data Management Planning and Study Start-up), data collection systems must be fully validated, tested, and released before enrollment begins to ensure:

Real-time data entry and quality control

Proper tracking of adverse events (AEs/SAEs)

Audit trails and traceability for regulatory compliance

Option A highlights the most critical consequence - without an operational EDC, data collection and verification processes cannot occur, compromising data quality and study oversight.

While options B, C, and D may be partially true, they are secondary effects. The fundamental consideration is data capture capability and monitoring control, making option A correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Management Planning and Study Start-up, Section 4.2 - EDC Readiness and System Validation ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation Before Use FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - System Qualification Prior to Data Entry

### NEW QUESTION # 111

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