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## SCDM CCDM Exam Syllabus Topics:

| Topic   | Details                                                                                                                                                                                                                                                                                                                                            |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Topic 1 | <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 2 | <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>                     |
| Topic 3 | <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 4 | <ul style="list-style-type: none"> <li>• <b>Design Tasks:</b> 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 5 | <ul style="list-style-type: none"> <li>• <b>Testing Tasks:</b> 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>                                                 |

## SCDM Certified Clinical Data Manager Sample Questions (Q94-Q99):

### NEW QUESTION # 94

Which protocol section most concisely conveys timing of data collection throughout a study?

- A. Protocol synopsis
- B. Study endpoints section
- **C. Study schedule of events**
- D. ICH essential documents

**Answer: C**

Explanation:

The Study Schedule of Events (SoE) section in the protocol is the most concise and comprehensive representation of the timing of data collection throughout a study.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Management Planning and Study Start-up) and ICH E6 (R2) GCP, the SoE outlines what assessments, procedures, and data collections occur at each study visit (e.g., screening, baseline, treatment visits, follow-up). This table is a foundational tool for CRF design, database structure, and edit-check development, ensuring alignment between the protocol and data management systems.

While the study endpoints section (A) defines what is measured, and the protocol synopsis (C) summarizes the design, only the schedule of events (B) specifies when data collection occurs for each parameter. The ICH essential documents (D) pertain to regulatory documentation, not study visit timing.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.1 - Using the Schedule of Events for Database Design ICH E6 (R2) GCP, Section 6.3 - Trial Design and Schedule of Assessments FDA Guidance for Industry: Protocol Design and Data Collection Standards

### NEW QUESTION # 95

Which is the best way to identify sites with high subject attrition?

- **A. Proportion of patients for which two visit periods have passed without data by site**
- B. Number of late visits per site
- C. Proportion of late visits by site
- D. Number of patients for which two visit periods have passed without data

**Answer: A**

Explanation:

The best method to identify sites with high subject attrition is to calculate the proportion of patients for which two visit periods have passed without data, by site.

According to the GCDMP (Chapter: Data Quality Assurance and Control), subject attrition is an important performance indicator for data completeness and site compliance. Evaluating missing or delayed data across multiple consecutive visit periods allows for early detection of potential dropouts or site-level operational issues.

By assessing this proportion at the site level, the Data Manager can distinguish between random missing data and systematic site underperformance. Counting or proportioning late visits (options B and C) identifies scheduling delays, not attrition. Looking at missing data without site context (option D) fails to identify site-specific patterns, limiting corrective action.

This metric aligns with risk-based monitoring (RBM) practices recommended by ICH E6 (R2) and FDA RBM Guidance, which promote proactive identification of sites at risk of data loss.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 5.4 - Site Performance Metrics ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Performance Evaluation FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section 6 - Site Performance Metrics

### NEW QUESTION # 96

Which mode of data entry is most commonly used in EDC systems?

- A. Blind verification
- B. Double entry
- C. Single entry
- D. Third party compare

**Answer: C**

Explanation:

The most common mode of data entry in Electronic Data Capture (EDC) systems is single data entry.

According to the GCDMP (Chapter: Electronic Data Capture Systems), EDC systems have built-in edit checks, validation rules, and audit trails that ensure data accuracy and integrity at the point of entry. These real-time validation capabilities make double data entry (a legacy practice from paper studies) unnecessary.

EDC systems automatically verify data as they are entered by site staff, generating queries for inconsistencies or out-of-range values immediately. Blind verification (option B) and third-party comparisons (option D) are not standard data entry modes but may be used for specialized reconciliation or external data imports.

Thus, single data entry (Option C) is the industry standard approach, ensuring both efficiency and compliance with FDA 21 CFR Part 11 and ICH E6 (R2) data integrity requirements.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 5.4 - Data Entry and Verification Processes ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Computerized Systems and Data Validation FDA 21 CFR Part 11 - Electronic Records and Electronic Signatures: Validation and Data Entry Requirements

### NEW QUESTION # 97

Which data are needed to monitor site variability in eligibility screening?

- A. Number of sites with high enrollment
- B. Number of subjects screened and number of subjects enrolled
- C. Number of subjects enrolled
- D. Number of sites with low enrollment

**Answer: B**

Explanation:

To monitor site variability in eligibility screening, you must analyze the number of subjects screened versus the number of subjects enrolled at each site. This allows identification of sites that are over- or under-screening relative to their enrollment yield.

The GCDMP (Chapter: Data Quality Assurance and Metrics) emphasizes that screening-to-enrollment ratios are critical indicators of protocol compliance and data quality. Sites with unusually low conversion rates may have unclear understanding of inclusion/exclusion criteria, requiring targeted training or monitoring.

Other options (A, C, D) provide enrollment metrics but do not reveal screening efficiency or variability, which depend on both screening and enrollment data.

Thus, option B correctly identifies the data necessary for monitoring eligibility screening performance across sites.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Metrics, Section 5.4 - Site Performance Metrics ICH E6(R2) GCP, Section 5.18 - Monitoring and Site Oversight Requirements

### NEW QUESTION # 98

A study numbers subjects sequentially within each site and does not reuse site numbers. Which information is required when joining data across tables?

- A. Subject number and site number
- B. Study number and subject number
- C. Site number
- D. Subject number

**Answer: A**

Explanation:

When subjects are numbered sequentially within each site, it means that the subject identification numbers (Subject IDs) restart from 001 at each site. For example, Site 101 may have Subject 001, and Site 102 may also have a Subject 001. In such cases, the subject number alone is not globally unique across the entire study. Therefore, when integrating or joining data across multiple database tables (for example, linking demographic, adverse event, and laboratory data), both the site number and the subject number are required to create a unique key that accurately identifies each record.

According to the Good Clinical Data Management Practices (GCDMP, Chapter on CRF Design and Data Collection), every data record in a clinical trial database must be uniquely and unambiguously identified. This is typically achieved through a composite key, combining identifiers such as site number, subject number, and sometimes study number. The GCDMP specifies that a robust data structure must prevent duplication or mislinking of records across domains or tables.

Furthermore, FDA and CDISC standards (SDTM model) also emphasize the importance of unique subject identifiers (USUBJID), which are derived from concatenating the study ID, site ID, and subject ID. This ensures traceability, integrity, and accuracy of subject-level data during database joins, data exports, and regulatory submissions.

Thus, in the described scenario, since subject numbering restarts at each site, both the site number and subject number are required to uniquely identify and correctly join subject data across different datasets or tables.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.1 - Unique Subject Identification  
CDISC SDTM Implementation Guide, Section 5.2 - Subject and Site Identification (Variable: USUBJID)

FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Data Integrity and Record Identification

## NEW QUESTION # 99

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